Federal Court  Cour fédérale

Date: 20100414

Docket: T-1868-09

Citation: 2010 FC 409

Toronto, Ontario, April 14, 2010

PRESENT: Madam Prothonotary Milczynski

BETWEEN:

PFIZER CANADA INC.,
WARNER-LAMBERT COMPANY AND
WARNER-LAMBERT COMPANY LLC

Applicants

and

NOVOPHARM LIMITED,
THE MINISTER OF HEALTH,
NORTHWESTERN UNIVERSITY AND
THE BOARD OF REGENTS FOR
THE UNIVERSITY OF OKLAHOMA

Respondents

REASONS FOR ORDER AND ORDER

[1] By letter dated October 1, 2009, Novopharm served the Applicant, Pfizer Canada Limited ("Pfizer") with a Notice of Allegation and Detailed Statement (the "NOA") pursuant to section 5 of the *Patented Medicines (Notice of Compliance) Regulations* ("PMNOC Regulations") in relation to the drug pregabalin.

[2] In response to the NOA, on November 13, 2009, Pfizer commenced the within application for judicial review pursuant to section 6 of the PMNOC Regulations for an order prohibiting the Minister of Health from issuing a Notice of Compliance ("NOC") to Novopharm until after the expiry of five patents: Canadian Patent Nos. 2,134,674, 2,297,163, 2,255,652, 2,325,045 and 2,327,285.

[3] The parties have agreed to the form of a confidentiality order, with the exception of the matter of the NOA which Novopharm seeks to have designated as confidential and sealed in the court record. It is not so much from the eyes of the public at large that Novopharm seeks to keep the NOA confidential, but the eyes of other generic drug manufacturers who are already in a the process of seeking an NOC for their pregabalin product and are parties to an application under the PMNOC Regulations (as in the case of ratiopharm Inc.), or more importantly, from those generic drug manufacturers who have yet to deliver their NOA's.

[4] There is no provision in the PMNOC Regulations relating to whether or not NOA's are confidential unlike other pieces of information or documents that are treated as confidential, such as Abbreviated New Drug Submissions. There is also no precedent in this Court for designating an NOA as confidential in the manner and for the purpose Novopharm seeks.

[5] To protect the confidentiality of the NOA prior to the hearing of this motion, Novopharm unilaterally marked the NOA as confidential and indicated to Pfizer when the NOA was delivered on or about October 1st , that it was being delivered by Novopharm to Pfizer on a confidential basis.

[6] Novopharm submits that it has "made a substantial investment in the production of the Novopharm NOA [and] has treated and maintained the Novopharm NOA as confidential. Novopharm argues that "there is no public benefit to disclosing the Novopharm NOA. If Novopharm is successful in this litigation and the Novopharm NOA is made available to Novopharm's competitors, those competitors could use the Novopharm NOA to 'springboard' onto the pregabalin market at considerably less expense than that incurred by Novopharm." Indeed, the evidence indicates that Novopharm incurred some $200,000.00 in costs to prepare its NOA.

[7] With respect to the nature of the information contained in the NOA, Novopharm concedes that the contents of the NOA do not contain trade secrets, commercially sensitive information or other types of confidential information. Novopharm confirmed at the hearing of the motion that there is nothing in the NOA that could or should be redacted to protect the confidentiality of the information. In this case, Novopharm essentially submits that the sum is greater than the parts – it is the entire work product that Novopharm seeks to protect (including the information that is publicly available), to prevent other generics from copying or relying in any way on Novopharm's NOA to further their own endeavours to obtain an NOC.

[8] What Novopharm seeks is truly exceptional to the principle of open and accessible court proceedings. For the reasons below, the order sought by Novopharm is denied.

NOA and Novopharm's Interest in Confidentiality

[9] The NOA is not a pleading or court document. The PMNOC Regulations require that an NOA containing a detailed statement of the legal and factual basis for the allegations of non-infringement and/or invalidity of a patent be delivered by a generic drug manufacturer. The NOA cannot be amended once it has been delivered, thus it is important that it be as detailed and thorough as possible.

