Federal Court  Cour fédérale

Date: 20110128

Docket: T-368-08

Citation: 2011 FC 109

Ottawa, Ontario, January 28, 2011

PRESENT: The Honourable Mr. Justice Mandamin

BETWEEN:

NOVOPHARM LIMITED

Plaintiff

and

NYCOMED CANADA INC., NYCOMED GMBH AND NYCOMED INTERNATIONAL MANAGEMENT GMBH

Defendants

REASONS FOR JUDGMENT AND JUDGMENT

[1] The Plaintiff Novopharm Limited (Novopharm) appeals the Protective Order issued by Madam Prothonotary Milczynski on March 24, 2010.

[2] Prothonotary Milczynski has been case managing an action commenced on March 7, 2008 by Novopharm against the Defendants, Nycomed Canada Inc., Nycomed GMBH and Nycomed

International Management GMBH (Nycomed), pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (NOC Regulations).

[3] Novopharm's section 8 claim arises from two proceedings under the NOC Regulations related to pantoprazole sodium. The Court found against Nycomed in both, dismissing the first, T-1799-06, because the patent at issue was not eligible for inclusion on the register and dismissing the second, T-1836-06, after the same patent at issue in T-836-06 was held to be not infringed and invalid in a different proceeding, T-1786-06 involving Apotex Inc. In this action, Novopharm is now required to substantiate its claim for damages arising from the delay because of the NOC proceedings.

[4] Novopharm brought a motion for a protective order to protect and maintain confidentiality of certain financial material and information to be disclosed between the parties. As part of the proposed protective order, Novopharm sought to include a "Restricted Access" category of documents which would exclude senior executives and employees from Nycomed Canada Inc. from accessing these financial documents. The documents are relevant to the quantum of damages which is the central issue in this litigation.

[5] Nycomed opposed including a restrictive access provision in the protection order, contending that it would prevent the executives and employees at Nycomed Canada Inc. from accessing the proposed restrictive access documents and hinder their ability to instruct outside counsel in the litigation.

[6] The Prothonotary was not satisfied that the restrictions sought by Novopharm were necessary or appropriate and found that such restrictions would diminish the ability of Nycomed to instruct counsel and conduct a defence in the litigation.

Decision Under Appeal

[7] The Prothonotary declined to include the restrictive access category as sought by Novopharm. In the Protective Order recitals, the Prothonotary states:

> Upon Motion by the Plaintiff for an order protecting and maintaining the confidentiality of certain material and information to be disclosed between parties in this proceeding;
>
> And Upon reviewing the motion records filed on behalf of the parties and hearing submission of counsel;
>
> And Upon not being satisfied that the breadth of the restrictions sought by Novopharm Limited are necessary or appropriate but rather, would diminish the ability of the Defendants to instruct counsel and conduct the defence of this action;

[8] The Prothonotary, after delineating the procedure by which the parties would designate information confidential and making provision for confidentiality of the information, set out the permitted disclosure of confidential information as follows:

> Permitted Disclosure of Confidential Information
>
> 13. Subject to paragraph 14 and 15 below, in the absence of written permission from the Party designating the information as confidential, designated Confidential Information shall not be disclosed to anyone except as listed below; however, this list does not limit the ability of a party or employees of a party to view that party's own confidential information or deal with it as they see fit:
>
> (a) The Court, Court personnel, stenographic and video reporters engaged in the within proceeding;
>
> (b) The following 7 individuals from Nycomed:
> (i) John Suk, President and CEO of Nycomed Canada Inc.

(ii) Frank Murphy, VP Finance of Nycomed Canada Inc.
(iii) Dr. Ulrich Wolf, Director Patent Litigation
(iv) Dr. Bradley Pamenter, VP Medical and Scientific Affairs of Nycomed Canada Inc.
(v) Sheila Critchlow, Director of Regulatory Affairs of Nycomed Canada Inc.
(vi) John Maletic, Senior Market Researcher of Nycomed Canada Inc.
(vii) A Financial Analyst of Nycomed Canada Inc.; the identity of the individual will be communicated by Nycomed to Novopharm at a later date.

(c) No more than 7 employees, officers and directors from Novopharm, who require access to designated Confidential Information for the purpose of assisting or instructing outside counsel in this action;
(d) Counsel for Novopharm and Counsel for Nycomed and their respective staff whose function in connection with this action requires access to Confidential Information;
(e) Litigation service contractors (such as copy services) engaged by Counsel for Novopharm or Counsel for Nycomed, whose function in connection with this action requires access to Confidential Information; and
(f) Independent experts for a Party, retained to assist a Party in this proceeding. For greater certainty, the independent experts shall not be employees, officers or directors of a Party or any companies related to or affiliated with a Party; and
(g) Such other persons as the Parties may agree in writing or the Court may order.

