SMART & BIGGAR / FETHERSTONHAUGH NOVEMBER 2001

IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Court of Appeal Addresses Registrability of Trade-marks for Pharmaceutical Appearance

Opponent is not limited by its pleading; distinctiveness is now more difficult to establish for colour, shape and size marks.

On October 18, 2001, the Federal Court of Appeal rendered decisions in three trade-mark opposition proceedings relating to the appearance of AstraZeneca's **LOSEC** (pink and reddish-brown capsules) and Ciba-Geigy's (now Novartis) **VOLTAREN SR** (pink, round, bi-convex tablets and light pink, triangular, bi-convex tablets) products (see links on page three of this issue).

In the VOLTAREN SR oppositions, the Trade-marks Opposition Board (TMOB) had rejected the Opponent's distinctiveness attacks on the ground that the Opponent's pleadings did not set out sufficient details to enable the Applicant to reply. Further, in all three oppositions, the TMOB concluded that the trade-mark Applicants had established, on a balance of probabilities, that the applied for marks were distinctive of the Applicants' wares (omeprazole and diclofenac sodium). The TMOB rejected the oppositions.

On appeal to the Federal Court, Trial Division, the presiding Judge ignored the procedural issue and found the TMOB's findings of fact to be "perverse". The Judge stated:

> ....it is not sufficient for [Ciba] to establish that Canadians know that Ciba's 75 mg diclofenac product is sold in a pink tablet or a pink and triangular tablet. Rather, it must show that physicians, pharmacists or patients can and do use the proposed trade-mark in choosing whether to prescribe, dispense or request Ciba's diclofenac product.

On further appeal, the Court of Appeal recognized that while section 38(3) of the *Trade-marks Act* requires a Statement of Opposition to set out sufficient detail to enable the Applicant to reply, in the Court's view, the trade-mark Applicant was not prejudiced, as it was completely aware of the Opponent's case by the time the matter came before the Trial Division and the Applicant could have filed further evidence on the appeal to the Trial Division.

On the distinctiveness issue, the Appeal Court agreed with the Trial Division Judge that it was insufficient for the Applicants to establish that the LOSEC and VOLTAREN SR products were popular and successful in the marketplace and that no other products were interchangeable with them. The Applicants had failed to present evidence from any consumers (doctors, pharmacists or patients) that the colour and shape of the Applicants' products served to distinguish those products within any marketplace.

This decision is considered significant in several respects.

First, it changes the law on the procedural aspects of trade-mark opposition proceedings. An Opponent is now excused from complying with the statutory requirement to provide a sufficient pleading as long as the Applicant becomes aware of the Opponent's case by the date of the Trial Division hearing, and the Applicant has an opportunity to file evidence to address the issues raised.

Second, the decision adopts the requirement, at least in pharmaceutical trade-mark appearance matters, that distinctiveness requires evidence that the mark is actually used to *prescribe, dispense or request* the Applicant's product. This conclusion is of questionable correctness as such an onerous standard has not been applied previously to other types of trade-marks.

Finally, the reference to "any marketplace" leaves unanswered whether (1) the relevant wares for distinctiveness is the specific active ingredient in respect of which registration is sought, compounds within a therapeutic class, or prescription pharmaceuticals generally; and (2) pharmacists must rely on colour and shape to the exclusion of other indicators of brand (such as markings on tablets) when choosing whether to dispense the particular brand.

It is expected that these decisions will not be the last word on the relevant procedural and substantive law in the important area of the registrability of trade-marks for the appearance of pharmaceuticals. We will report on any new developments in upcoming issues of *Rx IP Update*.

Gunars A. Gaikis

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Reddy-Cheminor v. *Minister of Health* (**omeprazole capsules** (**LOSEC**)), September 28, 2001

Judge refuses to add AstraZeneca as a party or intervener in Reddy-Cheminor's challenge to a decision of the Minister refusing to process its abbreviated new drug submission. Reddy-Cheminor also seeks a declaration that its product (omeprazole capsules) is pharmaceutically equivalent to a product marketed by AstraZeneca (omeprazole magnesium tablets). Judge finds that Reddy-Cheminor's challenge does not affect AstraZeneca's patent rights under the *Regulations* nor is there a need for AstraZeneca's presence as an intervener to assist the Court. AstraZeneca has appealed.

