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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Health Canada Seeks Representations On Patent Eligibility Under the NOC Regulations

By letter dated November 8, 2002 to the main trade associations, the Therapeutic Products Directorate (TPD) of Health Canada requested representations on an issue relating to the eligibility of patents for listing on the Patent Register under the *Patented Medicines (Notice of Compliance) Regulations ("Regulations")*.

The letter from TPD notes that in January 2002 it filed a Reference with the Federal Court of Canada (File No. T-139-02) with respect to patent eligibility, but that the Reference was dismissed by the Court on preliminary grounds, prior to the parties advancing substantive submissions on the question posed. TPD notes that in order to study the matter further, it is inviting representations on the following questions:

Question 1

- A first person files a new drug submission for Drug A, containing the medicinal ingredient compound x, on January 1, 2000, and then files an application for a patent on February 1, 2000.
- The patent is granted on March 1, 2002 (the '000 patent). The '000 patent claims the medicine itself (compound x).
- On September 1, 2000, the first person files a supplemental new drug submission, seeking to change the formulation of Drug A from formulation 1 to formulation 2. Along with this supplemental new drug submission, the first person includes a Form IV, seeking to list the '000 patent on the Patent Register.

Is the '000 patent eligible for listing on the Patent Register for Drug A pursuant to the requirements of the Patented Medicines (Notice of Compliance) Regulations?

Question 2

- The same circumstances as in Question 1 apply, except that patent, (now the '001 patent), contains a claim for the medicine itself or a claim for the use of the medicine, and claims formulation 2.

Is the '001 patent eligible for listing on the Patent Register for Drug A pursuant to the requirements of the Patented Medicines (Notice of Compliance) Regulations?

TPD has stipulated that written representations will be limited to twenty pages and must have been filed with TPD by November 25, 2002. All written representations received by TPD are to be posted on a designated website. In addition, TPD will be holding a one-day meeting on December 2, 2002, according a total of two hours each for first and second person representatives under the *Regulations*, with a further half hour each for reply. Those wishing to be present during the December 2, 2002, hearing were to advise TPD by November 22, 2002.

The questions posed by TPD are of considerable interest and of great potential importance to both pharmaceutical patentees and generic companies. Presumably, TPD will be guided by the submissions made

to the questions posed, in formulating a policy for the future administration of the *Regulations*, and in particular, patent eligibility.

We will report on further developments in future issues of *Rx IP Update.*

Gunars A. Gaikis

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott Laboratories v. Genpharm (**clarithromycin** (**BIAXIN**)), October 22, 2002

Court orders Genpharm to produce portions of its Drug Master File (DMF) and/or its Abbreviated New Drug Submission (ANDS) filed with the Minister of Health.

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

Eli Lilly v. Apotex (**nizatidine** (**AXID**)), October 22, 2002

Court of Appeal upholds Trial Division decision to allow Apotex leave to amend its claim so as to plead a previous section governing actions for damages under the *Regulations*.

For a discussion of the Trial Division decision, please see the November 2001 issue of *Rx IP Update*.

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

AB Hassle v. Apotex (**omeprazole capsules** (**LOSEC**)), November 1, 2002

Court of Appeal dismisses appeal of decision dismissing application for prohibition. The appellant Hassle owns Canadian Patent No. 2,025,668 relating to the use of omeprazole for the treatment of *Campylobacter* infections. Apotex had alleged non-infringement of the patent on the basis that Apotex' product would not be used or sold for the treatment of *Campylobacter* infections. The Hearing Judge had found that there was no evidence that Apotex would directly infringe the patent or that Apotex had induced or procured infringement of the patent. As to the latter finding, the Court of Appeal distinguished the recent case of *Genpharm v. Procter & Gamble*, which dealt with infringement by patients, on the facts: there was no evidence that Apotex' actions and intentions would lead inevitably to the use of its omeprazole product for the treatment of *Campylobacter* infections if it were to obtain the NOC it seeks.

For a discussion of the *Genpharm* case, please see the August 2002 issue of *Rx IP Update*.

Full Judgment

Biovail Corp v. RhoxalPharma (**diltiazem hydrochloride capsules** (**CARDIZEM SR**)), November 5, 2002

Court dismisses appeal of lower level decision not to order production of RhoxalPharma's New Drug Submission (NDS). The Court found that for an applicant to be successful on a motion for production, the applicant must satisfy three criteria: a timely request for disclosure of the information was made; the information already provided by the respondent is not sufficient to deal with the issues at stake; and the disclosure is necessary because it is relevant to the disposition of the issues in the proceeding. Biovail did not file affidavit evidence on any of the three criteria. Biovail has appealed.

