SMART & BIGGAR / FETHERSTONHAUGH AUGUST 2002

IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Infringement by Patients is Relevant Under *Patented Medicines (Notice of Compliance) Regulations*

The Federal Court of Appeal, in a decision released July 8, 2002 (*Genpharm v. Procter & Gamble*), has confirmed that infringement by patients is relevant to whether or not a generic's allegation of non-infringement of a claim for the use of a medicine under the *Regulations* is justified.

Prior to the decision in *Genpharm*, the Federal Court, Trial Division had released conflicting decisions regarding the type of infringement that was contemplated under the *Regulations* in the case of a claim for the use of a medicine. In the most recent such decision (see *AB Hassle v. Canada*), the Court concluded that infringement by the generic producer, not infringement by patients using the generic's product, is relevant and that such infringement must be established in order to prohibit the issuance of marketing approval to the generic. While this test still allowed for the possibility of infringement by the generic, if it induced or procured infringement by patients, the test for inducement or procurement is onerous and was expected to be difficult to meet, particularly on the written evidential record available in summary proceedings under the *Regulations*.

In *Genpharm*, the Court of Appeal stated:

> [44] In the case of a use patent, if the generic producer sells its product and infringement results by patients using the product for a use protected in a patent, there will be infringement of that patent for purposes of the Regulations.
>
> [45] ...Where infringement is by a patient in the case of a use patent, the issuance of the notice of compliance can be said to result in the infringement of the patent, if not directly, then at least indirectly.
>
> [47] ...The point is that use claims referred to in subparagraph 5(1)(b)(vi) contemplate use, not just by the generic producer, but by patients as well, and that infringement will result by patients using a medicine sold by a generic producer, even if there is no inducement or procurement by the generic producer.
>
> [48] The scheme of the Regulations seems obvious. If a generic producer sells a product and infringement by anyone using the product results, that is the infringement the Regulations are intended to preclude.
>
> [49]...Provided that the generic producer cannot establish that no claim for the use of the medicine would be infringed by patients or others by its selling of its product, it will not satisfy the justification test in subsection 6(2) of the Regulations and a prohibition order must be made.

Consequently, *Genpharm* is an important and useful decision for pharmaceutical patentees who have patents claiming the use of medicines listed on the Patent Register established pursuant to the *Regulations*. A generic seeking market entry will now be required to allege and justify non-infringement by patients as a consequence of the generic selling its product.

In a more recent case, on July 12, 2002, the Federal Court, Trial Division, in *AB Hassle et al. v. RhoxalPharma Inc et al.*, decided (without reliance on the easier test for infringement established in *Genpharm* which was not available at the date reasons were formulated) that RhoxalPharma would induce or procure infringement by patients if it was allowed to market its omeprazole tablets.

In *RhoxalPharma* the Court stated:

> [48] The mere fact that RhoxalPharma's product monograph will not include an indication of use in the treatment of *H. pylori* infections is not relevant. For those who do refer to RhoxalPharma's product monograph, it will there be apparent that RhoxalPharma anticipates the possibility, and indeed perhaps the likelihood, of the use of omeprazole in combination with certain antibiotics. RhoxalPharma's affiant acknowledged on cross-examination that he believes it to be correct that omeprazole, in combination with one or more of the named antibiotics is used for the treatment of *H. pylori* infections. In the result, I conclude that RhoxalPharma has "knowledge" of probable, if not inevitable, infringement.
>
> [49] I conclude on the basis of the foregoing that, if a Notice of Compliance is issued by the Minister to RhoxalPharma in respect of omeprazole tablets, RhoxalPharma will do something that it knows, regardless of its intent, will lead doctors to prescribe RhoxalPharma's omeprazole tablets, pharmacists to fill prescriptions that are either generic or specifically for RhoxalPharma's omeprazole tablets, and patients to utilize RhoxalPharma's omeprazole tablets in a manner that will infringe the '668 patent, that is to say to treat *H. pylori* infections. Put another way, I am satisfied that failure to prohibit the issuance of a Notice of Compliance by the Minister to RhoxalPharma in connection with omeprazole tablets will lead inevitably to RhoxalPharma inducing or procuring infringement of the '668 patent.

In conclusion, the decisions in *Genpharm* and *RhoxalPharma* confirm the importance of patent claims for the use of medicines as well as their usefulness under the *Regulations* in preventing generic market entry in circumstances where infringement by patients will result.

