

**Date: 20080704**

**Docket: T-811-08**

**Citation: 2008FC840**

**Toronto, Ontario, July 4, 2008**

**PRESENT: Kevin R. Aalto, Esquire, Prothonotary**

**BETWEEN:**

**NOVOPHARM LIMITED**

**Plaintiff**

**and**

**“COMPANY X”**

**Defendant**

**REASONS FOR ORDER AND ORDER**

[1] Are there circumstances in which a statement of claim should be allowed to be issued against a known corporation, but identified only as Company “X”, involving a known patent but identified only as the “X” Patent and a known drug but identified only as the “X” drug? That, essentially, is the issue raised in this case. There does not appear to have been any prior cases in this court that have proceeded on this basis.

[2] This motion was held in open Court. At the outset of the hearing it was noted that an unidentified individual was present observing the proceedings. Plaintiff's counsel requested that the Court be cleared because of concerns that during the course of argument either the name of the Defendant or the patent or drug in issue would be identified. If so, the whole purpose of the order sought on this motion would be lost. It is only in the rarest of circumstances where *in camera* hearings should be permitted, for example, where there is sensitive information relating to national security. In my view, this was not an appropriate case in which to have the matter heard *in camera* and I therefore refused to have the court cleared. The motion materials, as filed, do not identify the name of the Defendant nor do the motion materials identify the patent or drug in issue. The Statement of Claim was filed in a sealed envelope at the time this motion was filed. The Statement of Claim will remain sealed pending the final outcome of this motion.

[3] This motion is premised on the fact that if the details of Novopharm's Statement of Claim to impeach the "X" Patent are made available to the public prior to obtaining a protective order, its business strategy with respect to its "X" Product would be disclosed to competitors and Novopharm would be prejudiced by reason of the loss of its competitive advantage and of its confidential business strategy.

#### Background

[4] Novopharm wishes to commence this action to impeach the "X" Patent of the Defendant. Apparently, the Statement of Claim alleges that the "X" Patent is invalid on various grounds and should be removed from the Canadian Patent Register. Novopharm alleges that it is an interested

party in accordance with section 60(1) of the *Patent Act* in that Novopharm is in the business of manufacturing and selling generic pharmaceutical products and is currently developing a generic version of a drug product against which the “X” Patent has been listed. It also appears that Novopharm has filed an abbreviated new drug submission in Canada for its “X” Product. Further, there appears to be no generic versions on the market in Canada of the drug for which the “X” Patent is listed. Novopharm also believes that no other generic pharmaceutical manufacturer is currently developing an equivalent to its “X” Product for sale in Canada.

[5] Thus, potentially, Novopharm’s “X” Product may be the only generic form of the drug for which the “X” Patent is listed available in Canada. Novopharm's concern is that if any documents disclosing the “X” Product, the “X” Patent or the identity of the Defendant becomes public, then Novopharm’s business interests have the potential to be greatly prejudiced. Novopharm argues that the public has no legitimate interest in the disclosure of the name of the "X" Company, the "X" Patent or the "X" Product.

#### Confidentiality Orders

[6] Quite apart from its general jurisdiction to control its own process, pursuant to Rule 151(1) of the *Federal Courts Rules*, the Court may order that material to be filed shall be treated as confidential. Rule 151(2) provides that the Court must be satisfied that the material should be treated as confidential notwithstanding the public interest in open and accessible court proceedings.

[7] Confidentiality orders are frequently issued in this Court particularly in patent actions and *Patented Medicine (Notice of Compliance) (“PM(NOC)”) Regulations* (the “Regulations”) cases.

Confidentiality orders are issued to prevent a serious risk to the proprietary, commercial or scientific interests of a party that would be seriously harmed by production or disclosure of the information.

The tests for granting confidentiality orders are set out in *Atomic Energy of Canada Limited v. Sierra Club of Canada*, [2002] 2 S.C.R. 522 as follows:

53. Applying the rights and interests engaged in this case to the analytical framework of *Dagenais* and subsequent cases discussed above, the test for whether a confidentiality order ought to be granted in a case such as this one should be framed as follows:

A confidentiality order under Rule 151 should only be granted when:

- (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
- (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.

54. As in *Mentuck*, I would add that three important elements are subsumed under the first branch of this test. First, the risk in question must be real and substantial, in that the risk is well grounded in the evidence, and poses a serious threat to the commercial interest in question.