[10] In the case of the Novopharm NOA, I accept that its preparation required substantial time (approximately 10 months), effort, resources and money. This included consulting with and obtaining opinions from internal scientific experts at Novopharm and its related company Teva, and from Bennett Jones who developed the legal arguments and assembled the prior art. The construction of the five patents, the reliance on specific pieces of prior art and the arguments advanced in the NOA were all developed as a result of the skill, knowledge and effort of Novopharm and its advisors, experts and counsel. The NOA may well be unique, novel and original as Novopharm contends in the structure and support of its arguments and be a first-class piece of work.

[11] As Novopharm noted, the purpose of this "investment" is to be a very close second if not the first generic to obtain an NOC for its pregabalin product. As detailed in the affidavit of Ildiko Mehes, general counsel at Novopharm, Novopharm is seeking the advantage to capture the greatest possible portion of the market share for its pregabalin product and the reinforcement of Novopharm's reputation as a market leader with the purchasers of its products.

[12] Novopharm is the second applicant in Canada to deliver an NOA for generic pregabalin, ratiopharm Inc. being the first – and whose NOA is publicly available in the Court record. But as indicated, Novopharm is most concerned with other generic drug manufacturers who may be in the queue and who may gain insight and assistance from reviewing the Novopharm NOA. As stated by Novopharm:

> If Novopharm's generic competitors are allowed to free-ride on Novopharm's investment and are able to again market access at the same time or shortly after Novopharm, then Novopharm would forever lose the opportunity to benefit from being the first or one of the first generics in the generic pregabalin market in terms of market share, after having incurred substantial cost to do so. Novopharm's competitors would profit from having access to the Novopharm NOA by gaining earlier and less expensive market entry, to Novopharm's direct detriment. This constitutes the impairment of a significant commercial interest of Novopharm.

Confidentiality and Rule 151 of the *Federal Courts Rules*

[13] Confidentiality orders are an exception to the rule that court proceedings should be open and subject to public scrutiny. The public's interest in open and accessible court proceedings should not be compromised absent exceptional circumstances. As held by the Supreme Court of Canada in *Sierra Club of Canada v. Canada (Minister of Finance)*, [2002] 2 SCR 522, confidentiality orders under Rule 151 of the *Federal Courts Rules* should only be granted when:

> (i) such an order is necessary to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonable alternative measures will not prevent the risk; and
>
> (ii) 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.

There are three elements to the first part of the *Sierra Club* test:

> (i) 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;
>
> (ii) in order to qualify as an "important commercial interest", the interest in question cannot merely be specific to the party requesting the confidentiality order, the interest must be one which can be expressed in terms of a public interest in maintaining confidentiality; and
>
> (iii) the Court must consider not only whether reasonable alternatives to a confidentiality order are available, but must also restrict the order as much as is reasonably possible while preserving the commercial interest in question.

[14] In addition, a party seeking a confidentiality order must establish that at all relevant times the information was treated as confidential. The information must be of a "confidential nature" such that a reasonable expectation of it being kept confidential has arisen, as opposed to information which a litigant would simply prefer to keep confidential.

[15] Novopharm has acknowledged that the content of the information in its NOA is not confidential, and agreed that no part or parts should be redacted to preserve confidentiality. From Novopharm's perspective, the entire NOA must be kept confidential from a particular segment of the public (other generics) to prevent those generics from relying on the way Novopharm researched, compiled, organized and argued its allegations and detailed statement of fact and law relating to the validity of the patents in issue and non-infringement. Novopharm's commercial

interest in so doing, is to ensure these generics do not gain market entry any faster or for less expense than they would otherwise as a result of their relying on Novopharm's NOA and not doing their own work.

