Federal Court of Appeal | Cour d'appel fédérale

Date: 20101005

Docket: A-252-10

Citation: 2010 FCA 258

Present: **EVANS J.A.**

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

PFIZER CANADA INC.,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY LLC,
NORTHWESTERN UNIVERSITY and
THE BOARD OF REGENTS FOR THE
UNIVERSITY OF OKLAHOMA

Respondents

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on October 5, 2010.

REASONS FOR ORDER BY: EVANS J.A.

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REASONS FOR ORDER

EVANS J.A.

[1] The motion before me arises from a prohibition proceeding brought by Pfizer Canada Inc. under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, (Regulations) to restrain the Minister of Health from issuing a Notice of Compliance (NOC) to Novopharm Limited in respect of its drug pregabalin, until after the expiry of the patents listed on the patent register by Pfizer with respect to pregabalin.

[2] Novopharm sought a confidentiality order for the Notice of Allegation (NOA) that it had served on Pfizer, in which it addressed the patents listed in respect of pregabalin. Prothonotary Milczynski of the Federal Court refused the order (2010 FC 409). Justice Crampton dismissed Novopharm's motion appealing from the Prothonotary's decision, finding the motion to be improper and vexatious (2010 FC 668). Novopharm has appealed to this Court from Justice Crampton's decision.

[3] Novopharm's present motion requests two forms of interim relief pending the disposition of the appeal by this Court, both of which are designed to protect the confidentiality of its NOA. First, it seeks a stay of Justice Crampton's order; second, in the alternative, it seeks an order restraining the parties to the prohibition proceeding, and the Court's Registry, from disclosing the NOA to others.

[4] Novopharm alleges that its competitive position as potentially the first or second generic pharmaceutical company on the market with pregabalin would be prejudiced by the disclosure of its NOA to its competitors, who could copy Novopharm's NOA when applying for their own NOC for pregabalin. In this way, competitors would obtain for free the benefit of the considerable effort and resources that Novopharm has devoted to producing its pregabalin NOA.

[5] The Regulations are silent on the confidentiality of NOAs filed by generics in support of their NOC applications. The Court has yet to determine in what circumstances, if any, NOAs are to be treated as confidential.

[6] In this case, Novopharm unilaterally marked its NOA as confidential and treated it as such. Further, Pfizer agreed to treat it as confidential pending the Federal Court's disposition of Novopharm's motion for a confidentiality order. However, after Justice Crampton dismissed Novopharm's appeal from Prothonotary Milczynski, Pfizer informed Novopharm that it had ceased treating the NOA as confidential from the date of Justice Crampton's decision. The copy of Novopharm's NOA filed with the Court was under seal pending the determination of its confidentiality, and remains so.

[7] The purpose of a stay of the execution of a Court order is to preserve the *status quo ante* pending an appeal. Since Justice Crampton refused to grant Novopharm a confidentiality order for its NOA, the *status quo* is that the confidentiality of the NOA is not protected. Granting a stay of Justice Crampton's Order does not therefore achieve the result that Novopharm seeks, namely, the designation of its NOA as confidential.

[8] Novopharm is in effect seeking the relief that Prothonotary Milczynski and Justice Crampton refused to grant to it. Hence, it has also requested an order restraining Pfizer and other parties to the prohibition proceeding, as well as the Court's Registry, from disclosing the NOA pending the disposition of Novopharm's appeal.

[9] In order to obtain an interlocutory or interim injunction, an applicant must satisfy the three-prong test established in *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311: the existence of a serious issue to be tried, whether the applicant will suffer irreparable harm if

denied an injunction, and whether the harm that denying the remedy will cause to the applicant is outweighed by the harm likely to be caused by granting it.

[10] Whether an appeal raises a serious issue is a relatively low threshold for an applicant to cross. For the reasons outlined in the Federal Court, I entertain considerable doubt as to whether Novopharm can bring its claim to confidentiality within the tests established in *Sierra Club of Canada v. Canada (Minister of Finance),* 2002 SCC 41, [2002] 2 S.C.R. 522. The fact that the confidentiality of an NOA has never been determined by the Court is not in itself an adequate basis for concluding that the issue must be a serious one. Nonetheless, for present purposes, I am prepared to find that Novopharm's appeal raises a serious issue.

[11] However, I am not satisfied that Novopharm has demonstrated on a balance of probabilities that it would suffer irreparable harm if not granted an interim injunction. Novopharm says that if the injunction is not granted, and its NOA is disclosed, its appeal will become moot and it will effectively have been deprived of its right to appeal Justice Crampton's decision.

[12] That an appeal may become moot is not in itself sufficient to warrant the award of an interim injunction pending the appeal: *eBay Canada Ltd. v. Canada (Minister of National Revenue),* 2008 FCA 141, 292 D.L.R. (4th) 299 at para. 33. It is still necessary for the party requesting the injunction to establish that the disclosure of the information that it is seeking to protect will cause it irreparable harm (at para. 36).

[13] Prothonotary Milczynski concluded (at para. 16) that Novopharm had adduced no evidence that disclosure of its NOA posed a serious risk to its market position with respect to pregabalin. Novopharm's allegation of harm is contingent on its success in defeating the patents listed by Pfizer on the patent register, and assumes that its competitors would want to copy its NOA. However, there was no evidence that competitors had copied the first NOA filed in respect of pregabalin by another generic.

[14] On appeal, Justice Crampton agreed (at para. 37) with this analysis, describing Novopharm's evidence of harm as "entirely speculative and largely based on bald assertions and unsupported assumptions." Two other points about the confidentiality claim should be noted. First, Novopharm is seeking a confidentiality order for its entire NOA, and not merely parts which could be redacted. Second, it does not allege that the NOA contains trade secrets. It is seeking only to protect its work product from "free riders".

[15] In the absence of evidence in support of this motion materially adding to that considered in the Federal Court, the findings of Prothonotary Milczynski and Justice Crampton are equally applicable to the question before me. Consequently, I am not satisfied that Novopharm has demonstrated on a balance of probabilities that, if the Court does not grant the interim relief sought, disclosure of the NOA pending the disposition of the appeal, will cause irreparable harm to Novopharm's commercial interest.

[16] In view of this finding, it is unnecessary for me to consider where the balance of convenience lies. There is no harm to be balanced against the harm to the public interest in the openness of judicial proceedings if relief were granted.

[17] For these reasons, Novopharm's motion is denied, with costs in the lump sum of $4,000 payable to Pfizer forthwith.

"John M. Evans"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-252-10

STYLE OF CAUSE: NOVOPHARM LIMITED and PFIZER CANADA INC. et al

MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY: **EVANS J.A.**

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