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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

The Importance of the Timely Filing of Accurate Patent Lists

The November 1, 2001 decision of the Federal Court, Trial Division, *Syntex (U.S.A.) L.L.C.* v. *Apotex and Canada (Minister of Health)* [see December issue for link], is a reminder to pharmaceutical patentees that the benefits of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") will not be available absent strict compliance with the requirements of the *Regulations*. In this case, the Court struck out the proceeding on the basis that the applicants lacked standing to challenge an allegation made by the generic Apotex under the *Regulations* where the 45-day period for commencing a proceeding had expired. The Court noted that the applicants had not sought an extension of time under the *Regulations* because the jurisprudence establishes that such extensions will not be granted. The Court also confirmed that the *Regulations* are a complete code with respect to the rights of the patentee to prohibition and that, if a party misses a time period under the *Regulations*, a party is obliged to commence an ordinary action for patent infringement if it wishes to protect its interests.

The *Regulations* allow a first person (the party filing the patent list, usually a patentee or licensee) to preclude the issuance of marketing approval (a notice of compliance (NOC)) to a generic when a relevant patent is listed on a "patent list". Relevant patents include patents which contain a claim for the medicine itself or the use of the medicine. However, the remedies provided by the *Regulations* may not be available if the patent list is not accurate or is not submitted on time. Accordingly, it is critically important to adhere to the relevant requirements, some of which are reviewed below.

Subject to one exception, a first person must submit a patent list to the Minister "at the time" the first person files a regulatory submission for an NOC. The exception is for newly issued patents and allows the first person to file a patent list within 30 days after patent issuance, for a patent issued on the basis of a patent application that has a filing date that precedes the date of filing of the submission.

Furthermore, a patent list must, among other things, indicate the following information: the dosage form, strength and route of administration of the drug; set out any Canadian patent that contains a claim for the medicine itself or a claim for the use of the medicine; set out an address in Canada for the service of any notice of allegation; and, identify the submission to which the patent list relates. While the form provided by the Minister sets out the information required, extra care is necessary to avoid the submission of incorrect or incomplete information. It is therefore highly recommended that pharmaceutical patentees have the completed patent list form reviewed and double-checked before submission.

A first person who submits a patent list must also keep the information on the list up-to-date. For example, if the address for service changes in the course of moving corporate offices, a generic could serve a notice of allegation that may not come to the attention of the first person within the 45-day period for commencing a proceeding under the *Regulations*. Upon the expiry of the 45 days, in the absence of a proceeding, the prohibition on the Minister ceases and the generic could promptly obtain marketing approval. The patentee would then be left to commence an infringement action which may take several years to reach trial. Since interlocutory injunctions in patent cases are rarely available in

Canada, the patentee would face competition during the time the court action took to reach a trial on the merits. Consequently, it is critically important that the address for service on patent lists be updated contemporaneously with any change.

As the *Regulations* are unforgiving, pharmaceutical patentees must be particularly diligent in ensuring that patent lists comply with the strict requirements of the *Regulations* in order to avail themselves of the corresponding benefits.

Gunars A. Gaikis

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Novartis v. *RhoxalPharma* (**cyclosporin capsules** (**NEORAL**), November 28, 2001

Court of Appeal allows RhoxalPharma's motion to dismiss Novartis' appeal on the ground that the appeal is moot. Following the trial judge's denial of a prohibition order, the Minister issued a notice of compliance to RhoxalPharma on April 24, 2001.

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

Apotex v. *Syntex and Hoffmann-LaRoche* (**naproxen slow-release tablets** (**NAPROSYN SR**)), December 6, 2001

Judge sets aside order of Prothonotary in action for damages brought under *Regulations*. Prothonotary had struck Apotex' statement of claim. Judge finds that the contentious issues are of a complex nature better suited for determination at trial. Roche has appealed.

Full Judgment

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**Alendronate** (**FOSAMAX**)
Applicants:	Merck & Co, Inc and Merck Frosst Canada & Co
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	December 6, 2001
Comment:	Application for Order of prohibition until expiry of Patent No. 2,018,477. Novopharm alleges non-infringement.

