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Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

Federal Court Dismisses AstraZeneca's Applications to Quash Apotex NOC for Omeprazole

In our March 2004 issue of *Rx IP Update*, we reported that AstraZeneca had commenced two applications for judicial review of the issuance of a notice of compliance ("NOC") to Apotex for Apo-Omeprazole capsules. On September 20, 2004, the Federal Court dismissed AstraZeneca's applications.

In *AstraZeneca Canada v. Minister of Health* (2004 FC 1277), the Court dismissed an application seeking to quash the NOC on the basis that the Minister of Health had failed to require Apotex to address two patents listed on the Patent Register as required by the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"). The Minister had decided that AstraZeneca's omeprazole (LOSEC) 20 mg capsules had not been marketed in Canada following the listing of the patents and the requirement under the *Regulations* to make an allegation had therefore not been triggered. Section 5(1) of the *Regulations* requires an allegation when the innovator's drug "has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted".

First, the Court held that the proper interpretation of "marketed" under section 5 is a question of law, and the standard of review of the Minister's interpretation is one of correctness. The Court found that the Minister did not err in law. A "marketed" drug must be "on the market and available for comparative purposes". A generic drug manufacturer cannot be expected to compare its drug to a drug that is not available on the Canadian market when it cannot obtain such a drug. Also, the "marketing" must be carried out pursuant to a NOC issued to the innovator "in respect of which the patent list has been submitted" in order to trigger the requirement to make an allegation. In this case, the Court ruled that AstraZeneca had voluntarily withdrawn its LOSEC 20 mg capsules from the Canadian market in 1996, and since the patents at issue had been listed and the associated NOCs had been issued after 1996, the capsules could not have been "marketed".

Second, the Court found that the Minister's determination of whether AstraZeneca's LOSEC 20 mg capsules were marketed in Canada is a question of fact and should be reviewed on a standard of patent unreasonableness. At issue was whether AstraZeneca had resumed marketing of the capsules in 2002. On this question, the Court found that the Minister's decision was not patently unreasonable. The Court went on to define "marketing" as meaning something more than mere "sales" or "sold", adopting a dictionary meaning of "the action or business of promoting and selling products including market research and advertising".

In the second decision (2004 FC 1278), the Court dismissed AstraZeneca's application to set aside the Minister's decision to not require that Apotex serve a new allegation with respect to a revised formulation. The Minister had decided that, since Apotex had already successfully addressed the patents in an earlier proceeding under the *Regulations*, the Minister could not refuse to issue the NOC. The Court held that the Minister's decision is not one that is the proper subject of judicial review under the *Federal Courts Act*. Rather, recourse against misrepresentations by a generic lies in an infringement action under the *Patent Act* and the "grave consequences" that may be imposed by the Court such as punitive damages and solicitor-client costs. The Court reasoned that the Minister is not required, nor

able, to assess whether a revised formulation is materially different. The Minister cannot test the truthfulness of representations from drug companies, whereas the Minister can expect that drug companies will act honestly and in good faith when complying with the *Regulations*. Alternatively, even if the Minister's decision was subject to judicial review, the judge found that the appropriate standard of review would be one of reasonableness and the Minister had acted reasonably in relying on the consent order dismissing the earlier proceedings and in relying on Apotex to comply with the *Regulations*.

These decisions are likely to have a significant impact on when the Minister will require a generic to make an allegation. AstraZeneca has appealed these decisions. *Rx IP Update* will report on the outcome of the appeals.

J. Sheldon Hamilton

Minister of Health Appeals *Access to Information Act* Decision

In the lead article of the August 2004 issue of *Rx IP Update*, we reported on *Merck Frosst Canada & Co. v. Canada (Minister of Health)* (2004 FC 959), wherein a Federal Court judge determined that the comprehensive summary of a new drug submission (NDS), the associated reviewer's notes and the correspondence between Health Canada and the manufacturer for SINGULAIR are exempt from disclosure under the *Access to Information Act*. On September 29, 2004, the Minister of Health appealed this decision. We will report on the outcome of the appeal in a future issue.

Proposed Regulations Pursuant to Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act* (*The Jean Chrétien Pledge to Africa*) Published for Comment

On May 14, 2002, Parliament approved Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act* (*The Jean Chrétien Pledge to Africa*) which is intended to implement an August 30, 2003 decision of the General Council of the World Trade Organization (WTO). The amendments in the Bill will allow Canadian pharmaceutical manufacturers (typically generic manufacturers) to obtain compulsory licences authorizing the manufacture of eligible patented pharmaceutical products for export to eligible importing countries. An overview of the regime is provided in the June 2004 issue of *Rx IP Update*.

On October 2, 2004, proposed regulations under the amendments to the *Patent Act* (*Use of Patented Products for International Humanitarian Purposes Regulations*), and the *Food and Drugs Act* (*Regulations Amending the Food and Drug Regulations* and *Regulations Amending the Medical Devices Regulations (Developing Countries)*) were published. Bill C-9 will come into effect once the regulations have been passed.

Interested persons may make representations within 75 days after the date of publication of the notice (December 17, 2004).

