



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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New Court Proceedings

Federal Court Dismisses Application to Preserve Patent which Lapsed for Failure to Pay Maintenance Fees

In a decision released on November 25, 2003, the Federal Court has confirmed that the provisions of the *Patent Act* governing the payment of maintenance fees require strict compliance.

Payment of annual maintenance fees are required to maintain patent applications and patents. For patents issued on or after October 1, 1989, from an application filed before this date, annual maintenance fees must be paid commencing on the second anniversary of the issue date of the patent. The required maintenance fee may be paid up to one year late, provided an additional late payment fee is also submitted. Under the *Patent Act*, a patent may be reissued with a new patent number. However, the patent term remains the same and the maintenance fee provisions continue to apply to the reissued patent as if it were the original patent.

In *F. Hoffmann-La Roche AG ("Roche") v. The Commissioner of Patents (2003 FC 1381)*, Roche mistakenly classified a reissued patent as a new patent. As a consequence, it did not pay the maintenance fee due on the original patent's eighth anniversary (October 29, 1999) on the belief that no maintenance fee was required on the first anniversary of the reissued patent. The Commissioner of Patents (the "Commissioner"), also through error, did not advise Roche of the overdue maintenance fees until well after the one year period during which the maintenance fee could have been submitted with an additional late fee. It was not until November 5, 2001 that the Commissioner advised Roche that its patent had lapsed for non-payment of fees.

Roche brought an application to preserve its patent having regard to the purpose and context of the *Patent Act*. The Court found that the *Patent Act* provides no legal basis on which Roche might avoid the catastrophic consequences of non-payment of fees, stating:

[27] Patent holders ... must shoulder certain burdens and obligations. Among them is the duty to pay maintenance fees to keep a patent in good standing.

[28] Still, courts have recognized that the maintenance fee regime is complicated, the risk of innocent errors is great, and the failure to comply with the strict rule in s. 46(2) has "catastrophic" consequences. Accordingly, courts should give patent-holders the benefit of any omissions or ambiguities in the legislative provisions: *Barton No-till Disk Inc.*, above.

[29] In this case, while I find it lamentable, I see no omissions or ambiguities that might be resolved in Hoffmann-La Roche's favour. Nor do I find any legal basis on which the applicant might avoid the catastrophic consequences of failing to comply with s. 46(1). The legislation is clear. Indeed, provisions of the Patent Act relating to the duration of patents are expressly subject to the terms of s. 46, ss. 43, 44, 45.

Roche also relied on the principles of fairness, legitimate expectations, equity, and estoppel, in view of the failure of the Commissioner to provide timely notice of non-payment. The Court rejected these arguments, stating that there is no legal basis for imposing a duty on the Commissioner to provide a notice of the sta-

tus of maintenance fee payments and the Court cannot otherwise grant a remedy that contradicts the plain terms of the *Patent Act*.

The Court in its reasons referred to the Federal Court of Appeal decision *Barton No-till Disk Inc. (Dutch Industries Ltd. v. Canada (Commissioner of Patents) ("Dutch Industries")* (2003 FCA 121), which also related to the payment of maintenance fees and which was reported in the [June 2003 issue](#) of our *IP Perspectives* newsletter. In that case, the Court of Appeal held that if a small entity maintenance fee is incorrectly paid where a large entity maintenance fee was in fact required, and the time for reinstatement has passed, the patent is irrevocably lapsed and the payment of a "top-up" payment is not possible. In our [October 2003 issue](#) of *IP Perspectives*, we reported that, on August 8, 2003, the Government of Canada announced its intention to amend the *Patent Act* and *Rules* in order to address this issue (see [announcement](#)). Most recently, on December 11, 2003, the Supreme Court of Canada denied Dutch Industries leave to appeal the Court of Appeal's decision.

Both the Roche and Dutch Industries decisions highlight the importance of strictly adhering to the maintenance fee provisions of the *Patent Act* and *Rules*. While legislative amendments, if passed, may provide relief for mistakes made in determining whether an applicant or patentee is a small entity, amendment of the legislation to address missed deadlines for payment of maintenance fees would seem unlikely. Roche has appealed the Court's decision. We will report on the progress of this appeal in future issues of *Rx IP Update*.

Yoon Kang

Supreme Court of Canada Proceedings

Apotex v. AB Hassle (omeprazole magnesium(LOSEC)), December 2, 2003

On December 2, 2003, Apotex filed an application seeking leave to appeal a Federal Court of Appeal decision, which dismissed Apotex' motion for leave to file new evidence in an appeal from an Order of prohibition.

[Court of Appeal Decision](#)

Apotex v. AB Hassle (omeprazole magnesium (LOSEC)), December 23, 2003

On December 23, 2003, Apotex filed an application seeking leave to appeal a Federal Court of Appeal decision, which dismissed its appeal of an Order of prohibition. The Court of Appeal judgment was reported in our [December 2003 issue](#) of *Rx IP Update*.

