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# Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER



## Intervener Status Granted in Reference Under NOC Regulations

As first reported in the February 2002 issue of *Rx IP Update*, the Minister of Health filed a notice of application on January 28, 2002, referring the following question relating to the listing of a patent on the patent register, 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?

The generic industry organization (CDMA), the brand name industry organization (Rx&D), the Minister of Health and Eli Lilly were made parties to the reference (the latter because its drug ZYPREXA was referred to specifically).

On April 8, 2002, motions were heard on behalf of GlaxoSmithKline, Pfizer, AstraZeneca and Roche ("brand name companies"), each of which wished to be involved in the Reference on the basis that each has a drug that would be affected by the Court's decision. By orders dated April 17, 2002 [see link on page 2 of this issue], the brand name companies were allowed to intervene in the Reference, with leave to file memoranda of law addressing the legal questions brought before the Court on the Reference and to attend at the Reference and make oral submissions, with leave of the presiding Judge. While the Court was satisfied that the brand name companies have sufficient interest to intervene, the Court was not satisfied that they may be said to be "directly affected" or that their presence is "necessary" to ensure that matters in the Reference are fully and effectively determined. The brand name companies were therefore denied *party* status. AstraZeneca and Roche have appealed these Orders. These appeals are scheduled to be heard on May 7, 2002.

On April 18, 2002, Abbott also moved to be allowed to play a role in the Reference, however its motion was dismissed in its entirety by an Order dated April 23, 2002 [see link on page 2 of this issue]. The Prothonotary indicated that she was "unable to see how Abbott [could] bring a fresh aspect and contribute to the Court's understanding of the questions of law over and above the participation of the five other first persons".

On April 26, 2002, the Court heard Lilly's motion which seeks to replace the current set of facts constituting the case to be determined on the Reference with another set of facts proposed by Lilly; in the alternative, for an order permitting Lilly to file evidence to correct and complete the factual records; and, in the further alternative, for an order striking out the Reference. A decision on Lilly's motion is under reserve.

The attention given to the Reference by the brand and generic industries reflects the importance of the outcome of the Reference. In particular, the Court's answer to the question posed by the Minister of Health is expected to have a significant impact on the eligibility of patents on the patent register, and accordingly, the scope of protection accorded to pharmaceutical patentees by the *Patented Medicines (Notice of Compliance) Regulations*. We will report on further developments on this issue in future issues of *Rx IP Update*.

Gunars A. Gaikis

# Recent Court Decisions

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

*Lundbeck v. Apotex* (**citalopram hydrobromide** (**CELEXA**)), March 12, 2002

Judge dismisses Apotex' motion for summary dismissal of an application for Order of prohibition on the ground that it is frivolous, vexatious and an abuse of process. Judge is not convinced that the allegations of infringement are "inexorably doomed". Judge finds that issues of claim construction (whether there is an overlap between depressive illness, the use for which Apotex is seeking approval, and dementia and cerebrovascular disorders, the uses claimed in the patent at issue) are contentious and debatable issues of fact and law better left for the hearing judge. Apotex has appealed.

Full Judgment

*In the Matter of a Reference by the Minister of Health regarding a Question as to the Application of Section 4 of the Regulations* (**olanzapine** (**ZYPREXA**)), April 17, 2002

Prothonotary grants GlaxoSmithKline, Pfizer, AstraZeneca and Roche leave to interevene in reference, but denies the companies party status. AstraZeneca and Roche have appealed. For more information, please refer to the article on page one of this newsletter.

Full Judgment (representative order in respect of AstraZeneca only)

*In the Matter of a Reference by the Minister of Health regarding a Question as to the Application of Section 4 of the Regulations* (**olanzapine** (**ZYPREXA**)), April 23, 2002

Prothonotary denies Abbott party status and leave to interevene in reference. For more information, please refer to the article on page one of this newsletter.

Full Judgment

*RhoxalPharma v. AstraZeneca* (**omeprazole tablets** (**LOSEC**)), April 23, 2002

Court of Appeal dismisses RhoxalPharma's appeal of Order of prohibition. Court finds that the evidence before the motions Judge allowed her to conclude that the notice of allegation was based on a pure assertion of fact and that the motions Judge properly held that RhoxalPharma could not, in effect, rewrite its notice of allegation after realizing that it was unable to establish the facts asserted in support of it.

Full Judgment (Court of Appeal)

Full Judgment (Trial Division)

# New Court Proceedings

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

**Medicine:** **Levodopa/carbidopa controlled-release tablets** (**SINEMET CR**)
**Applicant:** Apotex Inc
**Respondents:** Merck Frosst Canada & Co, Merck & Co and The Minister of Health
**Date Commenced:** March 25, 2002
**Comment:** Application for a declaration that Patent No. 1,318,602 is not properly listed on the patent register in respect of levodopa/carbidopa and requiring the Minister to issue an NOC to Apotex for Apo-Levocarb CR. Apotex alleges improper listing on the register on the basis that it was too late to do so: the NOC issued in 1991; no patent list containing the patent was filed within 30 days after patent issuance on June 1, 1993; second NOC issued on August 15, 2000 in respect of revisions to product monograph but for same drug product and formulation as initial NOC; patent added to patent register on August 25, 2000.

