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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

FCA Delays Registration of AstraZeneca's Trade-marks for the Appearance of its Plendil (Felodipine) 5 and 10 mg Tablets

In a decision rendered on October 15, 2002, the Canadian Federal Court of Appeal (FCA) allowed appeals of two decisions of the Trial Division and remitted the matters back to the Trial Division for a determination of the merits.

The proceedings in the Trial Division were appeals, under Section 56 of the *Trade-marks Act*, of two decisions of the Registrar of Trade-marks. The Registrar had rejected Novopharm's Statements of Opposition to AstraZeneca's applications to register two trade-marks in relation to tablets containing the active ingredient felodipine. One application was in relation to tablets that are pink, round and bi-convex in shape (5 mg) and the other in relation to tablets that are red-brown in colour, round and bi-convex in shape (10 mg). The primary basis for the Registrar's rejection of the oppositions was that Novopharm's Statements of Opposition were insufficiently detailed to enable AstraZeneca to respond to the assertions that its trade-marks were not distinctive. A secondary basis for the Registrar's rejection was that there was no quantitative, and insufficient qualitative, evidence of the sale and use of any pharmaceutical tablets that have a colour and shape combination resembling the marks applied for by AstraZeneca. The Trial Judge dismissed Novopharm's appeals and upheld the Registrar's decisions.

On appeal to the Trial Division, Novopharm filed additional evidence, presumably in view of the Registrar's secondary basis for rejection of the oppositions. However, the Trial Judge was of the opinion that she was to review the Registrar's decisions on a standard of reasonableness *simpliciter*. She found that the Registrar was not clearly wrong in rejecting the Novopharm oppositions on the basis that the oppositions were insufficiently detailed to enable AstraZeneca to know the case it had to meet and to respond to it. As the requirement for detailed pleadings was statutory, the Trial Judge found that she could not say that the Registrar was unreasonable for requiring compliance with the statute. Because that conclusion was dispositive of the appeal, the Trial Judge did not go on to consider the Registrar's secondary, insufficient evidence, basis for rejecting the oppositions.

The FCA found its intervening decision in *Novopharm Limited v. Ciba-Geigy Canada Limited; Novopharm Limited v. Astra Aktiebolag*, [2002] 2 F.C. 148 to be dispositive of the procedural issues on the appeal. In particular, the FCA deduced the following principles to apply from the *Novopharm* case with respect to the adequacy of pleadings:

1. A Statement of Opposition must be in conformity with Section 38 (3)(a) of the Act and hence must set out the grounds of opposition in sufficient detail to enable the trade-mark applicant to reply.
2. The sufficiency of pleadings should be determined on an interlocutory basis, at which time only the pleadings need to be considered in making that determination.

3. In determining the sufficiency of a Statement of Opposition after evidence is filed, regard must also be had to the evidence to see if the applicant has been provided with sufficient detail to make an adequate reply.

In view of these principles, the FCA concluded that once evidence is filed, the Registrar must take that evidence into consideration when deciding whether the parties know the case they have to meet and whether they are able to respond. The evidence filed may cure whatever inadequacy there may have been in the pleadings. In a departure from existing practice in Canada, the FCA ruled that Section 40 of the *Trade-mark Regulations* (which provides a procedure for amendment of a Statement of Opposition and a Counter-statement) can be relied on by a trade-mark applicant or opponent to not only amend its own pleading, but also to strike all or any portion of the other party's pleading.

Consequently, the FCA reasoned that the Registrar had, in the circumstances, failed to consider the evidence in assessing whether AstraZeneca knew the case it had to meet and was able to respond to it. This constituted a failure to consider a relevant factor and therefore, a failure to apply the correct legal test for determining the adequacy of the pleadings. Similarly, the Trial Judge should have found that the Registrar's failure to consider the evidence constituted a reviewable error.

The FCA reviewed the additional evidence filed by Novopharm and concluded that whatever deficiency there may have been in the evidence before the Registrar, it was cured by the additional evidence filed in the Trial Division. While the FCA appears to have been tempted to decide the merits of the distinctiveness issue, it concluded that it is normally preferable to remit to the Trial Division matters involving the assessment of evidence for determination on the merits.

The FCA's decision is noteworthy in several respects. Firstly, it represents another setback in the attempts of the brand-name industry to obtain trade-mark registration for the arbitrary features of appearance of prescription pharmaceuticals. Secondly, the decision appears to be unfair to AstraZeneca who filed the trade-mark applications in 1992 and fought Novopharm's oppositions based on Novopharm's Statements of Opposition filed in 1993 and the jurisprudence at the time, only to find out many years later that it could not rely on the *prima facie* inadequacy of Novopharm's pleadings. Thirdly, the decision represents a significant change to trade-mark opposition practice in Canada insofar as the FCA has now determined that subsequently filed evidence can cure a deficient pleading in a Statement of Opposition. The latter will require both sides in trade-marks opposition proceedings to revisit long-established procedural strategies in such matters.

