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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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NOC Regulations Limited to Infringement by Generics

In the recently released decision *AstraZeneca* v. *Apotex*, the Federal Court-Trial Division has ruled that the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") only apply to infringement by a generic drug manufacturer. As a result, even if patients, physicians or pharmacists infringe the patent in issue, as long as the generic itself does not infringe, the Court will not prohibit the issuance of a Notice of Compliance to the generic.

The patent at issue in this case was for a new therapeutic use of **omeprazole** (**LOSEC**). Apotex alleged that it would not infringe AstraZeneca's patent because it was not seeking regulatory approval for the claimed use. AstraZeneca argued that Apotex' assertion was irrelevant since patients would use the Apotex product for the claimed use regardless of whether Apotex actually sought approval for such use. AstraZeneca's position was based on the unique nature of the pharmaceutical marketplace in Canada where the dispensing pharmacists do not typically know the indication for which a doctor prescribes a medication. AstraZeneca argued that infringement by patients was sufficient grounds for an order of prohibition. Alternatively, AstraZeneca argued that Apotex was inducing and procuring infringement.

The Court rejected both of AstraZeneca's arguments. First, after considering the language of the allegation of non-infringement and the enabling legislation, the Court ruled that the *Regulations* only extend to infringement by the second person (i.e. generic). Accordingly, infringement by physicians, patients or pharmacists was not sufficient.

Second, while the Court accepted that a generic could infringe by inducing or procuring infringement by others such as patients, it rejected AstraZeneca's evidence that such infringement would occur. In order to demonstrate inducing and procuring infringement, the Court ruled that a patentee must prove that (a) the act of infringement was completed by the direct infringer; (b) the seller influenced the act to the point where, without said influence, infringement by the buyer would not occur; and (c) the influence must be knowingly exercised by the seller, such that the seller knows that the influence will result in completion of the act of infringement.

In applying the above, the Court rejected AstraZeneca's evidence that patients would use generic omeprazole for unapproved (and infringing) uses. The Court also ruled that unless AstraZeneca could demonstrate that Apotex would encourage the claimed use of omeprazole, knowledge by Apotex that pharmacists and physicians were prescribing and dispensing the drug for the patented purpose would not be sufficient to find Apotex an infringer by inducement.

This case is particularly significant as it holds that the *Regulations* are only intended to prevent infringement by generics. Further, in the case of a claim for the use of a medicine, which obviously can only be directly infringed by patients, not by corporate entities, provided that a generic does not take any active steps with respect to the claimed use, such as seeking approval for a patented use, the generic will be able to avoid a finding of inducement. Thus, a generic could obtain market entry even if the generic is aware that such infringement will occur.

J. Sheldon Hamilton

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Procter & Gamble v. *Genpharm* (**etidronate tablets** (**DIDROCAL**)), October 23, 2001

Judge grants prohibition order. Notice of allegation and detailed statement of facts are fatally flawed in that the notice of allegation does not allege that no claim under the patent will be infringed and the detailed statement does not raise sufficient facts to show that all claims of the patent would not be infringed. Genpharm has appealed.

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

Schering v. *Canada* (**ribavarin capsules and interferon alfa-2b for injection** (**REBETRON**)); *Pfizer* v. *Canada* (**azithromycin dihydrate tablets** (**ZITHROMAX**)); *Pfizer* v. *Canada* (**atorvastatin calcium tablets** (**LIPITOR**)), October 26, 2001

Judge grants Canadian Drug Manufacturers' Association leave to intervene in applications for orders requiring the Minister of Health to add certain patents to the patent register on the basis that the "filing date" of a patent under the *Regulations* includes the priority date. Leave granted in part on the basis that the Minister had sought comments from the CDMA before making the decisions under review.