14. Prior to the disclosure of designated Confidential Information to the persons listed in paragraph 13(b), (c), (e), (f) and (g), counsel of record responsible for making such disclosure shall furnish the intended recipient with a copy of this Order and shall obtain from the intended recipient an acknowledgement in writing, in the form of the undertaking set out in paragraph 15 below, that the intended recipient has read this Order, understands it, agrees to be bound by it and expressly consents to the jurisdiction of the Court in connection with any proceeding or hearing relating to the designated Confidential Information and the terms of this Order. For persons listed in paragraph 13(b), (c), (e), (f) and (g), outside counsel shall retain a copy of the signed undertaking and shall provide a copy of same to other outside counsel upon request by any Party.

15. The undertaking as required by paragraph 14 above shall be in the following form:

UNDERTAKING

> I, _____ hereby acknowledge that I am about to receive from _____ Confidential Information as defined in the Protective Order dated March 24, 2010 in Court File No. T-368-08.
>
> I certify my understanding that this Confidential Information is being provided to me pursuant to the terms and restrictions of the Protective Order referred to above in this proceeding, and that I have been given a copy of and have read an understand my obligations under that Order.
>
> I hereby agree to be bound by the terms of the Protective Order. I hereby agree to utilize the Confidential Information solely for the purposes of this litigation. I clearly understand that the Confidential Information and my copies or notes relating thereto shall not be disclosed to anyone not similarly bound by the Protective Order.
>
> On request from counsel for the party who provided me with the Confidential Information, I will return to said counsel, or in the alternative, on request of said counsel, I will destroy all materials containing the Confidential Information, copies thereof and notes that I have prepared relating thereto.
>
> I hereby submit to the jurisdiction of the Federal Court for the purpose of enforcement of this Protective Order.
>
> …

17. Subject to the terms of this Order or any further Order of this Court, designated Confidential Information shall be used solely for the purpose of the within proceeding and may not be used for any purpose whatsoever other than for the purpose of the within proceeding, except as required by law. For greater certainty, nothing in this Order varies, modifies, or relieves any Party from its implied undertaking in this action.

18. The termination of the within proceeding shall not relieve any person to whom designated Confidential Information was disclosed pursuant to this Order from the obligation of maintaining the confidentiality of such information in accordance with the provisions of this Order.

Issues

[9] The issues as raised by Novopharm are:

(a) Did Prothonotary Milczynski exercise her discretion based upon a wrong principle by issuing an Order

(i) without reasons,
(ii) without addressing the facts inconsistent with her conclusions,
   a. without explaining why she declined to apply binding precedent governing the situation before her, and/or
   b. supplementing the Defendants' position on the motion before her with grounds not advanced in written submissions or orally before her (e.g., application of the implied undertaking rule to competitors in the marketplace)?

(b) If she did so err, such that *de novo* review is required,

(i) Should a "Restricted Access" category of documents be included in the Protective Order governing the parties?
(ii) If so, is the form proposed in the attached Amended Protective Order acceptable?

[10] In my view the issues are whether, in respect of the Protective Order:

1. Are the reasons given adequate;

2. Is there reliance on a wrong principle:

3. Was there a misapprehension of the facts?

Standard of Review

[11] Discretionary orders of prothonotaries ought not to be disturbed on appeal unless they are clearly wrong in the sense that the exercise of discretion was based on a wrong principle or misapprehension of the facts or that they raise questions vital to the final issue of the case: *Canada v Aqua-Gem Investments Ltd.*, [1993] 2 FC 425, 149 NR 273 (FCA).

[12] In *Merck & Co. v Apotex Inc.*, 2003 FCA 488 (Merck), the Court further decided that a judge should first determine whether the question is vital to the final issue. Secondly, whether "the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts": *Merck* at para. 19.

[13] In this proceeding, the Protective Order is not determinative of the final issue. Accordingly, the standard of review is whether the Protective Order is clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

Background

[14] Novopharm commenced its action against Nycomed on March 7, 2008. The Parties were, pursuant to a March 25, 2009 Court Order, to exchange affidavits of documents by July 31, 2009. Novopharm provided an unsworn, incomplete affidavit of documents on July 30, 2009 containing documents used by Novopharm in prior NOC applications which had been designated as confidential by previous protective orders.