Gunars A. Gaikis

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. *Canada* (**azithromycin dihydrate tablets** (**ZITHROMAX**)); *Pfizer* v. *Canada* (**atorvastatin calcium tablets** (**LIPITOR**)); and *Schering* v. *Canada* (**ribavirin capsules** and **interferon alfa 2-b for injection** (**REBETRON**)), June 25, 2002

Court dismisses three applications for judicial review, seeking to set aside decisions of the Minister of Health refusing to list patents on the Patent Register on the basis that the regulatory submissions were filed after the patent application. In all three cases, the patent applications had priority dates preceding the filing dates of new drug submissions but Canadian filing dates subsequent to the filing dates of the new drug submissions. The Minister was correct in interpreting the term "filing date" in the *Regulations* as referring solely to the filing date of an application for patent in Canada. Pfizer and Schering have appealed.

For a discussion of "The Importance of Timely Filing of Accurate Patent Lists", please see the article on page one of the January 2002 issue of *Rx IP Update*.

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

Novartis v. *RhoxalPharma* (**cyclosporine soft gel capsules** (**NEORAL**)), July 3, 2002

Judge dismisses RhoxalPharma's motion to have Novartis' prohibition application dismissed. RhoxalPharma had previously obtained a Notice of Compliance (NOC) for its 100 mg cyclosporine capsules and sought to rely on this previous success as determinative of its new Notice of Allegation (NOA) for 25 and 50 mg cyclosporine capsules. Judge finds that Novartis' application relating to RhoxalPharma's new NOA cannot vex or be unfair to RhoxalPharma and cannot bring the administration of justice into disrepute.

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

Genpharm v. *Procter & Gamble* (**etidronate disodium tablets** (**DIDROCAL**)), July 8, 2002

Court of Appeal upholds decision (originally reported in the December 2001 issue of *Rx IP Update*) granting a prohibition Order on the basis that, *inter alia*, Genpharm's NOA was fatally flawed. For more information, please refer to the article on page one of this issue of the newsletter.

Full Judgment (Court of Appeal)

Full Judgment (Lower Court)

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

AB Hassle v. *RhoxalPharma* (**omeprazole tablets** (**LOSEC**)), July 12, 2002

AB Hassle successful in obtaining a prohibition Order. RhoxalPharma alleged that it would not infringe the applicants' patent pertaining to omeprazole used for the treatment of *Campylobacter* (i.e., *H. pylori*) infections because its product monograph does not mention the use of the drug for treatment of *H. pylori* infections. Although the Judge found that RhoxalPharma would not directly infringe the applicants' patent, inducing or procuring infringement would inevitably result from the issuance of an NOC, because it is well known among physicians and pharmacists that omeprazole is useful in the treatment of *H. pylori* infections.

Full Judgment

Pfizer v. *Apotex* (**azithromycin capsules** (**ZITHROMAX**)), July 19, 2002

Pfizer successful in obtaining a prohibition Order. Apotex sought an NOC pre-patent expiry in order to obtain a listing on provincial formularies so as to enter the market soon after patent expiry. Apotex argued that a submission for listing on a provincial formulary falls within the early working provisions of the *Patent Act* and accordingly is not an infringement of the relevant patent. The Court found that while Apotex could rely on the early working provision in its NOA, the NOA was nevertheless unjustified because provincial regulatory schemes are subordinate to the federal NOC scheme under the *Regulations* and cannot be engaged until the federal scheme has been engaged and completed.

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

Other Decisions

Syntex v. *Apotex* (**ketoralac tromethamine ophthalmic solution** (**ACULAR**)), July 8, 2002

Court of Appeal dismisses appeal of Order (originally reported in the December 2001 issue of *Rx IP Update*) striking an application seeking to prohibit the Minister of Health from granting an NOC to Apotex on the ground that Apotex' NOA contains "deceptive and misleading" information. The Applicants commenced the judicial review application after the 45-day time period to commence a proceeding under the *Regulations* had expired. Court affirms finding that if an issue arises outside of the time periods provided in the *Regulations*, then an applicant must rely on its common law rights.

