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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Federal Court Finds that Patents Cannot be Listed on Patent Register in Connection with Supplemental New Drug Submission for Additional Manufacturing Site

On November 3, 2004, the Federal Court dismissed an application by Hoffmann-La Roche ("Roche") for an Order requiring the Minister of Health ("Minister") to list two patents on the Patent Register in connection with trastuzumab (HERCEPTIN) (*Hoffman-La Roche v. The Minister of Health* (2004 FC 1547)).

Roche had submitted a patent list in connection with a supplementary new drug submission (SNDS) for an additional manufacturing site. The judge found that an SNDS was required under the *Food and Drug Regulations* and that the SNDS was not filed in an effort to circumvent the time limitations stipulated in section 4 of the *Regulations*. However, the judge found that the Minister was correct in his refusal to list the patents despite a recent Court of Appeal decision which found that the existence of such facts in that case were sufficient for the SNDS to support a patent listing (*Abbott Laboratories v. Canada (Minister of Health)* (2004 FCA 154)). The judge distinguished *Abbott*, finding that the case "stands for the proposition that a person may submit a patent list with an SNDS as long as the SNDS relates to the drug or to its use".

While there was no evidence in this case of a missed opportunity to file the patent list, it does highlight the importance of filing patent lists at the first available opportunity, given the uncertainty in the law as to whether an SNDS can subsequently support such a filing. Roche has appealed, and therefore it is expected that the Court of Appeal will provide further guidance on the criteria by which the Minister should determine whether an SNDS can support the filing of a patent list.

Judge Finds Patent Claiming Enantiomer of Ofloxacin Obvious

In *Janssen-Ortho v. Novopharm* (2004 FC 1631), a judge dismissed Janssen-Ortho's application for an Order of prohibition, finding the patent at issue invalid for obviousness. (As the finding was made in the context of an NOC proceeding, the patent remains valid.)

The patent claims the levo-enantiomer of ofloxacin, levofloxacin (LEVAQUIN). In finding the invention obvious, the judge made the following findings:

(1) the properties of levofloxacin were not unexpected or surprisingly superior to what had already been disclosed with ofloxacin; and

(2) an average chemist would have been led directly to the conclusion, prior to such testing, that one enantiomer was likely to have more beneficial characteristics than the racemate, or the other optical

isomer, in relation to the same beneficial qualities that had already been discovered (namely antimicrobial activity, solubility and toxicity). Therefore, in undertaking experimentation to verify which enantiomer possessed comparatively better qualities in these areas, no inventive step was involved.

Any analysis of obviousness is fact-specific and therefore must be based on the evidence brought forward. This case, however, highlights the importance of evidence that a claimed enantiomer's properties were unexpected or surprising in order to support inventiveness of a claim to an enantiomer. Janssen-Ortho has appealed.

Health Canada Publishes Report on Compliance Inspections of Internet Pharmacies

Health Canada performed compliance inspections on 11 pharmacies involved in the sale of prescription drugs via the internet or other forms of distance dispensing in February and March 2004. A report has now been released showing that overall the pharmacy activities were in compliance with the *Food and Drugs Act and Regulations*, but pointed to some areas of non-compliance. Further inspections will be conducted in 2005.

Full Report

Patented Medicines Prices Review Board (PMPRB) Matters

On November 22, 2004, the Chair of the PMPRB announced that the PMPRB will begin a dialogue with stakeholders early next year to consider:

1. Whether the PMPRB should be permitted to review a price increase before it comes into effect and, if it is not justified, to take action to stop it from coming into effect; and
2. Whether price increases, up to all or some portion of increases in the Canadian Price Index, should only be allowed if the manufacturer can justify such increases.

News Release
Speech by Chair of PMPRB

Supreme Court of Canada Appeals

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

A full panel of the Supreme Court of Canada heard Biolyse's appeal on November 5, 2004. The appeal involves the question of whether the Minister should have required Biolyse to serve a notice of allegation (NOA) on BMS, pursuant to subsection 5(1.1) of the *Regulations*. The judgments below were reported in the May 2003 issue of *Rx IP Update*.

Press Release

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex v. Merck (**lovastatin (MEVACOR, APO-LOVASTATIN)**), October 20, 2004

In an action for damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), Prothonotary dismisses Apotex's motion to strike portions of Merck's defence and counterclaim. Merck pleaded that Apotex is not entitled to damages on the basis that Apotex has infringed the patent at issue and would not have been in a position to market non-infringing lovastatin had an NOC been issued earlier. Merck sought a set-off against the damages claimed by Apotex, specifically those arising from infringement. Merck has also commenced a separate patent infringement action.

Full Judgment (2004 FC 1452)

Apotex v. AstraZeneca (**omeprazole magnesium (LOSEC)**), November 1, 2004

Court of Appeal dismisses Apotex's appeal of an Order of prohibition. Apotex had alleged invalidity on the bases of anticipation and obviousness.