Percy Schmeiser v. Monsanto Canada (**glyphosate-resistant canola (ROUNDUP READY CANOLA)**)

On January 20, 2004, the Supreme Court will hear Mr. Schmeiser and Schmeiser Enterprises' appeal of the decision of the Federal Court of Appeal, dismissing their appeal from a decision of a trial judge. The trial judge had found that the appellants had infringed Monsanto's patent by planting a crop of glyphosate-resistant canola having a gene or cell that is the subject of the patent and granted Monsanto an injunction and damages.

Court of Appeal Decision (2002 FCA 309)

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Genpharm v. Procter & Gamble (**etidronate disodium (DIDROCAL)**), December 3, 2003

Court of Appeal dismisses Genpharm's appeal. Genpharm appealed an Order dismissing Genpharm's motion for dismissal of a P&G prohibition application. Genpharm submitted that the relevant patent was not properly listed on the Patent Register as P&G filed the amendment to its patent list to include the patent more than 30 days after the patent issued (based on the date shown on the face of the patent). Court of Appeal agrees with Genpharm regarding the issue date. However, Court concludes that Genpharm is estopped from raising the patent eligibility question in this proceeding. Court finds that "given that a prohibition order issued in the previous litigation, for purposes of issue estoppel in these proceedings, that decision must be taken to have implicitly determined that the 376 patent was eligible for inclusion on the Patent Register." Genpharm has appealed.

Court of Appeal Decision (2003 FCA 467)

Motions Judge's Decision (2003 FCT 583)

Merck v. Apotex (**alendronate sodium (FOSAMAX)**), December 22, 2003

Judge allows Apotex' appeal of an Order which limited Apotex to reliance on the evidence of five of a total of nine experts for which affidavits were filed. Judge finds that the Prothonotary should have followed previous jurisprudence that has interpreted section 7 of the *Canada Evidence Act* to limit the total number of experts to five per issue, rather than for the case as a whole. Merck has appealed.

Motions Judge's Decision (2003 FC 1511)

Prothonotary's Decision (2003 FC 1242)

AstraZeneca v. Genpharm (omeprazole (LOSEC)), December 22, 2003 (*confidential reasons for order issued on December 11, 2003*)

Judge grants Order of prohibition with respect to four patents. Genpharm had alleged invalidity with respect to two patents and non-infringement with respect to the other two patents. Genpharm has appealed.

[Full Judgment](#) (2003 FC 1443)

Apotex v. AstraZeneca (omeprazole (LOSEC)), December 22, 2003

Prior to the hearing on the merits of an application for an Order of prohibition, Court of Appeal strikes scientific references included in AstraZeneca's book of authorities filed in connection with the application. Court finds "there is no basis to support the conclusion that this Court can take judicial notice of these materials in the circumstances of this case."

[Court of Appeal Decision](#) (2003 FCA 487)

[Motions Judge's Decision](#) (2003 FC 981)

Other Decisions

Hoffmann-La Roche v. The Commissioner of Patents, November 25, 2003

Judge dismisses Roche's application for judicial review of Commissioner of Patent's notice to Roche that its patent had lapsed for failure to pay maintenance fees on a reissued patent. Roche has appealed. For further information, please see the lead article on page one of this issue.

[Full Judgment](#) (2003 FC 1381)

Apotex v. The Minister of Health (ofloxacin (APO-OFLOX)), December 17, 2003

Apotex sued the Minister in negligence, breach of statutory duty and discrimination because the Minister issued a Notice of Compliance (NOC) to Apotex eight months after a settlement between the patentee and Apotex. Judge affirms Order of Prothonotary, requiring disclosure of communications between officials of Health Canada and their legal advisors over which solicitor-client privilege is asserted if they intend to rely at trial on the fact of having sought legal advice to explain the delay in the issuance of the NOC. The Minister has appealed.

[Full Judgment](#) (2003 FC 1480)

AstraZeneca and Merck v. Apotex (lisinopril (APO-LISINOPRIL, ZESTRIL, PRINIVIL)), December 22, 2003

In an action for patent infringement, Court of Appeal denies Apotex leave to amend its statement of defence, to withdraw an admission of infringement. Court finds that Apotex failed to demonstrate that the new defence is a reasonable one and that it is more consonant with the interests of justice that the amendments be denied. In denying the amendments, the Court refers to admissions made in the course of previous proceedings under the *Regulations*.

[Court of Appeal Decision](#) (2003 FCA 488)

[Motions Judge's Decision](#) (2003 FCT 159)

[Prothonotary's Decision](#) (2002 FCT 509)

Decisions of the Trade-marks Opposition Board

Opposition by Pharmacia to application no. 887,975 for trade-mark NICOTINEX filed by Homeocan, August 8, 2003

Board allows opposition to application for trade-mark NICOTINEX for "homeopathic product, namely: drops and grains taken to help stop smoking and to detoxify the body," on the basis of, among other grounds, confusion with the trade-marks NICORETTE, NICORETTE & Design and NICOTROL.

