



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Supreme Court Rejects Leave Applications Related to Claims For Use of the Medicine Under the *Patented Medicines (Notice of Compliance) Regulations*

The Supreme Court of Canada has refused to grant leave to appeal from two possibly inconsistent decisions of the Federal Court of Appeal regarding the infringement of claims for the use of a medicine. The decisions were made in proceedings brought pursuant to the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations").

Under the *Regulations*, in the case of a patent claim for the use of the medicine, if the generic producer alleges non-infringement, the Court must determine the substantive issue of whether the generic producer's allegation that the claim for the use of the medicine will not be infringed, is justified. If the allegation is not justified, the Court will prohibit issuance of marketing approval (a Notice of Compliance or "NOC") to the generic producer.

As reported in the August 2002 issue of *RxIP Update*, the Court of Appeal in *Procter & Gamble v. Genpharm* (now reported (2002), 20 C.P.R. (4th) 1) ("*Genpharm*") ruled that, in the case of the use patent, where a generic producer sells its product and infringement results through patients' use of the product for a patented use, there will be infringement for purposes of the *Regulations*. As a result, the Court concluded that the patentee was not required to establish that the generic producer induced or procured infringement. The Court of Appeal noted:

[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 may be made.

Subsequently, another panel of the Court of Appeal (containing one member from *Genpharm*) considered the issue in *AstraZeneca v. Apotex* (now reported (2002), 22 C.P.R. (4th) 1) ("*Apotex*"). While the Court accepted that infringement by patients was relevant in considering whether an allegation of non-infringement is justified, the Court declined to apply the test set out in *Genpharm*, placing the onus on the applicants to prove infringement of a claim for the use of the medicine.

In *Apotex*, the Court expressed concern about keeping a generic producer out of the marketplace solely on the basis that a patient might consume the generic's product for the patented use.

[57] Thus Apotex cannot be prevented from obtaining a NOC solely on the basis that it will sell omeprazole. If it were otherwise, then serious policy issues would arise. If there was any likelihood that a patient would consume a generic product for a patented use, then the generic product would not be approved. This would prevent new uses from being approved for existing drugs because there is always the possibility that someone somewhere will use the drug for the prohibited, patented use. This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the

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monopoly held by patent holders. The patent holder would, therefore, effectively control not just the new uses for the old product, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have. In the end, society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at lower cost.

Moreover, the Court of Appeal suggested that something more than demonstrating infringement by patients was necessary. However, the Court did not define the nature of the required “nexus” between the generic producer and the infringement. An issue that remains to be determined by the Court is the level of generic activity that will lead to the conclusion that an allegation of non-infringement of a use claim is not justified. Based on *Apotex*, the “nexus” would seem to be something more than simple marketing, but perhaps less than inducing or procuring infringement. In addition, the two decisions appear to be inconsistent on the issue of onus to prove infringement.

In view of the refusal to grant leave, any inconsistencies in the law remain to be resolved by the Federal Court of Appeal in future decisions.

J. Sheldon Hamilton

Supreme Court of Canada Leave Applications

SmithKline Beecham Pharma v. Apotex (**paroxetine hydrochloride tablets (PAXIL)**), March 20, 2003

Supreme Court of Canada dismisses SmithKline’s leave application from decision of Federal Court of Appeal, finding its formulation patent for paroxetine hydrochloride tablets invalid. The Court of Appeal decision was reported in the July 2002 issue of *Rx IP Update*.

Syntex v. Apotex (**ketorolac tromethamine ophthalmic solution (ACULAR)**), March 20, 2003

Supreme Court of Canada dismisses Syntex’ leave application from a decision of the Federal Court of Appeal. The FCA upheld an Order striking an application seeking to prohibit the Minister of Health from granting an NOC to Apotex on the grounds that Apotex’ Notice of Allegation (NOA) contains “deceptive and misleading” information. The Court of Appeal decision was reported in the August 2002 issue of *Rx IP Update*.

Genpharm Inc. v. Procter & Gamble (**etidronate disodium tablets (DIDROCAL)**), March 27, 2003

Supreme Court of Canada dismisses Genpharm’s leave application from decision of Federal Court of Appeal, granting an Order of prohibition on the basis that, *inter alia*, Genpharm’s NOA was fatally flawed. The Federal Court of Appeal also 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. For more information, please refer to the article on page one of this issue of *Rx IP Update*.

AstraZeneca v. Apotex (**omeprazole capsules (LOSEC)**), March 27, 2003

Supreme Court of Canada dismisses AstraZeneca's leave application from decision of Federal Court of Appeal, which dismissed its appeal from motions judge's decision, dismissing its application for an Order of prohibition with respect to a "use" patent. For more information, please refer to the article on page one of this issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Novartis v. Apotex (**cyclosporine oral solution (NEORAL)**), February 26, 2003

Judge grants Order dismissing application for Order of prohibition on grounds of mootness, as Apotex withdrew its NOA. Judge awards costs to Novartis on a party and party scale.

