Date: 20061213

Docket: A-500-06

Citation: 2006 FCA 406

Present: **SHARLOW J.A.**

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

JANSSEN-ORTHO INC.,
and DAIICHI PHARMACEUTICAL CO., LTD.

Respondents

Heard at Toronto, Ontario, on December 12, 2006.

Order delivered at Toronto, Ontario, on December 13, 2006.

REASONS FOR ORDER BY: SHARLOW J.A.

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REASONS FOR ORDER

SHARLOW J.A.

[1] The appellant Novopharm Limited seeks a stay of the judgment of Justice Hughes dated October 17, 2006 (2006 FC 1234). The judgment declares claim 4 of Canadian Letters Patent No. 1,304,080 (the 080 Patent) to be valid and infringed by Novopharm, and grants certain remedies including an injunction that took effect on November 17, 2006, and an order for the destruction of the infringing products or its delivery to the respondents. The appellant's notice of motion for a stay was filed on November 29, 2006.

Litigation history

[2] Canadian Patent Number 1,304,080 is entitled "*Optically Active Pyridobenzoxazine Derivatives and Intermediates Thereof*". Claim 4 reads:

> *4. S(-)-9-fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3- de][1,4]benzoxazine-6-carboxylic acid.*

[3] The Patent was issued and granted to the respondent Daiichi Pharmaceutical Co. Ltd. on June 23, 1992 and will expire on June 23, 2009. The respondent Janssen-Ortho Inc. is a licensee of the Patent. The short name of the compound named in Claim 4 is levofloxacin. Levofloxacin is the principal ingredient in a drug called Levaquin, an antibiotic. Janssen has marketed Levaquin in Canada since 1997. It is also the principal ingredient in Novo-levofloxacin, which has been marketed in Canada by Novopharm since 2004.

[4] On December 6, 2004, Janssen and Daiichi commenced a patent infringement action against Novopharm on the basis that its manufacture and sale of Novo-levofloxacin infringed the 080 Patent. Novopharm defended and counterclaimed, alleging that the 080 Patent was invalid. The issues were narrowed so that by the time of trial, only Claim 4 of the 080 Patent was in issue and infringement was admitted, leaving only the issue of validity of Claim 4 to be litigated.

[5] The trial occurred in September and October of 2006. The judgment under appeal was issued on October 17, 2006. The Judge concluded that Claim 4 was valid.

[6] One of the grounds of invalidity alleged in the infringement action was obviousness. Substantially the same argument had been made and rejected in prohibition proceedings under the *Patented Medicines (Notice of Compliance Regulations)*, SOR/93-133 (*Janssen-Ortho Inc. v. Novopharm Ltd.*, 2004 FC 1631, appeal dismissed as moot, *Janssen-Ortho Inc. v. Novopharm Ltd*., 2005 FCA 6, leave to appeal to the Supreme Court of Canada dismissed, [2005] 1 S.C.R. 776).

However, it is well established by the jurisprudence of this Court that conclusions about infringement and invalidity of a patent in a prohibition application are not final determinations, but merely provisional findings for limited regulatory purposes. That is why it was open to Janssen and Daiichi to commence an action to seek a remedy for infringement even though their prohibition application did not succeed.

[7] The parties agree that the applicable legal principles are those set out in *RJR – MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311. The respondents concede that the first test for the granting of a stay, the existence of an arguable case on appeal, is met. The issues are whether the appellant will suffer irreparable harm if the stay is not granted, and if so whether the balance of convenience favours granting a stay.

[8] Novopharm alleges two forms of harm. One is irreparable harm to its reputation. I agree that irrevocable damage to reputation may form part of the basis for a stay. The issue is whether the evidence adduced by Novopharm on this point substantiates this claim.