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**)), October 17, 2001

Prothonotary strikes statement of claim in action for damages brought under *Regulations*. It was clear that, at the time the amended *Regulations* came into effect, there was no "application pending" by the Defendants and therefore, pursuant to the transitional provision, Apotex is precluded from seeking relief. Apotex has appealed.

Full Judgment

Novartis v. *Apotex* (**cyclosporin** (**NEORAL**)), October 18, 2001

Judge dismisses application for prohibition order in respect of Apotex' third notice of allegation of invalidity with respect to Patent No. 1,332,150. Apotex' explanation that it withdrew its previous notices of allegation because of problems regarding compliance with the *Food and Drug Regulations* is reasonable. Therefore, Apotex' further notice of allegation is not an abuse of process. Judge refuses to disregard new prior art introduced by expert, but not referred to in detailed statement, as Novartis was granted leave to file further evidence to reply thereto and should have raised this question by way of motion before the hearing. Apotex not permitted to rely on US file wrapper. Claims at issue anticipated, obvious and over broad. Novartis has appealed.

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

Apotex v. *Eli Lilly* (**nizatidine** (**AXID**)), October 22, 2001

Judge sets aside order of Prothonotary, in action for damages brought under *Regulations*. Prothonotary had refused Apotex leave to amend its claim to plead the previous section governing actions for damages under the *Regulations*, as the proposed amendment revealed no reasonable cause of action. Judge finds that the jurisprudence does not provide a clear understanding of the provision at issue and therefore Apotex should be permitted leave to amend its claim. Eli Lilly has appealed.

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

Other Decisions

Bristol-Myers Squibb v. *Apotex* (**nefazodone hydrochloride** (**SERZONE 5HT2**)), October 3, 2001

Judge refuses interlocutory injunction to prevent sales of Apo-nefazodone pending a trial for patent infringement. Judge finds that plaintiffs failed to demonstrate irreparable harm. Any "springboarding" resulting from Apotex' early market entry can be quantified in damages. Further, any decline in overall market for nefazodone and any harm resulting therefrom is purely speculative. Finally, there is no clear evidence of a loss of goodwill.

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

AstraZeneca v. *Novopharm* (**omeprazole capsules** (**LOSEC**)); *Ciba-Geigy* v. *Novopharm* (**diclofenac slow-release tablets** (**VOLTAREN SR**)), October 18, 2001

Court of Appeal dismisses appeals of decisions of Trial Judge. Trial Judge had reversed decisions of Trade-marks Opposition Board, rejecting Novopharm's oppositions to registrations of trade-marks relating to appearance of Losec capsules and Voltaren SR tablets. For more information, please refer to the article on page one of this newsletter.

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

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**Paroxetine hydrochloride tablets (PAXIL)**
Applicants:	GlaxoSmithKline Inc and SmithKline Beecham PLC
Respondents:	Genpharm Inc and The Minister of Health
Date Commenced:	October 4, 2001
Comment:	Application for Order of prohibition until expiry of Patent Nos. 1,287,060, 2,178,637 and 2,214,575. Genpharm alleges non-infringement and invalidity.

Medicine:	**Carvedilol tablets (COREG)**
Applicants:	GlaxoSmithKline Inc and SmithKline Beecham Corporation
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	October 18, 2001
Comment:	Application for Order of prohibition until expiry of Patent Nos. 1,259,071 and 2,212,548. Pharmascience alleges non-infringement and invalidity.

Medicine:	**Paclitaxel solution for injection (TAXOL)**
Applicants:	Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Inc
Respondents:	Biolyse Pharma Corporation and The Attorney General of Canada
Date Commenced:	October 22, 2001
Comment:	Application for Order quashing NOC to Biolyse; declaration that Minister failed to comply with section 5 of *Regulations*, including requiring Biolyse to send a notice of allegation to Bristol-Myers; and an Order of prohibition.

Medicine:	**Omeprazole magnesium tablets (LOSEC)**
Applicants:	AB Hassle and AstraZeneca Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	October 24, 2001
Comment:	Application for Order of prohibition until expiry of Patent No. 1,264,751. Apotex alleges invalidity.

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