[15] There were several months of negotiations between the parties on the wording of a protective order. The parties reached an impasse which necessitated a ruling by the Prothonotary. Before the Prothonotary was the following material:

a) correspondence from each party;
b) motion records as well as supplemental records including affidavits from: Novopharms' in-house counsel (Ms. Mehes), Nycomed Canada's Vice President, Financial and Information Management (Mr. Murphy) and a law clerk with Nycomed's outside counsel (Ms. Rinne);
c) three case managements conferences held with the Prothonotary and
d) proceedings of an oral hearing held December 22, 2009,

[16] Ms. Mehes, in-house counsel, generally set out Novopharm's proposed list of documents for restricted access in her affidavit at paragraphs 14 and 28:

> 14. Novopharm has identified (and continues to identify) specific highly sensitive financial information and documents that it may be required to produce in this proceeding. Such information and documents are so sensitive that disclosure should be limited to only outside counsel, outside experts and a limited number of persons internally who do not, as part of their employment, make strategic business or marketing decisions with respect to pantoprazole in Canada. The disclosure of this small but sensitive set of information to competitors such as Nycomed (or through them to Ranbaxy) would pose a real and substantial risk to Novopharm and would be immensely harmful to the important commercial and financial interests of Novopharm and to its competitive position. Once individuals at a competitor such as Nycomed have reviewed such information, it will not be possible for such individuals to make decisions as part of their employment responsibilities without any influence from the knowledge of such information.
>
> 28. Specifically, it appears that the main point of disagreement revolves around whether any or all of the information to be disclosed can be dealt with on a "restricted access" basis. Novopharm only requests this designation for certain individuals (not "counsel's-eyes only") and with respect to the small but sensitive set of financial documents set out in the draft protective order accompanying this motion, specifically:
>
> i. non-public commercial strategic planning materials for Novopharm's or Nycomed's pantoprazole products;
> ii. non-public information regarding the costs and expenses of developing, manufacturing and selling Novopharm's or Nycomed's pantoprazole products;
> iii. non-public information regarding the sales of Novopharm's or Nycomed's pantoprazole products;
> iv. financial statements of the parties that contain information not otherwise available to the public; and
> v. non-public agreements between Novopharm or Nycomed and their customers (direct and indirect) relating to the sale of Novopharm's or Nycomed's pantoprazole products.

[17] Novopharm submitted, in its proposed draft order, that the restricted access information be only provided to the following:

> 8 (b) In the absence of written permission from a Party, any Confidential Information – Restricted Access produced by that Party, or otherwise made available, shall not be

> disclosed to anyone, except the Court and its staff and stenographic and video reporters engaged in the within proceeding, and the following individuals:
>
> (i) Up to two in-house counsel for each party who need to know the Confidential Information – Restricted Access for the purposes of assisting or instructing outside counsel;
> (ii) Counsel for Novopharm and Counsel for Nycomed and their respective staff whose function in connection with this action requires access to Confidential Information – Restricted Access; and
> (iii) Litigation service contractors (such as copy services) engaged by Counsel Novopharm or Counsel for Nycomed, whose function in connection with this action requires access to Confidential Information – Restricted Access; and
> (iv) Up to ten (10) independent experts for a Party, retained to assist a Party in this proceeding with respect to issues that require access to Confidential Information – Restricted Access; for greater certainty, the independent experts shall not be employees, officers or directors of a Party or any companies related to or affiliated with a Party.
> (v) Three designees from the business, financial and/or patent group(s) or department(s) of each party who are not involved in sales, marketing, strategic commercial planning or the authorized generic agreement with Ranbaxy Pharmaceuticals Canada Inc. regarding Ran-Pantoprazole Tablets, who shall not further disclose to anyone such information that he or she receives that is designated as Confidential Information – Restricted Access.

[17] Novopharm's concerns relate to Nycomed Canada Inc.'s contractual relationship with a generic company, Ranbaxy Pharmaceuticals Canada Inc. (Ranbaxy) which sells pantoprazole sodium manufactured by Nycomed. The thrust of Novopharm's submissions before the Prothonotary was that the directing mind of Nycomed Canada Inc., its senior executives and employees, may use the highly confidential Novopharm financial information to the detriment of Novopharm's commercial interests and viability. Hence there was a need for a restrictive access provision in the protection order.

[18] Nycomed's submission to the Prothonotary was the restrictive access provision would impair the ability of Nycomed Canada Inc. to instruct counsel in the litigation. Nycomed submitted that a protective order as developed in various Federal Court proceedings would be sufficient.

Analysis

[19] Generally, a confidentiality order is a discretionary order and, not being vital to the final issues in the case, should not be interfered with unless it was based on wrong facts or error of principle: *Bristol-Myers Squibb Co. v Apotex Inc.*, 2003 FCA 59.