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

Merck v. Apotex (**levodopa/carbidopa controlled-release tablets (SINEMET CR)**), March 7, 2003

Judge dismisses Merck's motion for an Order directing Apotex to produce certain excerpts from its Abbreviated New Drug Submission (ANDS) for "x" controlled release tablets; directing the Minister to verify that these portions correspond with the information on file; and permitting Merck to file reply affidavits.

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

Janssen-Ortho v. The Minister (**fentanyl transdermal patch (DURAGESIC)**), March 7, 2003

Judge dismisses application for judicial review of Minister's decision to remove patent from Patent Register. Judge finds that the DURAGESIC patch (in particular, the release membrane, the drug reservoir, and the backing) does not fall within the definition of "medicine" for the purposes of the *Regulations*.

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

Ferring v. Apotex (**desmopressin acetate nasal solution (DDAVP, MINRIN)**), March 11, 2003

Judge directs Minister to relist patent on Patent Register and to revoke Apotex' NOC for Apo-Desmopressin. Minister refused to add the patent to the Patent Register in respect of DDAVP as Ferring's patent application was not filed before the date of filing of the Supplemental New Drug Submission (SNDS) for DDAVP. Ferring therefore filed a second SNDS, solely on the basis of a name change to MINRIN. The Minister listed the patent but later removed it. Judge distinguishes the facts from a previous decision of the Court of Appeal (*Bristol-Myers Squibb v. Apotex*) on the basis that, unlike the BMS case, there was no existing patent list for desmopressin acetate when Ferring filed its SNDS for MINRIN. Both the Minister and Apotex have appealed. On March 20, 2003, the Court of Appeal granted a stay of the Order, pending the outcome of Apotex' motion for a stay, pending appeal, which is returnable April 11, 2003.

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

Pfizer v. Attorney General of Canada (**azithromycin dihydrate tablets (ZITHROMAX)**), (**atorvastatin calcium tablets (LIPITOR)**); *Schering v. Attorney General of Canada* (**ribavirin capsules and interferon alfa-2b solution for injection (REBETRON)**), March 14, 2003

Court of Appeal dismisses appeals from decision of motions judge, dismissing applications for judicial review of decisions of Minister of Health, refusing to list certain patents on patents lists. Court of Appeal confirms applications judge's finding that the term "filing date" in s.4(4) of the *Regulations* refers solely to the filing date for an application for patent in Canada and therefore the relevant patents were ineligible for listing on Patent Register.

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

New Court Proceedings

New NOC Proceedings

Medicine:	fenofibrate (LIPIDIL SUPRA)
Applicants:	Fournier Pharma Inc and Laboratoires Fournier SA
Respondents:	Cipher Pharmaceuticals Limited and The Minister of Health
Date Commenced:	March 5, 2003
Comment:	Application for Order of prohibition until expiry of Patent No. 2,219,475. Cipher alleges non-infringement.

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

Medicine:
Applicant:
Respondent:
Date Commenced:
Comment:

verapamil hydrochloride sustained release tablet (CHRONOVERA)
 Pharmacia Canada Inc
 The Minister of Health
 March 19, 2003
 Application for a declaration that Patent No. 2,088,376 is eligible for listing on the Patent Register with respect to Chronovera and directing the Minister to add the patent to the Patent Register. The Minister took the position that the patent is ineligible for listing on the Patent Register as it does not contain a claim to the medicine verapamil hydrochloride or its use.

Other New Proceedings

Product:
Plaintiffs:
Defendants:
Date Commenced:
Comment:

whey protein isolate (HMS 90)
 Immunotec Research Ltd and 2458781 Canada Inc
 Duncan Crow and Widewest Enterprises Ltd
 March 10, 2003
 Patent infringement action regarding Patent Nos. 1,338,682; 2,090,186 and 2,142,277 and trade-mark infringement action regarding Trade-mark Registration No. 485,414 for the trade-mark HMS 90.

Products:
Plaintiff:
Defendant:
Date Commenced:
Comment:

CALMYLIN and DAMYLIN (cough syrups)
 Ratiopharm Inc
 Laboratoire Riva Inc
 March 11, 2003
 Trade-mark infringement action regarding Trade-mark Registration No. 296,416 for the trade-mark CALMYLIN for a cough syrup and expectorant. Riva is alleged to use DAMYLIN in association with a cough syrup and expectorant.

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

Nancy P. Pei (Editor)
 nppei@smart-biggar.ca

Pharmaceutical Practice Group

James D. Kokonis, Q.C.
 John Bochnovic
 Michael D. Manson
 Solomon M.W. Gold
 David E. Schwartz
 Nancy P. Pei
 Denise L. Lacombe
 James Jun Pan

A. David Morrow
 Joy D. Morrow
 Tokuo Hirama
 Steven B. Garland
 Brian G. Kingwell
 Thuy H. Nguyen
 Sally A. Hemming

John R. Morrissey
 Gunars A. Gaikis
 J. Christopher Robinson
 J. Sheldon Hamilton
 Yoon Kang
 Daphne C. Ripley
 May Ming Lee

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