[Full Decision](#)

Opposition by Maria Clementine Martin Losterfrau to application no. 837,008 for trade-mark MELISA filed by Melisa Medica Foundation, November 26, 2003

Board rejects opposition to application for trade-mark MELISA for "diagnostic services relating to allergies and the treatment thereof," finding that the applicant had shown that it is not confusing with the opponent's trade-mark MELISANA for "liquid preparations being liniments, carminatives and cosmetics, namely, skin lotions."

[Full Decision](#)

Update on Health Canada Proposal for Review of Look-alike / Sound-alike Names

In our [December 2003 issue](#) of *Rx IP Update*, we reported on Health Canada's release of a draft Issue Analysis Summary entitled, "Look-alike Sound-alike (LA/SA) Health Product Names: The Development of a Comprehensive Policy Recommendation." Health Canada has since released a report from a consultative workshop held on October 20-21, 2003, regarding LA/SA health product names and the current policy development process.

[Executive Summary: Look-Alike Sound-Alike \(LA/SA\) Health Product Names Consultative Workshop](#)

New Court Proceedings

New NOC Proceedings

Medicine: **unidentified**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: November 25, 2003
Comment: Application for an Order requiring the Minister to issue Apotex an NOC for "Apo-X." Apotex pleads that the subject patent was added to the Patent Register after the date that Apo-X became approvable and that Apotex could not have compared and did not compare its Apo-X to a drug marketed in Canada pursuant to an NOC and in respect of which a patent list containing the subject patent had been submitted to the Minister.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Cobalt Pharmaceutical Inc and the Minister of Health
Date Commenced: December 1, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Cobalt alleges non-infringement and that certain claims are not claims to the medicine itself or to the use of the medicine.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: December 1, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Pharmascience alleges non-infringement.

Medicine: **clarithromycin (BIAXIN BID)**
Applicant: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Genpharm Inc and The Minister of Health
Date Commenced: December 2, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,261,732. Genpharm alleges non-infringement, invalidity, and that the patent is not properly listed on the Patent Register.

Medicine: **vinorelbine tartrate (NAVELBINE)**
Applicant: GlaxoSmithKline Inc
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: December 4, 2003
Comment: Application for an Order directing the Minister to include Patents Nos. 1,211,712 and 1,211,049 on the Patent Register in respect of NAVELBINE.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: December 5, 2003
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,258,606; 2,261,732; 2,277,274; 2,386,527; 2,386,534; 2,387,356; and 2,387,361. Pharmascience alleges invalidity and that the patents are not properly listed on the Patent Register.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: RhoxalPharma Inc and The Minister of Health
Date Commenced: December 9, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. RhoxalPharma alleges non-infringement, invalidity and that the patent is not properly listed on the Patent Register.

Medicine: **ursodiol (URSO)**
Applicant: Axcan Pharma Inc
Respondents: Pharmascience Inc and the Minister of Health
Date Commenced: December 15, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,318,590. Pharmascience alleges non-infringement.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Dominion Pharmacal Inc and The Minister of Health
Date Commenced: December 16, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,049,368. Dominion alleges non-infringement and that the patent is not properly listed on the Patent Register.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Pharmel Inc and the Minister of Health
Date Commenced: December 16, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,049,368. Pharmel alleges non-infringement and that the patent is not properly listed on the Patent Register.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: December 16, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Apotex alleges non-infringement.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Apotex Inc and The Minister of Health
Date Commenced: December 19, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,393,614. Apotex alleges non-infringement.

Medicine: **citalopram hydrobromide (CELEXA)**
Applicants: H Lundbeck A/S and Lundbeck Canada Inc
Respondents: Pharmel Inc, Pharmascience Inc, Dominion Pharmacal Inc and The Minister of Health
Date Commenced: December 19, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,353,693. Lundbeck pleads that the detailed statement is on the letterhead of Pharmel, contains a statement that it is sent by Dominion, the Abbreviated New Drug Submission (ANDS) is said to have been filed by PHI, and the tablets for which approval is sought are those of Pharmascience. Non-infringement is alleged.

Medicine: **rofecoxib (VIOXX)**
Applicant: Merck Frosst Canada & Co
Respondents: Novopharm Limited and the Minister of Health
Date Commenced: December 19, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,176,974. Novopharm alleges invalidity and that certain claims are irrelevant to the drug in Novopharm's submission.

Medicine: **cefotaxime sodium (CLAFORAN)**
Applicant: Aventis Pharma Inc
Respondents: Aventis Pharma SA, Mayne Pharma and the Minister of Health
Date Commenced: December 22, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,319,682. Mayne alleges non-infringement and invalidity.

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Medicine: **azithromycin monohydrate (ZITHROMAX)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: December 23, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,148,071. Novopharm alleges non-infringement and invalidity.

Medicine: **ramipril (ALTACE)**
Applicants: Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents: Apotex Inc and The Minister of Health
Date Commenced: December 29, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 1,246,457. Apotex alleges invalidity.

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