Medicine: **Ciprofloxacin tablets** (**CIPRO**)
Applicants: Bayer AG and Bayer Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: December 10, 2001
Comment: Application for Order of prohibition until expiry of Patent No. 1,218,067. Apotex alleges non-infringement and invalidity.

Medicine: **Cefuroxime axetil tablets**, **suspension** and **sachet suspension** (**CEFTIN**)
Applicant: GlaxoSmithKline Inc
Respondents: Apotex Inc, The Attorney-General of Canada and The Minister of Health
Date Commenced: December 21, 2001
Comment: Application for Order requiring the Minister of Health to add Patents Nos. 1,240,313, 1,282,331, 1,265,511 and 1,328,405 to the patent register. The Minister refused to add these patents to the patent register. A patent list was submitted to the Minister in conjunction with a new drug submission, changing the name of the manufacturer.

Medicine: **Hepatitis A vaccine** (**HAVRIX**), **rosiglitazone** (**AVANDIA**), **valacyclovir** (**VALTREX**), **mupirocin** (**BACTROBAN**), **atovaquone** (**MEPRON**), **atovaquone-proguanil** (**MALARONE**), **INFANRIX Hib vaccine**, **INFANRIX-IPV vaccine**
Applicant: GlaxoSmithKline Inc
Respondents: The Attorney-General of Canada and The Minister of Health
Date Commenced: December 21, 2001
Comment: Application for Order requiring the Minister to add Patents Nos. 1,260,392 (HAVRIX), 2,143,849, 1,328,452 (AVANDIA), 1,258,149 (VALTREX), 2,174,658, 1,242,437 (BACTROBAN), 1,336,266 (MEPRON), 2,150,234 (MALARONE), 1,253,073 (INFANRIX Hib and INFANRIX-IPV) to the patent register. The Minister refused to add these patents to the patent register. Patent lists were submitted to the Minister in conjunction with new drug submissions, changing the name of the manufacturer.

Medicine: **Azithromycin tablets** (**ZITHROMAX**)
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Apotex Inc and the Minister of Health
Date Commenced: December 27, 2001
Comment: Application for Order of prohibition until expiry of Patent No. 1,314,876. Apotex alleges non-infringement.

Medicine: **Paroxetine** (**PAXIL**)
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: December 27, 2001
Comment: Application for Order requiring the Minister to remove Patents Nos. 2,168,829, 2,211,522, 2,210,023 and 2,214,575 from the patent register; a declaration that these patents are not relevant to Apotex' ANDS for Apo-Paroxetine; and a declaration that, as of October 5, 1999, Apotex had a vested right to issuance of an NOC.

Medicine:	**Omeprazole capsules** (**LOSEC**)
Applicants:	AstraZeneca AB and AstraZeneca Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	December 31, 2001
Comment:	Application for Order of prohibition until expiry of Patent No. 2,133,762. Apotex alleges non-infringement and that the patent does qualify for listing on a patent list for LOSEC.

Other New Proceedings

Medicine:	**Omeprazole capsules** (**LOSEC**), **diclofenac slow-release tablets** (**VOLTAREN SR**)
Applicants:	AstraZeneca AB and Ciba-Geigy Canada Ltd
Respondents:	Novopharm Limited, Apotex Inc and The Registrar of Trade-marks
Date Commenced:	December 17, 2001
Comment:	Application for leave to appeal to the Supreme Court of Canada from decisions of Court of Appeal, dismissing appeals of decisions of Trial Judge [as reported in November 2001 issue of *Rx IP Update*]. Trial Judge had reversed decisions of Trade-marks Opposition Board, rejecting oppositions to registration of trade-marks relating to appearance of LOSEC capsules and VOLTAREN SR tablets.

Medicine:	**Methacholine** (**PROVOCHOLINE**)
Plaintiff:	Methapharm Inc
Defendants:	The Attorney General of Canada, The Minister of Health, Omega Laboratories Limited and Medisca Pharmaceutique Inc
Date Commenced:	December 17, 2001
Comment:	Action for damages or profits from Omega and Medisca for unfair and illegal competition, an Order requiring the Minister to enforce the provisions of the *Food and Drugs Act* and *Regulations* as they apply to unauthorized and illegal marketing and sales by Omega and Medisca and damages from the Government of Canada for failing to enforce the provisions of the *Act* and *Regulations*.

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