55. In addition, the phrase “important commercial interest” is in need of some clarification. In order to qualify as an “important commercial interest”, the interest in question cannot merely be specific to the party requesting the order; the interest must be one which can be expressed in terms of a public interest in confidentiality. For example, a private company could not argue simply that the existence of a particular contract should not be made public because to do so would cause the company to lose business, thus harming its commercial interests. However, if, as in this case, exposure of information would cause a breach of a confidentiality

agreement, then the commercial interest affected can be characterized more broadly as the general commercial interest of preserving confidential information. Simply put, if there is no general principle at stake, there can be no “important commercial interest” for the purposes of this test. Or, in the words of Binnie J. in *F.N. (Re)*, [2000] 1 S.C.R. 880, 2000 SCC 35, at para. 10, the open court rule only yields “where the public interest in confidentiality outweighs the public interest in openness” (emphasis added).

56. In addition to the above requirement, courts must be cautious in determining what constitutes an “important commercial interest”. It must be remembered that a confidentiality order involves an infringement on freedom of expression. Although the balancing of the commercial interest with freedom of expression takes place under the second branch of the test, courts must be alive to the fundamental importance of the open court rule. See generally Muldoon J. in *Eli Lilly and Co. v. Novopharm Ltd.* (1994), 56 C.P.R. (3d) 437 (F.C.T.D.), at p. 439.

57. Finally, the phrase “reasonably alternative measures” requires the judge to consider not only whether reasonable alternatives to a confidentiality order are available, but also to restrict the order as much as is reasonably possible while preserving the commercial interest in question.

[8] The Federal Court of Appeal in *AB Hassle et al. v. Minister of National Health and Welfare et al.* (2003), 5 C.P.R. (4<sup>th</sup>) 149 has discussed the role of confidentiality orders in *PM(NOC)* proceedings. Mr Justice Décaré, speaking for the Court, made the following observations:

[3] Protective orders with respect to methods or processes of manufacture of pharmaceutical drugs are routinely sought early in NOC Regulations proceedings and, it is fair to say, are generally granted subject to certain conditions. There are obvious reasons why this is so.

[4] First, whether one looks at it from the perspective of a brand-name pharmaceutical manufacturer or from that of a generic drug manufacturer, the perceived confidentiality of information is a

cornerstone of the regulatory scheme set out in the *Food and Drug Regulations* (C.R.C. 1978, c. 870, s. C.08.001) and in the *Patented Medicines (Notice of Compliance) Regulations*:

[quotation and citations omitted]

...

[6] Second, in endorsing the principle that confidentiality orders can issue in these types of proceedings and in crafting their terms on an ad hoc basis so as to restrict their application to what was strictly necessary in any given case, the courts have carefully attempted to strike a balance between the need for public scrutiny of the court process and, to use the words of MacKay J. in *Apotex Inc. v. Wellcome Foundation Ltd.* (1993), 51 C.P.R. (3d.) 305 at 309-10, “the interests of justice between the parties, including the *bona fide* commercial and propriety interests of parties to litigation”.

[7] Let us not be naïve. 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 order and the Court will always be prepared to hear challenges by a third party, whether or not the terms of the order so provide.

Certainly, in *PM(NOC)* proceedings and in patent infringement actions there is good reason to protect trade secrets, drug formulations and other confidential information in which the public would have no interest. However, it is to be remembered that one of the fundamental aspects of the Canadian system of justice is that court proceedings are carried out in an open and accessible process. Confidentiality Orders are the exception not the rule.

### Analysis

[9] In considering the tests established by the Supreme Court of Canada in *Sierra Club* it is necessary to first establish whether there is a “serious risk to an important interest” because the

alternative measures will not prevent that risk. Secondly, the granting of the confidentiality order must create a beneficial result which outweighs the injurious effect of the confidentiality order precluding open and accessible court proceedings.

[10] The important interest which Novopharm wishes to protect is its commercial interest in the development of the “X” Product. It argues that the confidentiality of its business strategy is important and that if it is prematurely disclosed to its competitors, Novopharm would suffer serious prejudice and lose any advantage gained by its early development of the “X” Product. If competitors learn of the name of the Defendant and the details of the “X” Patent, a competitor would be able to “catch up” with Novopharm and enter the market at the same time as Novopharm resulting in a loss of generic exclusivity in the Canadian market causing serious and detrimental economic impact to Novopharm.