Court of Appeal Decision (2004 FCA 369)

Applications Judge's Decision (2003 FCT 771)

Apotex v. Bristol-Myers Squibb (**pravastatin (PRAVACHOL)**), November 15, 2004

In an action for damages pursuant to section 8 of the *Regulations*, Judge requires BMS to answer certain discovery questions, including relating to the involvement of general counsel at BMS US (the patentee) with respect to the prohibition proceeding.

Full Judgment (2004 FC 1598)

Genpharm v. Procter & Gamble (**etidronate disodium (DIDROCAL)**), November 22, 2004

Court of Appeal dismisses Genpharm's appeal of an Order of prohibition. Court confirms that the standard of proof on a second person with respect to an allegation of invalidity is proof on a balance of probabilities, and that the doctrine of sound prediction has no application to the doctrine of obviousness.

Court of Appeal Decision (2004 FCA 393)

Applications Judge's Decision (2004 FC 204)

Pfizer v. Novopharm (**azithromycin (ZITHROMAX)**), November 22, 2004

Judge grants Order of prohibition, finding that Novopharm's NOA is inadequate as it does not address the issue of possible infringement by Novopharm through manufacture of the bulk active ingredient (produced off-shore).

Full Judgment (2004 FC 1633)

Other Proceedings

Aventis v. Attorney General of Canada (**influenza vaccine**), October 7, 2004

Judge orders that the quantity of doses and volume ranges in an influenza vaccine contract shall not be disclosed pursuant to an *Access to Information Act* request.

Full Judgment (2004 FC 1371)

Apotex v. Minister of Health (Ontario) (**perphenazine (APO-PERPHENAZINE), lisinopril (APO-LISINOPRIL)**), October 28, 2004

Apotex challenged two policies of the Ontario government with respect to drug benefit pricing: the 75/90 rule (the maximum price for the first listed interchangeable drug is 75 per cent of the price of the brand name drug; the maximum price for the second listed generic drug is 90 per cent of the first generic drug); and the price freeze policy that only allows the price of one product to rise if it is offset by a price reduction of another product. The Ontario Court of Appeal found that these policies are authorized by the *Drug Interchangeability and Dispensing Fee Act* and the *Ontario Drug Benefit Act* and are legal, as they are not arbitrary, discriminatory, or outside the purpose of the legislation.

Full Judgment

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **ramipril (ALTACE)**
Applicants: Aventis Pharma Inc and Aventis Pharma Deutschland GmbH
Respondents: Laboratoire Riva Inc and The Minister of Health
Date Commenced: October 22, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,055,948. Riva alleges non-infringement.

Medicine: **pemetrexed disodium (ALIMTA)**
Applicant: Eli Lilly Canada Inc
Respondents: The Minister of Health and The Attorney General of Canada
Date Commenced: November 3, 2004
Comment: Application for a declaration that Patent No. 2,051,520 is eligible for listing on the Patent Register in respect of ALIMTA. The Minister indicated that he refused to list the patent on the basis that the patent did not contain a claim to the medicine or its use.

Medicine: **atorvastatin (LIPITOR)**
Applicants: Pfizer Canada Inc and Warner-Lambert Company, LLC
Respondents: Ranbaxy Laboratories Inc, Ranbaxy Laboratories Limited and The Minister of Health
Date Commenced: November 15, 2004
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,268,768; 2,021,546; 2,150,372; 2,220,018; 2,220,458, and 2,220,455. Ranbaxy alleges non-infringement and invalidity with respect to the 768, 546, 372, 018, and 455 patents and non-infringement with respect to the 458 patent.

Medicine: **olanzapine (ZYPREXA)**
Applicant: Eli Lilly Canada Inc
Respondents: Novopharm Limited, The Minister of Health, Lilly Industries Limited, and Eli Lilly and Company
Date Commenced: November 19, 2004
Comment: Application for Order of prohibition until expiry of Eli Lilly Industries Limited and Eli Lilly and Company's Patent No. 2,214,005. Novopharm alleges non-infringement.

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Medicine:	**bupropion hydrochloride (WELLBUTRIN SR) and diltiazem hydrochloride (TIAZAC XC)**
Applicants:	Biovail Corporation (dba Biovail Pharmaceuticals Canada)
Respondents:	The Minister of National Health and Welfare
Date Commenced:	November 19, 2004
Comment:	Application for a declaration that Patent No. 2,286,684 is suitable for listing on the Patent Register in connection with specified submissions. The Minister had refused to list the patent on the Patent Register, stating that the patent does not contain a claim to the medicine bupropion hydrochloride or its use nor to the medicine diltiazem hydrochloride or its use.

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