**Medicine:** **Pravastatin** (**PRAVACHOL**)
**Plaintiff:** Apotex Inc
**Defendants:** Her Majesty the Queen, Bristol-Myers Squibb Canada Inc and Bristol-Myers Squibb Company
**Date Commenced:** March 25, 2002
**Comment:** Action for damages against the Queen for damages caused to Apotex by reason of the unlawful refusal of the Minister to process its ANDS for Apo-Pravastatin and for damages or profits against Bristol-Myers by reason of the commencement of prohibition proceedings.

**Medicines:** **Salmeterol xinafoate** (**SEREVENT, SEREVENT DISKUS, SEREVENT DISKHALER**); **salmeterol xinafoate** and **fluticasone proprionate** (**ADVAIR DISKUS** and **ADVAIR HFA**); **fluticasone proprionate** (**FLOVENT, FLOVENT DISKUS** and **FLOVENT HFA**); **salbutemol sulphate** (**VENTOLIN DISKUS** and **VENTOLIN HFA**)
**Applicant:** GlaxoSmithKline Inc
**Respondents:** Attorney-General of Canada and The Minister of Health
**Date Commenced:** March 28, 2002
**Comment:** Application for Order requiring the Minister to add Patent No. 2,125,665 to the patent register. The Minister refused to list the patent in respect of the product because it is purportedly not relevant to the drugs described in the submission for an NOC.

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**Medicine:** **Paroxetine** (**PAXIL**)
**Applicants:** GlaxoSmithKline Inc and SmithKline Beecham PLC
**Respondents:** Pharmascience Inc and The Minister of Health
**Date Commenced:** April 5, 2002
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 1,287,060, 2,178,637, 2,214,575, 2,168,829, 2,210,023, 2,211,522. Pharmascience alleges non-infringement ('060, '637, '575, '829, '023 and '522 patents) and invalidity ('637, '575, '829, '023 and '522 patents).

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**Medicines:** **Salmeterol xinafoate** (**SEREVENT DISKUS, SEREVENT DISKHALER**); **salmeterol xinafoate** and **fluticasone proprionate** (**ADVAIR DISKUS**); **fluticasone proprionate** (**FLOVENT DISKUS**)
**Applicant:** GlaxoSmithKline Inc
**Respondents:** Attorney-General of Canada and The Minister of Health
**Date Commenced:** April 5, 2002
**Comment:** Application for Order requiring the Minister to add Patent No. 2,125,667 to the patent register. The Minister refused to list the patent in respect of the products because it is purportedly not relevant to the drugs described in the submission for an NOC.

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**Medicine:** **Acyclovir** (**ZOVIRAX**)
**Applicant:** GlaxoSmithKline Inc
**Respondents:** Attorney-General of Canada and The Minister of Health
**Date Commenced:** April 18, 2002
**Comment:** Application for Order requiring the Minister to add Patent No. 2,098,108 to the patent register. The Minister refused to list the patent in respect of the products because it is purportedly not relevant to the drugs described in the submission for an NOC.

**Medicine:** **Lamotrigine** (**LAMICTAL**)
**Applicant:** GlaxoSmithKline Inc
**Respondents:** Attorney-General of Canada and The Minister of Health
**Date Commenced:** April 18, 2002
**Comment:** Application for Order requiring the Minister to add Patent No. 2,277,722 to the patent register. The Minister refused to list the patent in respect of the products because it is purportedly not relevant to the drugs described in the submission for an NOC.

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**Medicine:** **Salbutamol sulphate** (**VENTOLIN HFA**)
**Applicant:** GlaxoSmithKline Inc
**Respondents:** Apotex Inc, Attorney-General of Canada and The Minister of Health
**Date Commenced:** April 19, 2002
**Comment:** Application for Order quashing the Minister's decision to issue an NOC to Apotex for Apo-Salvent CFC Free, an Order prohibiting the Minister from taking any steps in processing Apotex' submission unless and until Apotex has served a notice of allegation and a declaration that Apotex must fully comply with the *Regulations* before an NOC can be granted.

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**Medicine:** **Omeprazole tablets** (**LOSEC**)
**Applicant:** AstraZeneca Canada Inc
**Respondents:** Apotex Inc, Takeda Chemical Industries, Inc and The Minister of Health
**Date Commenced:** April 23, 2002
**Comment:** Application for Order of prohibition until expiry of Patent No. 1,338,377. Apotex alleges non-infringement.

## Other New Proceedings

**Medicine:** **Unidentified**
**Applicant:** Apotex Inc
**Respondent:** The Minister of Health
**Date Commenced:** March 22, 2002
**Comment:** Application for Order requiring the Minister to treat notice of non-compliance as a "Clarifax" (a clarification request) under the Minister's Management of Drug Submissions Policy and to immediately process Apotex' response thereto and, in the alternative, an order quashing the notice of non-compliance.

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| **Medicine:** | **Unidentified** |
| **Applicant:** | Apotex Inc |
| **Respondent:** | The Minister of Health |
| **Date Commenced:** | March 26, 2002 |
| **Comment:** | Application for Order requiring the Minister to inform Apotex of the outcome of its first level appeal and, if the appeal is denied, to provide Apotex with a letter of decision detailing the basis for its decision in the first level appeal of the Minister's issuance of a notice of non-compliance in respect of Apotex' new drug submission for Product X. |

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