[11] Novopharm further argues that one of the significant benefits to granting the order which meets the second part of the test is that it is proceeding by way of a patent infringement action as opposed to a *PM(NOC)* proceeding. Under the Regulations, Novopharm would be required to serve a Notice of Allegation on the Defendant and thereafter a Notice of Application would likely be commenced to prohibit the Minister of Health from issuing a Notice of Compliance to Novopharm for the “X” Product. The Regulations require that a decision be rendered within 24 months of the filing of the Notice of Application.

[12] However, in this case, Novopharm is intending to proceed by way of action and thus, it argues, there is no guarantee that the decision will be rendered within twenty four months or that

Novopharm will benefit from any period of generic exclusivity. This proceeding, therefore, will ultimately benefit the public because the Regulations are not engaged and duplicative litigation will be avoided. Novopharm argues that if there is successful impeachment of the “X” Patent there will not have been the necessity of both a *PM(NOC)* proceeding and an action for patent infringement; and, the impeachment of the “X” Patent would be effective *in rem*, precluding further litigation of the same patent between different parties. The public benefit generated by this approach is that the level of judicial resources would be less and it would not add to the already high volume of *PM(NOC)* proceedings in this court. Novopharm states in its written representations as follows:

22. In fact, the requested Protective Order will ultimately benefit the public. The Court has repeatedly stated that the volume of NOC proceedings are overwhelming an already heavily-burdened system. In pursuing its NOC for the X Product in a novel fashion (by way of an action to impeach the X Patent), Novopharm will ultimately lessen the burden on the Court by freeing up future judicial resources. In effect, by circumventing the *Regulations*, duplicative litigation could be avoided in two ways, both premised on the successful impeachment of the X Patent: (1) there will not have both an NOC proceeding and an action for patent infringement; and (2) the impeachment of the X Patent would be effective *in rem*, precluding further litigation of the same patent between different parties.

...

25. Therefore, in order to encourage the more efficient use of judicial resources, it is essential that generics are able to maintain the confidentiality of their proposed drug products when pursuing impeachment actions. Otherwise, their competitors could “ride their coattails” and enter the generic market at the same time, greatly reducing the market share of the “first” generic at very little cost or effort to the “second” generic. In other words, there would be no incentive for generics to proceed by way of action and thereby reduce the unnecessary litigation propagated by the *Regulations*.



[13] In the end result, Novopharm argues that both private and public interests are met by allowing Novopharm to obtain a confidentiality order in respect of the “X” Product, the “X” Patent and the Defendant in this action and that there are no “reasonable alternative measures” to the confidentiality order.

[14] In at least one prior case, a generic manufacturer in a *PM(NOC)* proceeding sought to protect by way of a confidentiality order the name of the drug product, the Canadian Reference Product and its manufacturer from the inquisitive eyes of the public. In *Apotex Inc. v. Canada* [2006] FCJ 1070, Prothonotary Milczynski declined to grant the protective order requested by the applicant until it had given notice to and named all of the proper and necessary parties as respondents to its application. Prothonotary Milczynski adjourned the motion for a protective order until a date to be fixed and ordered Apotex to remedy the deficiency in notice within twenty days of the date of the order. On appeal, Mr. Justice Mosley upheld the decision of Prothonotary Milczynski and made the following observation:

14. ... It [Apotex] 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.

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. [emphasis added]

[15] While both Justice Décaré in *AB Hassle* and Justice Mosley were addressing *PM(NOC)* proceedings there is no real difference between this intended patent invalidity action and a *PM(NOC)* proceeding.

[16] This motion was brought *ex parte*. It may very well be, as Novopharm argues, that the Defendant, when served, will support a confidentiality order that does not disclose its name, the “X” Product or the “X” Patent because it too would wish to limit the number of generic manufacturers that may move to enter the market. That is not the issue. The consent or agreement of a defendant to a confidentiality order does not result in an automatic order of the Court granting the order. The Court is required in exercising its discretion to weigh each of the elements prescribed by the Supreme Court of Canada in *Sierra Club* and to bear in mind Justice Mosley’s declaration that “[T]he overarching principle at issue in this matter is that of the public interest in open and accessible court proceedings.”

[17] On balance, I am not persuaded that the Court should exercise its discretion to permit this proceeding to go forward on the basis requested under the cloak of a confidentiality order. Without the Court having the benefit of the input of the Defendant, or the Minister of Health, or the Attorney General or other potentially interested parties, the Court should be leery of granting such an order. Confidentiality orders in both *PM(NOC)* proceedings and patent actions generally protect documents dealing with trade secrets, drug formulations and the like. As noted by Justice Décary in *AB Hassle*, it is naïve to believe that the public has any interest in any such scientific formulations and drug processes. However, that is not what is sought to be protected in this case. Here, the Applicant seeks to protect information that the public does have an interest in knowing – the parties that appear before the courts and the issues in the proceeding including the name of the drug and the patent in issue.