Full Judgment

Pfizer v. Apotex (**sertraline** (**ZOLOFT**)), November 5, 2002

Court dismisses application for prohibition. Apotex served a Notice of Allegation (NOA) so that it might obtain an NOC to sell sertraline for use in connection with Obsessive Compulsive Disorder (OCD) and Panic Disorder (PD). The basis of the allegation was that Pfizer's Canadian Patent No. 2,029,065 covering the uses of sertraline was invalid as anticipated and/or obvious. The Court found that the applicants failed to show that the allegations of obviousness and anticipation were not justified.

Full Judgment

Novartis v. Apotex (**cyclosporin** (**NEORAL**)), November 8, 2002

Court of Appeal dismisses appeal of order dismissing application for prohibition on the basis of mootness. Following the hearing of the prohibition application (decided on the basis of patent invalidity and not patent infringement), the Minister of Health issued to Apotex an NOC for 100mg/ml oral solution of cyclosporin. In dismissing the appeal, the Court relied on earlier jurisprudence finding an appeal moot where an NOC had been issued following a finding of non-infringement. The Court found no clear-cut distinction in these cases between a finding of non-infringement and a finding of invalidity for the purpose of deciding whether an appeal is moot.

For a discussion of the Hearing Judge's decision, please see the November 2001 issue of *Rx IP Update*.

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

Merck v. Apotex (**simvastatin** (**ZOCOR**)), November 18, 2002

Court dismisses application for prohibition. The Court found that the applicant provided no answer or evidence to dispute Apotex' evidence of non-infringement. The applicant's evidence was directed to operability and workability of Apotex' process.

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

Parke Davis v. Apotex (**atorvastatin calcium** (**LIPITOR**)), November 18, 2002

Court of Appeal allows appeal of Order dismissing application for prohibition. Warner-Lambert had dedicated Canadian Patent No. 1,268,768 ('768 patent) to the public and Apotex relied on this dedication in its NOA. The Court of Appeal accepted Parke-Davis' (Warner-Lambert's Canadian subsidiary) arguments that the NOA was of no legal effect because there was no evidence that Apotex had ever filed an NDS and that the dedication to the public of the '768 patent was a mistake.

For a discussion of the Hearing Judge's decision, please see the October 2001 issue of *Rx IP Update*.

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

Other Decisions

Apotex v. AstraZeneca Canada, October 31, 2002

Court orders Federal Court copyright action stayed pending resolution of parallel proceeding before Ontario Superior Court of Justice. Both cases deal with copyright in drug product monographs. The Federal Court found that the two cases dealt with the same parties, the same subject matter, the same issues and similar remedies, other than a claim for expungement of AstraZeneca's copyright registrations in the Federal Court.

For a discussion of the Ontario Court action, please see the September 2002 issue of *Rx IP Update*.

Full Judgment

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**clarithromycin (BIAXIN BID)**
Applicants:	Abbott Laboratories and Abbott Laboratories Limited
Respondents:	Ratiopharm, a division of Ratiopharm Inc and The Minister of Health
Date Commenced:	November 1, 2002
Comment:	The Applicants seek an Order prohibiting the Minister of Health from issuing an NOC to Ratiopharm for 250 mg and 500 mg clarithromycin tablets until after the expiry of Canadian Patent No. 2,261,732. Ratiopharm alleges that it will not infringe, that the patent is improperly listed and that certain of the patent claims are invalid. The Applicants deny Ratiopharm's allegations and allege that the NOA is deficient.

Medicine: **omeprazole magnesium (LOSEC)**
Applicants: AB Hassle, AstraZeneca AB and AstraZeneca Canada Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: November 8, 2002
Comment: The Applicants seek an Order prohibiting the Minister of Health from issuing an NOC to Apotex for 10 mg and 20 mg omeprazole magnesium tablets until after the expiry of Canadian Patents Nos. 1,292,693, 1,302,891, and 2,166,483. Apotex alleges that it will not infringe, and that the patents are invalid. The Applicants deny Apotex' allegations and allege that the NOA is deficient and an abuse of process.

Other New Proceedings

Medicine: **amino acid derivatives**
Applicant: Merck & Co, Inc
Respondents: Brantford Chemicals Inc, the Commissioner of Patents and the Attorney General of Canada
Date Commenced: November 12, 2002
Comment: The Applicants appeal to the Federal Court, Trial Division from the decision of the Chairman of the Patent Appeal Board, Mr. Peter Davies, dated October 18, 2002. The Chairman dismissed the Appellant's motion to dismiss Brantford's application for a compulsory licence in respect of Canadian Patent No. 1,275,349 based on issue estoppel or *functus officio*. Brantford has raised two grounds of statutory abuse, namely, that the demand for the patented article is not being met and that the patentee is refusing to grant a licence on reasonable terms. Merck alleges that this application is essentially the same as a previous application, which was refused.

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