Federal Court  Cour fédérale

Date: 20100302

Docket: T-1048-07

Citation: 2010 FC 241

Ottawa, Ontario, March 2, 2010

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

ELI LILLY CANADA INC.,
ELI LILLY AND COMPANY,
ELI LILLY AND COMPANY LIMITED and
ELI LILLY, SA

Plaintiffs
(Defendants by Counterclaim)

and

NOVOPHARM LIMITED

Defendant
(Plaintiff by Counterclaim)

REASONS FOR ORDER AND ORDER

[1] Novopharm Limited (Novopharm) seeks an extraordinary remedy in a unique situation.

[2] Novopharm seeks an order in the nature of a *Mareva* injunction enjoining Eli Lilly Canada Inc. (Lilly Canada) from transferring its revenues to its parent company, Eli Lilly and Company (Lilly US). In the alternative, Novopharm seeks an order requiring Lilly Canada to post security for damages, that have yet to be quantified, which it asserts it will be awarded pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the NOC Regulations), and an order that Lilly Canada disclose its financial accounts to Novopharm on a quarterly basis.

[3] Novopharm's concern is that even though they have prevailed over Lilly Canada in a dispute regarding Canadian Patent No. 2,014,113 (the '113 patent), the continued transfer of revenues to Lilly US may render Lilly Canada judgment-proof by the time the proceedings in this Court to determine the section 8 damages have been completed.

[4] For the reasons that follow, this motion is dismissed.

Background

[5] In response to a Notice of Allegation from Novopharm dated August 5, 2004, Lilly Canada brought an application (Court file T-1734-04), pursuant to section 6 of the NOC Regulations, for an order preventing Novopharm from marketing its olanzapine tablets. This application was subsequently discontinued when Novopharm withdrew its Notice of Allegation on or about April 21, 2005.

[6] On July 20, 2005, Novopharm served Lilly Canada with a second Notice of Allegation regarding its olanzapine tablets. Lilly Canada filed a second application pursuant to section 6 of the NOC Regulations (Court File T-1532-05), again seeking an order preventing Novopharm from marketing its olanzapine tablets. On June 5, 2007, Justice Hughes rejected Lilly Canada's application. He held that Novopharm's allegation that the '113 patent was invalid was justified: *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596. The next day, June 6, 2007, Novopharm received an NOC and began marketing its product. An appeal of Justice Hughes' decision was dismissed for mootness, and leave to appeal to the Supreme Court was dismissed: *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359, leave to appeal to S.C.C. refused, 32415 (March 13, 2008).

[7] Also on June 6, 2007, Lilly Canada, along with its parent and Eli Lilly SA, brought the current action against Novopharm for patent infringement. Novopharm, by way of counterclaim, brought an action for damages pursuant to section 8 of the NOC Regulations. Despite the protestations of Novopharm, the Court ordered the trial of the action to be bifurcated; the counterclaim for section 8 damages would proceed only if Lilly Canada was unsuccessful at trial.

[8] Section 8 of the NOC Regulations provides a disincentive designed to make an innovator pharmaceutical company cautious when considering whether to institute NOC proceedings. If the innovator loses, then the generic can sue for damages resulting from any delay in obtaining its NOC caused by the statutory stay on approval that the proceedings create.

[9] On October 5, 2009, Justice O'Reilly dismissed the action against Novopharm, finding that the '113 patent was invalid. He further found that Novopharm was entitled to relief under section 8 of the NOC Regulations: *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018. An appeal to the Federal Court of Appeal was filed by the plaintiffs on November 3, 2009 (A-454-09) and has yet to be heard. The Judgment of Justice O'Reilly of this Court was as follows:

> 1. The claims of the '113 patent at issue are invalid;
>
> 2. Lilly's action for patent infringement is dismissed;
>
> 3. Novopharm is entitled to relief under s. 8 of the Patented Medicines (Notice of Compliance) Regulations to be determined in a separate proceeding, and to its costs.

[10] There was a question as to what paragraph 3 of the Judgment meant. Justice O'Reilly, in a subsequent Order dated December 16, 2009, addressed that question and in the course of so doing wrote the following.

> I agree with Lilly's submission that there are some issues relating to remedies that could have been decided during the liability phase of the trial (*e.g.* the start and end date of any losses suffered by Novopharm). However, there was no requirement for me to do so. I determined that the question of the duration of any losses, and other issues directly related to s. 8 relief, should be decided at a hearing on remedies, and so ordered. Contrary to Lilly's submission, the bifurcation order did not specify the issues to be decided at the liability stage; it identified categories of evidence that should *not* be presented.