[18] While it is laudable that Novopharm seeks to raise the conservation of judicial resources as a public interest matter to support the confidentiality order it seeks, in my view, the concern for the utilization of judicial resources is a matter to be managed by the Court and should not enter into the Court's exercise of discretion in the granting of confidentiality orders. While there has been a proliferation of *PM(NOC)* proceedings in this Court together with a concomitant increase in the use of judicial resources, this Court has and will continue to exercise its inherent right to control its own process. Justice Hughes in *Pfizer Canada Inc. et al. v. Canada (Minister of Health) et al.*, 2008 FC 11 observed:

NOC proceedings are flooding the Court system at a rate which, roughly calculated, at the current pace, means that three proceedings are instituted for each one disposed by the Court. The NOC

Regulations require that the proceedings be disposed of by the Court within 24 months from institution barring consent of the parties to an extension. Rarely is such consent, except for perhaps a few weeks, forthcoming. The Court accepts the challenge. However, where essentially the same matters as were previously disposed of are raised again, the Court must come to grips as to whether there is an unnecessary waste of the Court's resources.

[19] While Novopharm may proceed by way of action with the intention of lightening the burden on the Court and making better use of judicial resources, the Court has already taken proactive measures to deal with *PM(NOC)* proceedings. Recent examples of the Court's ability to respond to the challenge of the proliferation of *PM(NOC)* proceedings include:

- the Practice Direction issued by the Chief Justice issued on December 7, 2007;
- the active case management of *PM(NOC)* proceedings from their inception;
- the establishment of a Users' Committee dealing with both *PM(NOC)* and intellectual property matters;
- the promotion of best practices by the intellectual property bar such as:
  - encouraging more communication between counsel;
  - encouraging more cooperation in the drafting of what has become standard orders in *PM(NOC)* proceedings (confidentiality orders for example);
  - exercising more common sense insofar as procedural issues are concerned (i.e. reversal of evidence on validity issues in *PM(NOC)* proceedings; voluntary production to avoid unnecessary section 6(7) motions); and
  - promoting continued courtesy and civility among counsel

[20] These are some practical examples underscoring the expectation of the Court that counsel will engage in best practices in matters coming before this Court resulting in *PM(NOC)* proceedings which move fairly and expeditiously through the Court without straining judicial resources. Thus, while Novopharm may use the fact that it is intending to proceed by way of action to support its public interest argument in obtaining this confidentiality order, that is not a sustainable argument and does not overrule the overarching principle of public access to court proceedings.

[21] It may very well be that during the course of whatever proceeding Novopharm pursues specific aspects of the content of the drug processes and other documentation of the parties will be determined to be of such a nature that it should be protected by way of a confidentiality order. That issue will be addressed as it arises.

[22] Further, it is also essential that where extraordinary and discretionary orders such as this are sought that other potential parties be heard. It is no answer to say that another party may come to court to vary the order after they receive notice of its issuance. The Court ought not to be put in the position of dealing with important policy matters such as this on an *ex parte* basis. All affected parties should be before the Court.

[23] Thus, in balancing all of the factors in the cases noted above, this is not a case where the discretion of the Court should be exercised to grant such an extraordinary confidentiality order. The motion is therefore dismissed. Counsel for Novopharm requested that in the event the Court dismissed the motion that there be a period of delay before the order went into effect to allow a

period for appeal if Novopharm is so advised. During this time the names of the Defendant, the “X” Patent and the “X” Product will not be revealed and the statement of claim will remain sealed.

**ORDER**

**THIS COURT ORDERS that**

1. This motion is dismissed.
2. This order shall not be effective for a period of 20 days from its issuance and the statement of claim will remain sealed in order to allow the Applicant to take such further steps concerning this order as it is so advised.

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"Kevin R. Aalto"  
Prothonotary

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-811-08

**STYLE OF CAUSE:** NOVOPHARM LIMITED  
v.  
"COMPANY X"

**PLACE OF HEARING:** Toronto

**DATE OF HEARING:** June 16, 2008

**REASONS FOR ORDER:** AALTO P.

**DATED:** July 4, 2008

**APPEARANCES:**

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Andrew McIntyre

FOR THE PLAINTIFF

No one appearing for the Defendant

FOR THE DEFENDANT

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No one appearing for the Defendant

FOR THE DEFENDANT