Adequacy of Reasons

[20] Novopharm states that where the Prothonotary does not provide written reasons, the appellate Court is to examine the surrounding circumstances including the nature of the order made, the evidence before the Prothonotary and whether the exercise of discretion involves consideration of legal principles. If the manner in which the Prothonotary exercised her principles is not apparent, the Court must proceed *de novo* in the appeal: *Anchor Brewing Co. v Sleeman Brewing & Malting Co.*, 2001 FCT 1066 at para. 32.

[21] Novopharm submits that the one sentence recital in the Prothonotary's Order does not reveal how facts were found contrary to the evidence or how binding jurisprudence was distinguished.

[22] In considering the reasons given in the Protective Order, I am mindful to Justice Harrington's statement in *Savanna Energy Services Corp. v Technicoil Corp.*, 2005 FC 842 at para. 19:

> The Prothonotaries deal with an extraordinary volume of procedural issues. It would be intolerable, and the wheels of justice would grind most slowly indeed, if each discretionary order had to be accompanied by a full set of motivated reasons in order to discourage the unsuccessful party from appealing and inviting the Court to exercise its discretion anew.

[23] The Prothonotary had ample material before her upon which to come to a decision. After all, not only did she have the written record and an oral hearing but also the outcome of three case management conferences. Her recital confirms she was mindful both of the evidence and of the submissions of the parties.

[24] It is clear from the Prothonotary's pointed recital that she considered and weighed both parties' submissions: namely Novopharm's request to shield its documents from Nycomed Canada Inc. and the disadvantages to Nycomed Canada Inc. in not being able to fully instruct counsel.

[25] I find no paucity of reasons in the Prothonotary's Order such as to necessitate a *de novo* review.

Wrong Principle

[26] Novopharm insists the Prothonotary erred in considering the implied undertaking rule would be sufficient assurance of the protection of Novopharm's sensitive confidential information.

[27] The express provisions in the Protective Order dispose this claim. The Protective Order provides for a signed undertaking by persons receiving the information to use the information solely for the purpose of the litigation. The Order also expressly requires that the confidential information "shall be used solely for the purpose of the within proceeding and may not be used for any purpose whatsoever other than for the purpose of the within proceeding." (emphasis added) In result, the Prothonotary made explicit provision for protection of confidential information.

[28] Further, by specifically naming individual Nycomed Canada Inc. executives and employees, the Prothonotary makes it clear the Protective Order applies to them personally and places each under an obligation to abide by the requirement to use the information obtained solely within the scope of the litigation.

[29] I find the Prothonotary did not err by any reliance on any principle based on the implied undertaking rule.

[30] Novopharm submitted that "Counsel's Eyes Only" was appropriate where evidence demonstrates that a party's commercial interests could be harmed without such an order and that its proposed restrictive access provision is even less restrictive than a "Counsel's Eyes Only" requirement.

[31] Nevertheless, Novopharm's restrictive access proposal would preclude Nycomed Canada Inc.'s executives who instruct counsel from accessing financial documents that are central to the question of damages in this proceeding. Accordingly, the onus remains upon Novopharm to provide the evidence that would support the need for such a restriction: *Deprenyl Research Ltd. v Canguard Health Technologies Inc.*, (1992) 41 C.P.R. (3d) 228 at 229-220.

[32] Here, Novopharm had not produced a sworn affidavit of documents and described, in its motion, the documents in question in roundabout terms. Novopharm's affiant, Ms. Mehes, insisted the set of restrictive access documents was small but then elaborated by deposing that:

> 28. Specifically … Novopharm only requests this designation for certain individuals (not "counsel's-eyes only") and with respect to the small but sensitive set of financial documents set out in the draft protective order accompanying this motion, specifically:
>
> vi. non-public commercial strategic planning materials for Novopharm's or Nycomed's pantoprazole products;
> vii. non-public information regarding the costs and expenses of developing, manufacturing and selling Novopharm's or Nycomed's pantoprazole products;
> viii. non-public information regarding the sales of Novopharm's or Nycomed's pantoprazole products;
> ix. financial statements of the parties that contain information not otherwise available to the public; and
> x. non-public agreements between Novopharm or Nycomed and their customers (direct and indirect) relating to the sale of Novopharm's or Nycomed's pantoprazole products.
>
> (emphasis added)

[33] In my view, such a listing does not suggest a small set of documents nor does it provide a meaningful description of the type or class of documents for which Novopharm seeks to restrict access. The categories taken collectively are readily capable of extension to encompass a wide range of documents thereby confounding any precision in description.