[16] There are some significant problems with Novopharm's argument. First, there is no evidence of a serious risk to Novopharm's commercial advantage with respect to its market position and what it hopes to be the timing of its market entry. Novopharm assumes it will succeed on all five patents in issue in this case and makes assumptions about how its and ratiopharm's hearings will be scheduled by the Court. Novopharm may or may not be first or a close second on the market. There is also no evidence other than its own confidence in the quality of its work product to suggest that other generics will be lining up to copy any part of the Novopharm NOA, particularly when there is no evidence that ratiopharm's NOA has attracted such keen attention (or evidence that ratiopharm's NOA should not warrant it).

[17] Secondly, and in any event, Novopharm's market position cannot be characterized as an important commercial interest within the meaning of *Sierra Club*. The commercial interest identified by Novopharm is narrow and personal to Novopharm, namely, its first-to-market status and its investment of time and money in the preparation of its NOA. There is no principle or element of public interest in the confidentiality at stake of the NOA, unlike the public interest identified in *Sierra Club* in maintaining confidentiality of the information at issue in that case. In *Sierra Club*, disclosure would cause a breach of a confidentiality agreement – there is a public

interest in preserving such agreements. There is no public interest in ensuring Novopharm the time and/or exclusivity of its market entry over any other generic drug manufacturer.

[18] With respect to the second element of the *Sierra Club* test, I am satisfied that the deleterious effects of the confidentiality order proposed by Novopharm outweigh any alleged salutary effects. Open and accessible court proceedings are one of the hallmarks of a democratic society and promote public confidence in the integrity of the courts and administration of justice.

[19] To compromise the principle of an open judicial process in the manner sought by Novopharm is only to protect Novopharm's interest in maintaining a possible commercial advantage over other generics. It would also likely lead to even greater secrecy surrounding the proceeding and other parts of this application. If the NOA is designated as confidential, any documents referring to the purported novel and original arguments in the NOA may need to be designated in whole or have portions redacted, and any hearing regarding an interlocutory matter and/or the hearing on its merits may need to be conducted *in camera*. The order sought by Novopharm will therefore restrict public access to information, which information Novopharm has acknowledged is not in and of itself confidential and restrict access to the proceedings to the degree where much would be conducted in secret. While Novopharm submits that the NOA is of no value to the public and would be of little interest to anyone but the immediate parties and other generics, what Novopharm seeks would gravely diminish the importance and value of open and accessible court proceedings and the need to preserve the public's confidence in the integrity of the administration of justice.

[20] Accordingly, the motion must be dismissed.

ORDER

THIS COURT ORDERS that:

1. The motion be and is hereby dismissed.

2. In the event the parties cannot agree on the costs of this motion, the parties may, within fifteen days, file written submissions no longer than three pages in length.

"Martha Milczynski"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1868-09
STYLE OF CAUSE:	PFIZER CANADA INC., WARNER-LAMBERT COMPANY AND WARNER-LAMBERT COMPANY LLC v. NOVOPHARM LIMITED, THE MINISTER OF HEALTH, NORTHWESTERN UNIVERSITY AND THE BOARD OF REGENTS FOR THE UNIVERSITY OF OKLAHOMA
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 22, 2010
REASONS FOR JUDGMENT:	Milczynski P.
DATED:	April 14, 2010

APPEARANCES:

Peter Wilcox Alex Peterson	FOR THE APPLICANTS AND THE RESPONDENT UNIVERSITY OF OKLAHOMA
Kvita Ramamoorthy	FOR THE RESPONDENT NORTHWESTERN UNIVERSITY DEFENDANT
Barbara Murchie Jeilah Chan	FOR THE RESPONDENT NOVOPHARM LIMITED

SOLICITORS OF RECORD:

Bennett Jones	FOR THE RESPONDENT, NOVOPHARM LIMITED
Torys LLP	FOR THE APPLICANTS AND RESPONDENT, THE BOARD OF REGENTS FOR THE UNIVERSITY OF OKLAHOMA

Ogilvy Renault LLP	FOR THE RESPONDENT, NORTHWESTERN UNIVERSITY
Myles J. Kirvan Deputy Attorney General of Canada	FOR THE RESPONDENT, THE MINISTER OF HEALTH