

FEDERAL COURT OF CANADA REITERATES HIGH THRESHOLD OF IRREPARABLE HARM IN INTERIM INJUNCTIONS

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INTRODUCTION

In a case opposing two pharmaceutical giants, the Trial Division of the Federal Court of Canada, ruled that the Plaintiff had failed to discharge the high burden of showing irreparable harm in its request for an order for an interim injunction (*Pfizer Ireland Pharmaceuticals v. Lilly Icos LLC*, 2003 FC 1278, November 3, 2003, Kelen J.)

THE FACTS

The Plaintiff, Pfizer Ireland Pharmaceuticals (“Pfizer”), is an international pharmaceutical company with Canadian operations, known for, amongst others, a product for the treatment of erectile dysfunction sold under the trade-mark VIAGRA. The Canadian patent for VIAGRA is set to expire in the year 2014. Since the launch of this product in 1999, sales in Canada have totalled close to 182 million dollars, and 40 millions dollars have been spent on advertising and promotion.

The Defendant, Lilly Icos LLC (“Lilly”) also has a treatment for erectile dysfunction and its medication is sold under the trade-mark CIALIS. Lilly sells its CIALIS product in competition with Pfizer’s VIAGRA product in many countries around the world. In 2002, Lilly instituted proceedings for impeachment of Pfizer’s Canadian patent on the basis of obviousness. Pfizer in turn initiated a patent infringement action against Lilly, inclusive of a request for injunctive relief to prevent Lilly from importing and selling CIALIS in Canada. Pfizer’s infringement action was struck out as being premature since the CIALIS product had not yet been approved for importation and sale in Canada at the time the action was taken.

The CIALIS product was finally approved for importation and sale in Canada in September 2003 and was scheduled to be sold as of November 1, 2003. This recent turn of events lead Pfizer to take a second infringement action against Lilly, inclusive of a request for an interim and interlocutory injunctive relief.

THE JUDGEMENT

The Court began by reviewing the requirements for the issuance of an interim injunction. An interim injunction is an exceptional remedy and it is only issued if there is urgency justifying its issuance. The Court further reiterated the well established test for interim injunction (*RJR-McDonald Inc. v. Canada (Attorney General)*, (1994) 1 S.C.R. 311 (S.C.C.)), namely that the applicant is required to show :

- a serious question to be tried;
- irreparable harm (if the application for injunction is refused); and
- the balance of convenience (which party will suffer the greater harm pursuant to the issuance, or not, of the injunction).

An interim injunction in the Federal Court of Canada is valid for a period of fourteen (14) days. However, in this case, Pfizer sought an interim injunction which would have been valid until the parties were ready for the interlocutory injunction hearing, which it estimated would be approximately one or two months from the issuance of an interim injunction. This type of "extended" interim injunction is not contemplated by the *Federal Court Rules (1998)*, but the Court nonetheless ruled that it had inherent jurisdiction to grant same in certain special circumstances.

On the basis of the foregoing, the Court ruled as follows:

1 - Urgency

Since Lilly had not contested the issue of urgency, the Court accepted that same had been proved.

2 – Serious Issue to Be Tried

This is usually the "easiest" criteria to prove in the test for interim injunction. The Court was of the view that Lilly's 2002 patent impeachment action and the infringement action of Pfizer were sufficient facts in evidence showing that Pfizer's request for an interim injunction was based on a serious issues.

3 – Irreparable Harm

This is usually the most difficult criteria to overcome for a person seeking an interim injunction.

Pfizer argued that without an interim injunction, its exclusive patent rights, goodwill, brand equity, market share and its ability to build on these assets over the term of the patent would be irreparably damaged. According to Pfizer, any damage it would suffer after the launch of the CIALIS product on the Canadian market would affect its company image, strength in the market and the establishment of a strong trade-mark. Pfizer further argued that it would be impossible to do a proper accounting of its damages since the sale of the CIALIS product in Canada would lead to a different development of the market. It also argued that if the CIALIS product were to be removed from the market in two or three years, when a permanent injunction was issued, this would cause a backlash against it Pfizer and its VIAGRA product.

After reviewing the evidence, the Court concluded that Pfizer had not adduced “clear and not speculative” evidence of irreparable harm following the importation and sale of the CIALIS product in Canada (*Centre Ice Ltd. v. National Hockey League*, (1994) 53 C.P.R. 34 (F.C.A.)). The allegations of eventual “resentment” and backlash from consumers of CIALIS product against Pfizer was not, in the Court’s view, supported by evidence.

The Court noted that Pfizer had not brought any relevant Canadian cases granting an interim or interlocutory injunction in a patent infringement case : the general reasoning of the Federal Court is that patent rights usually involve monetary damages and same can usually be calculated. According to the Court, pharmaceutical companies usually have all the necessary resources to calculate damages based on a historical analysis of similar cases.

The Court also gave weight to the fact that Pfizer had not sought injunctive relief in any of the other countries where the CIALIS product was being sold, in direct competition with the VIAGRA product, likely because Pfizer could not establish irreparable harm.

4 – Balance of Convenience

When in doubt about the strength of the evidence relating to one or another part of the test for interim injunction, the Court must analyse whether one party would be prejudiced more than the other if the interlocutory injunction

was issued. However, since Court had concluded that there was no irreparable harm shown by Pfizer, it did not have to consider this criteria.

For the above reasons, the Court dismissed the interim injunction, with costs in the cause, and ordered the parties to submit a schedule for conduct of the file until interlocutory injunction.

CONCLUSION

This case constitutes a reminder that interim injunctions are rarely, if ever, granted in patent infringement cases before the Federal Court of Canada and that a high threshold of irreparable harm must be met by the party requesting such an injunction. Despite the fact that the Court did not consider it appropriate to issue an interim injunction in this case, it did not dismiss the request as being frivolous. There is still a faint hope that, one day, the “trend” of refusing interim injunctions will be reversed...

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