The proceeding required to determine the quantum of damages under section 8 of the NOC Regulations has not yet been scheduled and the materials before the Court indicate that it may not be heard until 2011.

[11] Novopharm submits that a conservative estimation of the damages it will be awarded is in the range of $86 to $138 million, exclusive of legal costs.

[12] The plaintiffs have taken the position that Lilly Canada is the only entity liable for section 8 damages because Lilly Canada was the only "first person" in the NOC proceedings. This position, combined with other evidence that will be referred to below, raised Novopharm's concern that Lilly Canada may become judgment-proof. Consequently, Novopharm brought this motion to enjoin Lilly Canada from transferring its revenues to its parent corporation in the United States, and in the alternative, for an order requiring it to post security for damages and to provide quarterly financial accounts.

Analysis

[13] Section 44 of the *Federal Courts Act* and Rule 373 of the *Federal Courts Rules* confer jurisdiction to issue a *Mareva* injunction before liability has been determined; this is the traditional purpose of *Mareva* injunctions, and the Court of Appeal has instructed that this Court does have jurisdiction to issue such injunctions: S*tandal Estate v. Swecan International Ltd.*, [1990] 1 F.C. 115 (C.A.). In my view, there can be no serious suggestion that this Court does not have jurisdiction to issue such an injunction when, as here, liability has been determined but not quantum.

[14] The real issue in dispute between these parties is whether Novopharm has met the test for the granting of the requested remedy.

[15] There is a general and long-standing rule in our common law system that there should be no execution before judgment: *Lister & Co. v. Stubbs*, [1886-90] All E.R. 797 (C.A.); *Bedell v. Gefaell*, [1938] O.R. 726 (C.A.). The probability that a plaintiff will succeed if a matter proceeds to a hearing, in and of itself, is not grounds for the defendant to be ordered to post security.

[16] Even before the advent of the *Mareva* injunction there were exceptions to the general rule described in *Lister*: see *Aetna Financial Services Ltd. v. Feigelman*, [1985] 1 S.C.R. 2 at 17. However, in *Nippon Yusen Kaisha v. Karageorgis*, [1975] 3 All E.R. 282 (C.A.) and *Mareva Compania Naviera SA v. International Bulkcarriers SA*, [1980] 1 All E.R. 213 (C.A.) Lord Denning opened the door to new judicial remedy that would become known as the *Mareva* injunction. In *Third Chandris Shipping Corporation v. Unimarine S.A.*, [1979] 1 Q.B. 645 at 668-669 (C.A.), Lord Denning outlined the requirements that a plaintiff must meet in order to obtain a *Mareva* injunction and thereby freeze the defendant's assets prior to judgment:

> (i) The plaintiff should make full and frank disclosure of all matters in his knowledge which are material for the judge to know.
>
> (ii) The plaintiff should give particulars of his claim against the defendant, stating the ground of his claim and the amount thereof, and fairly stating the points made against it by the defendant.
>
> (iii) The plaintiff should give some grounds for believing that the defendants have assets here. ….
>
> (iv) The plaintiff should give some grounds for believing that there is a risk of the assets being removed before the judgment or award is satisfied. …

> (v) The plaintiff must, of course, give an undertaking in damages -- in case he fails in his claim or the injunction turns out to be unjustified.
>
> [citations omitted]

[17] The guidelines described in *Third Chandris Shipping Corp.* have been cited in Canada with approval in numerous cases: See e.g. *Marine Atlantic Inc. v. Blyth et al.* (1993), 113 D.L.R. (4th) 501 (F.C.A.).

[18] In *Chitel et al. v. Rothbart et al.* (1983), 39 O.R. (2d) 513 at 532-533 (C.A.) a significant modification was made to the fourth requirement described in *Third Chandris Shipping Corp.*, namely:

> The applicant must persuade the court by his material that the defendant is removing or there is a real risk that he is about to remove his assets from the jurisdiction to avoid the possibility of a judgment, or that the defendant is otherwise dissipating or disposing of his assets, in a manner clearly distinct from his usual or ordinary course of business or living, so as to render the possibility of future tracing of the assets remote, if not impossible in fact or in law.

[19] In summary, in Canada the following requirements for a *Mareva* injunction must be established:

1. The plaintiff must establish a strong *prima facie* case for potential success at trial: *Aetna Financial Services Limited* at 27;

2. The plaintiff must meet the five guidelines set out in *Third Chandris Shipping* as re-articulated and modified in *Chitel*, namely (a) full and

frank disclosure, (b) particulars of the claim, (c) assets within the jurisdiction, (d) risk of removal or dissipation of assets in order to frustrate judgment, and (e) an undertaking as to damages; and

3. The plaintiff must satisfy the regular tripartite test for an interlocutory injunction described in *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311 at 334, namely (a) the presence of a serious question to be tried, (a) irreparable harm should the injunction not be granted, and (c) that the balance of convenience favours the moving party.