Supreme Court of Canada Appeals

Biolyse v. Bristol-Myers Squibb (**paclitaxel for injection (TAXOL)**), November 5, 2004

The Supreme Court of Canada will hear Biolyse's appeal on November 5, 2004. This is an appeal of a Federal Court of Appeal decision, which dismissed its appeal of an applications judge's decision. The applications judge had quashed Biolyse's notice of compliance (NOC). Biolyse submitted a new drug submission (NDS) for its paclitaxel, which contained many references to and comparisons with TAXOL, but not for the purpose of establishing bioequivalence. The Court of Appeal affirmed the applications judge's finding that the Minister should have required Biolyse to serve a notice of allegation (NOA) on BMS, since subsection 5(1.1) of the *Regulations* applied. The Federal Court decisions were reported in the May 2003 issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

AstraZeneca v. Apotex (**omeprazole magnesium (LOSEC)**), July 23, 2004

Judge allows Apotex's appeal of a Prothonotary's decision and permits Apotex to file four reply affidavits relating to Apotex's sample tablets. AstraZeneca has appealed.

Judge's Decision (2004 FC 1208)

Prothonotary's Decision

Merck v. Apotex (**norfloxacin (NOROXIN)**), September 15, 2004

Court of Appeal dismisses Merck's appeal of a judge's Order, which dismissed Merck's motion for summary judgment to dismiss Apotex' action for damages pursuant to section 8 of the *Regulations*. However, Court indicates that it does not endorse an aspect of the motions judge's reasons and states "evidence of the understanding of the parties as to the meaning of the *Regulations*, third party expert evidence on statutory interpretation, and evidence of legislative drafters, is not admissible or relevant for the purpose of interpreting legislation".

Court of Appeal Decision (2004 FCA 298)

Motions Judge's Decision (2004 FC 314)

AstraZeneca v. The Minister of Health and Apotex (**omeprazole (LOSEC, APO-OMEPRAZOLE)**), September 20, 2004

Judge dismisses AstraZeneca's application for judicial review of a Minister's decision to not require Apotex to make an allegation in respect of certain formulation patents. An earlier proceeding regarding an allegation of non-infringement involving the patents was dismissed. Subsequently, Apotex changed its formulation. However, the Minister decided that Apotex was not required to address the patents a second time. Judge finds that the decision is not properly the subject of judicial review and, in any event, the Minister's decision was reasonable. AstraZeneca has appealed. For further information, please see the article on page one of this issue of *Rx IP Update*.

Full Judgment (2004 FC 1278)

AstraZeneca v. The Minister of Health and Apotex (**omeprazole (LOSEC, APO-OMEPRAZOLE)**), September 20, 2004

Judge dismisses AstraZeneca's application for judicial review of the Minister's decision to not require Apotex to address certain patents listed on the Patent Register. Judge finds that the Minister did not err in his determination that the patents were not required to be addressed by Apotex as AstraZeneca had not "marketed in Canada" LOSEC capsules as required pursuant to section 5 of the *Regulations*. AstraZeneca has appealed. For further information, please see the article on page one of this issue of *Rx IP Update*.

Full Judgment (2004 FC 1277)

GlaxoSmithKline v. Apotex (**salbutamol sulphate oral inhalation (APO-SALVENT CFC FREE, AIROMIR, VENTOLIN HFA)**), September 23, 2004

Judge dismisses application to quash NOC issued to Apotex for Apo-Salvent CFC Free. GSK had argued that the Minister erred in issuing the NOC to Apotex because he failed to require Apotex to serve upon GSK an NOA as required by section 5(1.1) of the *Regulations*. Apotex had filed an "administrative new drug submission" as a licensee of 3M, cross-referencing its product to Airomir, for which 3M had a NOC. Judge finds that an administrative new drug submission is not a submission for a NOC pursuant to subsections 5(1) and (1.1) of the *Regulations*, and therefore Apotex was not required to serve a NOA on GSK. Judge finds in any event that section 5(1.1) did not apply because section 5(1) applied since Apotex compared its drug to that of 3M.

Full Judgment (2004 FC 1302)

Other Proceedings

Roche Palo Alto v. Apotex (**ketorolac (TORADOL, APO-KETOROLAC)**), August 24, 2004

Judge dismisses Roche's motion for a bifurcation Order in an Ontario Superior Court patent infringement action and action for common law and equitable remedial orders, which arose out of allegedly fraudulent, deceptive and misleading information in an NOA and detailed statement provided by Apotex under the *Regulations*.

Full Judgment

Apotex v. Pharmascience (**ticlopidine (APO-TICLOPIDINE, pms-TICLOPIDINE)**), August 31, 2004

Judge dismisses Apotex's appeal of Prothonotary's decision, ordering that certain questions refused on discovery need not be answered. The decision was made in the context of a patent infringement action brought by Apotex. Apotex has appealed.

Full Judgment (2004 FC 1198)

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New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **ramipril (ALTACE)**
Applicants: Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents: Apotex Inc and The Minister of Health
Date Commenced: August 16, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,055,948. Apotex alleges non-infringement.

Trade-mark: **ramipril (ALTACE)**
Applicants: Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: September 1, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,055,948. Pharmascience alleges non-infringement.

Other Proceedings

Trade-mark: **red clover derived menopausal isoflavone supplement (MENOFLAVON)**
Applicants: Novogen Research Pty Ltd and Novogen (Canada) Limited
Respondents: Jamieson Laboratories Ltd
Date Commenced: September 15, 2004
Comment: Patent infringement action relating to Patent No. 2,136,233, relating to Jamieson's sales of MENOFLAVON. Novogen pleads that it markets its health supplement product based on red clover isoflavones in Canada under the trademark PROMENSIL.

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