Full Judgment (Court of Appeal)

Full Judgment (Lower Court)

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

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	**APO-KETOROLAC**
Applicants:	Syntex (USA) LLC, Hoffmann-La Roche Limited, Allergan, Inc and Allergan Inc
Respondents:	Apotex Inc, The Minister of Health
Date Commenced:	June 26, 2002
Comment:	Applicants seek to quash an NOC issued to Apotex. After expiry of the 45-day time period to commence a proceeding under the *Regulations*, applicants learned that a statement in the NOA was inconsistent with Apotex' new drug application filed in the United States. Accordingly no prohibition proceeding was commenced and an NOC issued. Applicants now seek to obtain declaratory relief against Apotex and the Minister based on the argument that the NOA contained a misleading and deceptive statement.

Medicine: **salbutamol sulphate** (**VENTOLIN HFA**, **VENTOLIN DISKUS**)
Applicant: GlaxoSmithKline Inc ("GSK")
Respondents: Attorney General of Canada, The Minister of Health
Date Commenced: July 5, 2002
Comment: The Applicant seeks judicial review of a decision of the Minister of Health not to include Canadian Patent 2,217,950 ("'950") on the patent lists for VENTOLIN HFA and VENTOLIN DISKUS. The Applicant seeks a declaration that the '950 patent contains a claim for the medicine itself or the use of the medicine and an order that the '950 patent should be added to the Patent Register in respect of GSK's salbutamol sulphate.

Medicine: **clarithromycin** (**BIAXIN BID**)
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Pharmascience Inc, The Minister of Health
Date Commenced: July 5, 2002
Comment: The Applicants seek an Order prohibiting the Minister of Health from issuing an NOC to Pharmascience until after the expiry of Canadian Patent 2,261,732 ("'732"). Pharmascience alleges non-infringement and invalidity. The Applicants deny Pharmascience's allegations and allege themselves that the NOA does not comply with the *Regulations* and that Pharmascience has admitted infringement.

Medicine: **clarithromycin** (**BIAXIN BID**)
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Apotex Inc, The Minister of Health
Date Commenced: July 18, 2002
Comment: The Applicants seek an Order prohibiting the Minister of Health from issuing an NOC to Apotex until after the expiry of Canadian Patent 2,261,732 ("'732"). Apotex alleges non-infringement and invalidity. The Applicants deny Apotex' allegations and allege themselves that the NOA does not comply with the *Regulations*.

Other New Proceedings

Medicine: **Unidentified**
Applicant: Apotex Inc
Respondent: The Minister of Health
Date Commenced: July 4, 2002
Comment: Apotex seeks an Order requiring the Minister of Health to complete its consideration of Apotex' first level appeal against the issuance of a Notice of Non-Compliance (NON). Apotex relied on bioequivalence studies to obtain approval for the higher strengths of Product X. Apotex requested a waiver of the requirement for bioequivalence studies for the lower strength on the basis of proportionality of formulations. The Minister would not provide the requested waiver.

OTTAWA

55 Metcalfe Street, Suite 900
P.O. Box 2999, Station D
Ottawa, Ontario Canada
K1P 5Y6
t. 613.232.2486
f. 613.232.8440

ottawa@smart-biggar.ca

TORONTO

438 University Avenue
Suite 1500, Box 111
Toronto, Ontario Canada
M5G 2K8
t. 416.593.5514
f. 416.591.1690

toronto@smart-biggar.ca

MONTREAL

1000 de La Gauchetière St. W.
Suite 3400
Montreal, Québec Canada
H3B 4W5
t. 514.954.1500
f. 514.954.1396

montreal@smart-biggar.ca

VANCOUVER

650 West Georgia Street
Suite 2200
Box 11560, Vancouver Centre
Vancouver, B.C. Canada
V6B 4N8
t. 604.682.7780
f. 604.682.0274

vancouver@smart-biggar.ca

EDMONTON

10060 Jasper Avenue, Suite 1501
Scotia Place, Tower Two
Edmonton, Alberta Canada
T5J 3R8
t. 780.428.2960
f. 780.423.6975

edmonton@smart-biggar.ca

www.smart-biggar.ca

Contact Info
For more information, or to request a copy of any decision, pleading or legislation, please contact:

Gunars A. Gaikis
ggaikis@smart-biggar.ca

J. Sheldon Hamilton
jshamilton@smart-biggar.ca

Daphne C. Ripley (Acting Editor)
dcripley@smart-biggar.ca