[9] Novopharm argues that it has invested considerable time and resources in establishing for itself a well founded reputation for providing first access to the latest generic drugs, and for having the capacity to maintain a consistent supply, and that if a stay is not granted in this case, its reputation will be damaged beyond repair once its customers find themselves unable to look to Novopharm to provide them with Novo-levofloxacin.

[10] There is credible evidence that Novopharm has a good reputation. I am prepared to accept that Novopharm's customers may well believe what Novopharm apparently tells them, which is that

Novopharm is better than other generic producers in terms of first access and consistency of supply. I also accept that Novo-levofloxacin is a very important product to Novopharm, even though it represents only one of 190 products and brings in approximately 2% of Novopharm's sales revenue, because it is the best selling generic medicine of which Novopharm is the sole supplier. I also accept that if Novopharm can no longer supply Novo-levofloxacin to its customers, some of those customers may over time look to other suppliers for levofloxacin medicines, and for other products as well.

[11] However, I am unable to find on the record before me that, on a balance of probabilities, an interruption in the supply of Novo-levofloxacin will irrevocably damage the good reputation of Novopharm in terms of first access and consistency of supply where, as in this case, that interruption in supply is the result of a lost court case. I have no basis for attributing to Novopharm's customers the irrational belief that, because Novopharm has apparently failed in this instance to control the outcome of litigation, it does not deserve its good reputation.

[12] Novopharm also alleges that it will suffer irreparable financial loss if the stay is not granted and the appeal is allowed because it will have lost sales that it will never recover, and also because it may permanently lose other sales. There is merit in this allegation. However, Janssen and Daiichi say that they are prepared to make an undertaking in the form adopted by Evans J.A. in *Apotex Inc. v. Merck & Co., Inc.*, 2006 FCA 198, which will be a complete answer to Novopharm's concern about financial loss. The form of undertaking is as follows:

> The respondents undertake to abide by any order that the Court may make concerning damages if the appeal of [Appellant] of the judgment of [Judge] dated [date] in Court File No. [Docket] is allowed and it ultimately appears that the judgment has caused damage to [Appellant] for which the respondents ought to compensate [Appellant] during the time period beginning on

> the day that this Court dismisses the motion for a stay and ending on the day that this Court grants the appeal.

[13] It is common ground that this undertaking contemplates compensation for all financial losses that Novopharm would suffer as a direct or indirect result of the injunction, if the stay is not granted and the appeal succeeds.

[14] Novopharm says that this form of undertaking is flawed because it deals with the period that ends with the disposition of the appeal. Novopharm argues that if the stay is not granted, its losses will accrue even after the disposition of the appeal and for some indeterminable time after that, because it will take some time to re-establish its customer relationships and its market. Counsel for Janssen indicates that Janssen is prepared to agree to an undertaking in which the period of time for the accrual of damages will end at some reasonable time after the disposition of the appeal. Two to six months is suggested, because that is the amount of time Novopharm says would be required to have its product returned to provincial formularies. Counsel for Daiichi says that Daiichi has not agreed to such an extension.

[15] In my view, an undertaking in the form set out above, with the suggested extension of the term, would be a complete answer to Novopharm's allegation of irreparable financial harm. I conclude that, provided the undertakings indicated above are given, Novopharm has not established irreparable harm. The relevant period should extend for approximately four months after the date of the disposition of the appeal.

[16] It is not necessary for me to consider the balance of convenience, but I will do so because it was fully argued. I have not been persuaded that granting the stay would cause irreparable harm to

Janssen or Daiichi. The result of the stay would be to continue the situation that has existed since 2004, when Novopharm entered the market in competition with Janssen and Daiichi. That was damaging to them, but that damage is compensable.

[17] Janssen and Daiichi seek an expedited hearing of the appeal. That is a reasonable request, if they provide the undertakings as stated above. Dates are available in Toronto on March 13 and 14, 2007, and all counsel have indicated that they can be available for a hearing on those dates. An order will be made accordingly.

"K. Sharlow"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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APPEARANCES:

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