[20] If the applicant fails to meet any of these, the Court should refuse the *Mareva* injunction.

[21] Novopharm has not provided any undertaking as to damages. It submits that the Court has discretion to dispense with such an undertaking and that, in any event, the rationale for the requirement that the applicant provide an undertaking, does not apply here. The rationale, it is submitted, is as described by Justice Sharpe in his book, *Injunctions and Specific Performance*, loose-leaf (Canada Law Book: Aurora, Ontario, 2009) at 2.470:

> The rationale for the undertaking is to protect the defendant from the risk of granting a remedy before the substantive rights of the parties have been determined. In the event the defendant succeeds at trial, the interlocutory injunction will have prevented the defendant from acting in accordance with his or her legal rights. The undertaking in damages shifts all or a part of that risk to the party who is asking for a pre-trial remedy.

[22] Novopharm provided three submissions as to why no undertaking ought to be required in this instance. I can do no better than to reproduce its submissions from paragraphs 75-77 of its factum:

> First, Novopharm is not seeking a pre-trial remedy, so the logic of Justice Sharpe's analysis is not strictly and straightforwardly applicable. There is no risk that the injunction will cause harm to Lilly, as it is a certainty that Lilly will have to pay damages to Novopharm.
>
> Second, as stated above, the test is or should be different as the relief sought is a post-judgment injunction. Again, the fact that Lilly will have to make a payment to Novopharm is beyond debate, the only open question is in what amount. Just as Novopharm ought not to have to establish irreparable harm in these circumstances, it ought also be relieved from any requirement to post an undertaking in damages.
>
> Considerations should also be given Justice Hughes' characterization of s. 8 damages as a form of "undertaking" by first persons, such as Lilly, given in exchange for the statutory injunction, which is obtained without having to prove any of the criteria normally required for a statutory injunction. This Court should not require Novopharm to provide an undertaking to enforce Lilly's undertaking.

[23] I am not persuaded that in these admittedly unique circumstances, the requirement of an undertaking from the moving party should be waived.

[24] I do not accept Novopharm's submission that it is not seeking a pre-trial remedy because the Court has already determined that Novopharm is entitled to section 8 damages. A trial as to those damages remains to be heard. Although Justice O'Reilly adjudged that "Novopharm is entitled to relief under s. 8 of the Patented Medicines (Notice of Compliance) Regulations to be determined in a separate proceeding" this flows directly from the wording of section 8 of the NOC Regulations

which provides, in part, that "if an application made under subsection 6(1) is … dismissed by the court …the first person is liable to the second person for any loss suffered during the period."

[25] Novopharm says that "it is a certainty that Lilly will have to pay damages to Novopharm." In my view, on the materials before the Court, this is not a certainty. Section 8(5) of the NOC Regulations provides that "in assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount." Lilly Canada submits that it is far from certain that Novopharm will be awarded any damages based on the matters that it will urge the Court to consider when assessing damages.

[26] Lilly Canada submits that if Novopharm had not withdrawn its first NOA, it may not have been delayed in bringing its product to market because the first proceeding would have been concluded before Novopharm received its Notice of Approvability from Health Canada. It further submits that Novopharm waived all or part of its claim for section 8 damages. It points to an affidavit filed by Novopharm wherein it attests: "The fact that a decision on the merits of the case has been delayed by the withdrawal of the Notice of Allegation is entirely to the prejudice of Novopharm (with months lost in reaching marketing approval, loss of claims to s. 8 damages)." It also points to a subsequent affidavit wherein Novopharm attests that in withdrawing its first Notice of Allegation, Novopharm "abandoned its claim to s. 8 damages." Lilly Canada also submits that Novopharm should be disentitled to any section 8 damages being awarded because of "inaccuracies in Novopharm's NOAs." Lastly, Lilly Canada raises the defence of mitigation, submitting that

Novopharm has failed to mitigate any damages it may have suffered in failing to stockpile products and being in a market-ready position.

[27] It may be, following a full trial, that none of these defences and submissions of Lilly Canada are found to be valid; however, at this point, on an interlocutory motion, the Court cannot and should not engage in a detailed analysis of the matters raised by Lilly Canada. What is clear, however, is that it is not a certainty that Novopharm will be awarded any damages as a result of the section 8 hearing.