[34] In *Novopharm Ltd. v Glaxo Group Ltd.,* (1998) 227 N.R. 80, 81 C.P.R. (3^{d}) 185 at para. 6, the Federal Court of Appeal denied a request for a "counsel's eyes only" order when the evidence was "lacking in any description of the type or class of document that the respondents assert would cause prejudice if it reached the eyes of the appellant or of the public including any competitor."

[35] Novopharm's rather extensive and varied description of its documents did not meet the precision that the Federal Court of Appeal saw necessary to require a restrictive access order. I do

not see any basis for finding the Prothonotary was wrong in not accepting the interpretation Novopharm sought to place on its evidence.

[36] A Court will not lightly grant such an order that interferes with the solicitor-client relationship: *Glaxo Group Ltd. v Novopharm Ltd*., (1998) 81 C.P.R. (3d) 259 (FCA) at para. 2.

[37] The restrictive access provision would adversely affect the right of Nycomed Canada Inc.'s executives and employees to see all the documents that contain relevant evidence to the issue in dispute. In *Murphy Oil Co. Ltd. v Predator Corp. Ltd.*, 2002 ABQB 992, Justice McMahon identified the difficulty with restrictive confidentiality orders by drawing from *Warner-Lambert Co. v Glaxo Laboratories Limited*, [1975] RPC 354 a very apt quote to the effect that it is the corporate decision-makers who are authorized to make decisions on the company's behalf, such as whether to continue or abandon an action, not the legal or scientific advisors.

[38] In the alternative, Novopharm proposed that the list in the Protective Order be reduced to Dr. Wolf and Nycomed in-house counsel, both of whom are in Germany.

[39] Given that Novopharm is proceeding against Nycomed Canada Inc. here in Canada, I consider this alternative without merit. It is nonsensical to suggest a Canadian company involved in litigation in Canada must defend itself by relying on out-of-country personnel or out-of-country counsel to instruct counsel in litigation in Canada.

[40] More importantly, Nycomed's evidence is that Nycomed Canada Inc. does not have in-house counsel; it is a small company that has existed because of a single drug, pantoprazole, with the result that everyone in management was involved in some degree in the decision to authorize the generic entry of Ran-Pantoprazole tablets (by Ranbaxy) and its executive and senior employees are all involved with strategic planning for the company. Mr. Murphy, Nycomed's affiant, further states that Mr. John Suk, the CEO of Nycomed Canada Inc. and he are the individuals instructing outside counsel in this litigation. One other individual in Germany, Ulrich Wolf, has been involved as he coordinates pantoprazole litigation throughout the world but he is not an in-house counsel.

[41] The Prothonotary concluded the restrictive access provision would limit the ability of Nycomed to instruct counsel. In doing so, the Prothonotary did not disregard Novopharm's concerns and made adequate provision in making the Protective Order as I have previously noted in reference to the effect of specifically naming Nycomed's executives and officers.

[42] I am not persuaded that there exist unusual circumstances that justify imposing a restrictive access provision beyond the provisions contained in the Protective Order. I find no basis for intervening with the Prothonotary's solution to the issues raised by the parties.

Misapprehension of Facts

[43] Finally, the Prothonotary is entitled to assess and weigh the evidence before her. Novopharm vigorously insists its interpretation of the evidence ought to prevail but its submissions to this Court are no more than an invitation to reweigh the evidence.

[44] Novopharm's evidence of possible harm amount to speculative assertions not supported to any significant degree by undisputed or confirmed facts. For instance, Novopharm's affiant, Ms. Mehes, admits to not having any basis, other than a vague assertion of generalized knowledge of the industry, for asserting that Nycomed may have breached court orders or that Nycomed provides input on prices Ranbaxy sells its Ran-Pantoprazole products.

[45] I do not accept Novopharm's submission that the two unsuccessful NOC proceedings by Nycomed is evidence that supports a finding of an intention by Nycomed's management to misuse confidential information obtained under a protective order. Being an unsuccessful party in a proceeding may have its consequences but that does not extend to drawing inferences of the unsuccessful party's intent with respect to future court proceedings.

[46] I find that the Prothonotary did not misapprehend the facts. She had reason to find Novopharm's evidence insufficient to support the need for a restrictive access provision and had evidence upon which to conclude that such a provision would unduly restrict Nycomed Canada Inc.'s ability to instruct counsel.

Conclusion

[47] The appeal is dismissed.

[48] Costs are awarded to Nycomed.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that:

1. The appeal is dismissed.

2. Costs are awarded to the Defendants.

"Leonard S. Mandamin"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-368-08
STYLE OF CAUSE:	NOVOPHARM LIMITED v NYCOMED CANADA INC., NYCOMED GMBH AND NYCOMED INTERNATIONAL MANAGEMENT GMBH
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