

## Time is of the Essence When Appealing an Unsuccessful Prohibition Application

*Court of Appeal again finds that appeal is moot once NOC issues.*

As reported in the January issue of *Rx IP Update*, the Federal Court of Appeal, in *Novartis Pharmaceuticals Canada v. RhoxalPharma Inc.*, recently allowed a generic company's motion to dismiss an appeal on the ground that the appeal was moot. While not indicated in the Court's reasons, the apparent basis for the finding of mootness was the issuance of a notice of compliance ("NOC") to RhoxalPharma, following dismissal of Novartis' application for an order of prohibition. In dismissing the appeal, the Court of Appeal relied upon its previous decision, *Pfizer Canada Inc v. Apotex Inc* (January 10, 2001), without further comment.

In *Pfizer*, the Court of Appeal dismissed two appeals as moot because the NOCs had issued by the date of the appeal hearing. The Court, however, left open the question of whether the appeals would have been dismissed as moot had the appellants completed their appeals within the 30-month (now 24-month) statutory stay period. Similarly, it remains an open question whether an appeal is moot if the statutory stay expires, but the NOC has not issued.

Subsequent to the release of *Pfizer* and prior to *Novartis*, the issue of mootness based on issuance of an NOC was raised again before the Court of Appeal in *Merck Frosst Canada Inc v. Alcon Canada Inc* [see September 2001 issue for link]. However, the Court of Appeal declined to consider the issue and proceeded to dismiss the appeal on the merits.

In view of the *Pfizer* and *Novartis* decisions, if an Applicant under the *Regulations* does not succeed in obtaining an order of prohibition in the Trial Division, it should act expeditiously to either prevent issuance of the NOC or to have its appeal heard before the NOC is issued.

The Applicant may seek to prevent issuance of the NOC by moving for a stay of the Trial Division decision, pending appeal. However, such a stay will be difficult to obtain in view of the requirement to establish irreparable harm. In *Merck*, an interlocutory stay application was dismissed as the motions judge found that irreparable harm had not been shown. In a case relating to the Minister's decision to remove a patent from the patent register, the Court of Appeal in *Apotex Inc v. Bristol-Myers Squibb* (January 9, 2001), found that "any loss suffered by Bristol-Myers as the result of its inability to obtain an automatic stay under the *Regulations* [was] not 'irreparable harm'" and thus reversed the decision of the motions judge who had granted a stay of the Minister's decision.

The Applicant may also move to expedite the appeal. However, if the generic's new drug submission is otherwise approvable by the date of the Trial Division decision (a matter that the Applicant has no way of confirming), it may not be possible to advance the appeal quickly enough to be heard prior to issuance of the NOC.

*Novartis* is a further indication that the *Regulations* will be construed strictly by the Courts with harsh consequences to the patentee. Thus, in the face of an unsuccessful result in the Trial Division, and if there are no other patents preventing NOC issuance, an Applicant should move swiftly to seek to prevent NOC issuance prior to the hearing of the appeal, in view of the risk of its appeal being rendered moot.

*Denise L. Lacombe*

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## Recent Court Decisions

### *Patented Medicines (Notice of Compliance) Regulations*

*Eli Lilly v. The Minister of Health (ceftazidime injection (TAZIDIME and TAZIDIME ADD-VANTAGE))*, January 10, 2002

Judge upholds the Minister of Health's decision to remove a patent from the patent register. The Minister removed the patent on the basis that Eli Lilly's commercial formulation did not contain the formulation claimed in the patent and Eli Lilly did not receive an NOC for the subject-matter of the patent.

[Full Judgment](#) (\*For a printer friendly version, please scroll down to the end of the Judgment)

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*Bristol-Myers Squibb v. Apotex (nefazodone hydrochloride (SERZONE-5HT<sub>2</sub>))*, January 23, 2002

Court of Appeal dismisses appeal of Judge's decision, upholding the Minister of Health's decision that the patent at issue was ineligible for inclusion on the patent register. Appellant had attempted to add a patent to the patent register by filing a fresh patent list along with a supplemental new drug submission, changing only the brand name of the product from SERZONE to SERZONE-5HT<sub>2</sub>. While the Minister initially included the patent on the patent register, it was subsequently removed on the basis that a brand name change does not change the drug and thus the patent was effectively added to the existing patent list, outside of the strict time limits permitted by the *Regulations*.

[Full Judgment](#) (\*For a printer friendly version, please scroll down to the end of the Judgment)

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## Other Decisions

*Apotex v. Bayer (nifedipine capsules (ADALAT))*, January 24, 2002

Court of Appeal dismisses Apotex' appeal of trial judge's decision, allowing Bayer to elect an accounting of profits as a remedy for patent infringement.

[Full Judgment](#)

## New Court Proceedings

### *Patented Medicines (Notice of Compliance) Regulations*

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**Medicine:** **Diltiazem Hydrochloride Extended Release Capsules (Cardizem CD)**  
**Applicants:** Biovail Corporation and Galepharm PR Inc  
**Respondents:** Altimed Pharmaceutical Company and The Minister of Health  
**Date Commenced:** January 10, 2002  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,111,085. Altimed alleges non-infringement.

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**Medicine:** **Carvedilol (COREG)**  
**Applicants:** Hoffmann-La Roche Limited and SmithKline Beecham Corporation  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** January 16, 2002  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 1,259,071 and 2,212,548. Novopharm alleges non-infringement and invalidity.

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**Medicine:** **Sevoflurane (EVOTANE)**  
**Applicant:** Toba Pharma Inc  
**Respondents:** Attorney General of Canada and The Minister of Health  
**Date Commenced:** January 17, 2002  
**Comment:** Application for Order requiring The Minister to add Patent No. 2,278,133 to the patent register. The Minister refused to add the patent in connection with a submission for a change in the manufacturer's name.

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**Medicine:** **Citalopram Hydrobromide (CELEXA)**  
**Applicants:** H. Lundbeck A/S and Lundbeck Canada Inc  
**Respondents:** Genpharm Inc and The Minister of Health  
**Date Commenced:** January 24, 2002  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,049,368. Genpharm alleges improper listing of the patent on the patent register and non-infringement.

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**Medicine:** **Unidentified**  
**Applicant:** The Minister of Health  
**Respondent:** None  
**Date Commenced:** January 24, 2002  
**Comment:** Application to refer the following question to the Federal Court, Trial Division:  
"Does a patent list submitted with a supplemental new drug submission meet the requirements of section 4 of the *Regulations* where:  
(a) the patent has not been applied for at the time of the original new drug submission;  
(b) the timing requirements of subsection 4(4) are not met in respect of the original new drug submission; and,  
(c) the patent is not directed to the subject matter of the supplemental new drug submission?"

## Other New Proceedings

**Medicine:**

**Plaintiffs:**

**Defendant:**

**Comment:**

**Travoprost Ophthalmic Solution (TRAVATAN)**

Pharmacia Canada Inc, Pharmacia Aktiebolag and Pharmacia Enterprises SA

Alcon Canada Inc

Patent infringement action regarding Patent No. 1,339,132.

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