[28] For these same reasons I reject Novopharm's second submission that this is really a post-judgment injunction.

[29] Lastly, Justice Hughes did not quite state that section 8 was a form of undertaking from the innovator. What he said was that it acts like an undertaking:

> In many respects, section 8 can be analogized to the undertaking usually required by a party seeking an interlocutory injunction from a Court. This Court (*Rule* 372(2)) and most other courts in this country require, unless otherwise ordered, that an undertaking as to damages be provided. An undertaking is a serious matter and the damages afforded may be substantial, although as stated by the Ontario Court of Appeal in *Debrina Corporation v. Triolet Systems Inc.* (2002), 17 C.P.R. (4th) 289 at paragraph 87, they must be reasonably foreseeable at the time of the granting of the interlocutory injunction and must be caused by ("*naturally flow from*") the injunction and not something else.

[30] In its notice of motion Novopharm sought an order that Lilly Canada not transfer any profit to "any entity affiliated with or related to Lilly" or, in the alternative, "post a bond or other security in a form acceptable to Novopharm, with the Federal Court in an amount sufficient to cover a damage award of $100,000.000.00 and Novopharm's costs of this action." Although the evidence filed in support of the motion claims the section 8 damages will be between $86 to $138 million, during oral submissions, counsel conceded that if the period of damages was limited to 3.5 months, as Lilly Canada suggests is warranted, the damages would be in the order of $20 million.

[31] Novopharm has been unable to convincingly establish any amount as the likely award it will receive. It would be improper and inappropriate to issue the order requested in that circumstance. It would have a substantial impact on the business operations of Lilly Canada and also most likely on Lilly US. If, at the end of the day, the injunction should not have issued, then Novopharm should be liable for any damages to the plaintiffs that flows from such an order and it is for that reason that I find that if the injunction were to issue, an undertaking by Novopharm must be given. None has been offered and thus no injunction, or the security proposed as an alternative, will issue.

[32] Further, the fact that Novopharm has been unable to quantify its damages with any particularity goes as well to its failure to prove irreparable harm. Irreparable harm must be harm which will occur in the period between now and the time the damages are quantified and ordered to be paid. Irreparable harm is harm which cannot be cured, and Novopharm must establish the harm with clear and convincing evidence and also establish on a balance of probabilities that the alleged harm is likely to occur. The evidence must be credible and the harm non-speculative. The harm

alleged, its failure to be able to collect a judgment, meets none of these requirements as Novopharm can only speculate as to the amount of damages it says that it may fail to recover.

[33] I also find that Novopharm has failed to establish on the balance of probabilities that Lilly Canada will be unable to satisfy a judgment of the order it hopes to receive.

[34] Lastly, the *Chitel* test has not been met. Novopharm has failed to persuade me that Lilly Canada is removing or there is a real risk that it is about to remove its assets from Canada to avoid the possibility of a judgment, or that it is otherwise dissipating or disposing of his assets, in a manner clearly distinct from its usual or ordinary course of business so as to render the possibility of future tracing of the assets remote or impossible.

[35] The only evidence Novopharm has provided in this respect is:

a. That Lilly Canada retains no profits but sends all of its profits to Lilly US;

b. That Lilly Canada maintains only operating accounts used to maintain its business in Canada but does not maintain any investments;

c. That after Justice Hughes' decision when Lilly Canada lost market exclusivity on olanzapine, Lilly Canada laid off some employees and some described it as being in a "weakened state;" and

d. That Lilly Canada's General Counsel and Corporate Secretary made statements under oath that "suggested" that Lilly US would want to divest itself of any liability to Novopharm.

[36] This evidence does not establish, on the balance of probabilities, that Lilly Canada is about to remove its assets from Canada or that in sending its profits to its parent, it is acting in anything other than the ordinary and usual course of business. Further, there is nothing in the record that proves, on the balance of probabilities, that the plaintiffs would wind up their Canadian operations rather than pay Novopharm any judgment it is awarded. At best, to use the wording of Novopharm, the evidence "suggests" and that, quite simply, is insufficient evidence on which to base the grant of a *Mareva* injunction.

[37] For these reasons the motion is dismissed. In keeping with Justice O'Reilly's Order as to costs following the trial, Lilly Canada is entitled to its costs of this motion at the middle of Column III and is entitled to fees for a second counsel for attendance at the hearing of the motion.

ORDER

THIS COURT ORDERS that:

1. The motion is dismissed; and

2. Lilly Canada is entitled to its costs of this motion at the middle of Column III and is entitled to fees for a second counsel for attendance at the hearing of the motion.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1048-07
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