Full Judgments (*For a printer friendly version, please scroll down to the end of the Judgment)
Schering v. Canada (REBETRON)
Pfizer v. Canada (ZITHROMAX)
Pfizer v. Canada (LIPITOR)

Syntex v. *Apotex* (**ketorolac tromethamine ophthalmic solution** (**ACULAR**)), November 1, 2001

Judge strikes application for judicial review, seeking to prohibit the Minister of Health from granting an NOC on the ground that Apotex served a notice of allegation which contains "deceptive and misleading" information. After expiry of the 45-day time period to commence a proceeding under the *Regulations*, applicants learned that a statement in the notice of allegation was inconsistent with Apotex' new drug submission filed in the United States. Judge finds that application has no possibility of success - if an issue arises outside the time periods provided for in the *Regulations*, the patentee must use its common law rights. Syntex has appealed.

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

AstraZeneca v. *Apotex* (**omeprazole capsules** (**LOSEC**)), November 16, 2001

Judge dismisses application for order of prohibition, relating to use patent for omeprazole. For more information, please refer to the article on page one of this newsletter.

Full Judgment

Other Decisions

Apotex v. *Alberta* (**warfarin** (**COUMADIN**)), October 26, 2001

Apotex applied to Alberta Blue Cross to have Apo-Warfarin designated as interchangeable with Coumadin. In earlier litigation, Alberta Health had undertaken not to refuse to designate as interchangeable an Apotex product that had been issued an NOC or DIN unless Alberta Health could point to previously published criteria, which had been uniformly applied, that the Apotex product had failed to meet. Judge finds that Expert Committee or Crown is not in breach of undertaking by requiring higher content uniformity. Minister required to make a decision on Apotex' application for interchangeability by November 15, 2001. Judge refuses to quash expert committee's recommendation about higher content uniformity as it was not patently unreasonable. Apotex has appealed.

Full Judgment

AstraZeneca v. *Novopharm* (**felodipine tablets** (**PLENDIL**)), October 30, 2001

Judge dismisses appeal of Trade-marks Opposition Board, refusing AstraZeneca's application for registration of trade-mark relating to appearance of PLENDIL tablets. Judge finds that the fact that AstraZeneca has used this colour and shape in association with its felodipine tablets, and that pharmacists recognize the colour and shape of the tablets inside their packaging is not enough, in view of AstraZeneca's "heavy burden" to prove that the colour and shape are distinctive. Judge finds that it is the packaging that makes the drug distinctive, not the colour and shape. AstraZeneca has appealed.

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:	**Estradiol 17-ß patch** (**VIVELLE**)
Applicant:	Novartis Pharmaceuticals Canada Inc
Respondent:	The Attorney-General of Canada
Date Commenced:	October 30, 2001
Comment:	Application for order requiring Minister to add Patent No. 2,044,170 to the patent register.

Medicine:	**Omeprazole capsules** (**LOSEC**)
Applicants:	AB Hassle, AstraZeneca AB, AstraZeneca Canada Inc
Respondents:	Genpharm Inc, Takeda Chemical Industries Ltd and The Minister of Health
Date Commenced:	November 9, 2001
Comment:	Application for Order of prohibition until expiry of Patents Nos. 1,264,751, 2,025,668, 2,133,762, 2,166,483, 2,166,794, 2,170,647, 1,292,693, 1,302,891, and 1,338,377. Genpharm alleges non-infringement and invalidity.

Medicine:	**Ciprofloxacin tablets** (**CIPRO**)
Applicants:	Bayer AG and Bayer Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	November 19, 2001
Comment:	Application for Order of prohibition until expiry of Patent No. 1,218,067. Apotex alleges non-infringement and invalidity.

Other New Proceedings

Medicine:	**Sertraline capsules** (**ZOLOFT**)
Applicant:	Novopharm Limited
Respondents:	Pfizer Canada Inc and the Registrar of Trade-marks
Date Commenced:	November 5, 2001
Comment:	Appeal from decision of Trade-marks Opposition Board, rejecting opposition to registration of trade-mark relating to appearance of ZOLOFT capsules.

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