Gunars A. Gaikis

Supreme Court of Canada Hearings

Genpharm v. Procter & Gamble (**etidronate disodium tablets** (**DIDROCAL**)), September 30, 2002

On September 30, 2002, Genpharm filed an application seeking leave to appeal a decision of the Federal Court of Appeal granting a prohibition Order on the basis that, *inter alia*, Genpharm's Notice of Allegation (NOA) was fatally flawed. The decision of the Court of Appeal was reported in the August 2002 issue of *Rx IP Update*.

Syntex v. Apotex (**ketoralac tromethamine ophthalmic solution** (**ACULAR**)), September 30, 2002

On September 30, 2002, Syntex filed an application seeking leave to appeal the decision of the Federal Court of Appeal. The FCA upheld an Order striking an application seeking to prohibit the Minister of Health from granting a Notice of Compliance (NOC) to Apotex on the ground that Apotex' NOA contains "deceptive and misleading" information. The Court of Appeal decision was reported in the August 2002 issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Novartis Pharmaceuticals Canada Inc v. Canada (Minister of Health) (**norethisterone acetate/17ß estradiol patch** (**ESTRACOMB**)), October 7, 2002

Court upholds the Minister's decision to remove from the Patent Register a patent for which claims related to a patch for administration of the medicine. The Court finds that, while the patch in issue may be a medicine for certain purposes, the patent for the patch does not claim a medicine or the use of a medicine as defined and required under the *Regulations*.

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

Other Decisions

Eli Lilly v. Apotex Inc (**nizatidine** (**AXID**)), September 26, 2002

Apotex is successful in amending its pleadings to add allegations of a conspiracy to lessen competition against Eli Lilly and Novopharm and is successful in adding Novopharm as a defendant. This decision arises in the context of Eli Lilly's patent infringement action against Apotex relating to nizatidine. As a defence, Apotex pleaded that it is a licencee, having obtained the nizatidine under a supply agreement with Novopharm, where Novopharm obtained its nizatidine under a compulsory licence with Eli Lilly. By the amendments, Apotex alleges, *inter alia*, that Eli Lilly and Novopharm conspired to bring about a breach of the supply agreement, through a breach of the compulsory licence, in order to eliminate Apotex from competition in the market for nizatadine.

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

Novopharm Ltd v. AstraZeneca (**felodipine** (**PLENDIL**)), October 15, 2002

Court of Appeal remits to the Trial Division for rehearing appeals of decisions of the Registrar of Trade-marks respecting Novopharm's oppositions to AstraZeneca's applications to register two trade-marks relating to tablets containing felodipine. For more information, please see the article on page 1 of this issue.

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

New Court Proceedings

Regulations

Medicine: **alendronate sodium** (**FOSAMAX**)
Applicants: Merck & Co Inc and Merck Frosst Canada & Co
Respondents: Novopharm Ltd and The Minister of Health
Date Commenced: October 11, 2002
Comment: The Applicants seek an Order declaring Novopharm's NOA null and void. In the alternative, the Applicants seek to prohibit the Minister of Health from issuing an NOC in respect of alendronate sodium tablets until after the expiration of Canadian Patents Nos. 2,018,477 and 2,221,417. The Applicants allege, *inter alia*, that the NOA is void because it emanates from Blake, Cassels (a law firm) and not a "second person" as required by the *Regulations*. In the alternative, the Applicants allege that, if the NOA is sufficient, the facts cannot be assumed to be true as Blake, Cassels cannot have the requisite knowledge. The Respondents allege that they will not infringe the patent claims and that certain claims in the patent are not for the medicine itself or for use of the medicine.

Medicine: **fenofibrate** (**LIPIDIL SUPRA**)
Applicants: Fournier Pharma Inc and Laboratoires Fournier SA
Respondents: Apotex Inc and The Minister of Health
Date Commenced: October 23, 2002
Comment: The Applicants seek an Order prohibiting the Minister from issuing an NOC to Apotex Inc for 100 mg and 160 mg fenofibrate tablets until after the expiry of Canadian Patent No. 2,219,475. Apotex alleges that it will not infringe. The Applicants deny Apotex' allegation of non-infringement and allege that the NOA is deficient.

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