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Apotex Launches First Actions for Recovery of Losses Under *Patented Medicines (Notice of Compliance) Regulations*

Generic manufacturer Apotex Inc has become the first to launch an action for recovery of damages or profits under section 8 of the *NOC Regulations*. Pursuant to section 8, an innovator company can be held liable for “any loss” suffered by a generic as a result of a delay to the generic’s market entry created by an NOC proceeding that is subsequently withdrawn, dismissed or reversed on appeal.

Apotex has launched at least four such actions in the Federal Court:

- **Nizatidine (AXID)**: against Eli Lilly and Company and Eli Lilly Canada Inc, commenced February 23, 2001;
- **Norfloxacin (NOROXIN)**: against Merck & Co, Inc and Merck Frosst Canada & Co, commenced March 6, 2001;
- **Naproxen slow-release tablets (NAPROSYN SR)**: against Syntex Pharmaceuticals International Limited and Hoffmann-LaRoche Limited, commenced June 29, 2001; and
- **Lovastatin (MEVACOR)**: against Merck & Co, Inc and Merck Frosst Canada & Co, commenced June 29, 2001.

In the first action, Eli Lilly brought a preliminary motion to strike Apotex’ claim on the basis that it discloses no reasonable cause of action, as well as a motion to strike Eli Lilly and Company as a party. Mr. Justice Blanchard dismissed both of these motions on June 11, 2001, for failure to meet the “beyond doubt” standard applicable on such a matter. Eli Lilly has appealed.

Although the proceedings are still in the early stages, the outcome of these four actions will clearly have an impact on the business of all pharmaceutical manufacturers in Canada. We will report on the progress of Apotex’ claims in future issues of *RxIP Update*.

Nancy P. Pei

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Merck v. Alcon (timolol maleate ophthalmic solution (TIMOPTIC-XE)), June 6, 2001

Court of Appeal dismisses Merck's appeal of Order dismissing prohibition application. Trial Judge's finding that Merck failed to prove allegation of non-infringement not justified, affirmed. Although NOC had issued prior to appeal, Court declines to consider whether issuance of NOC made appeal moot.

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

AstraZeneca and Merck v. Nu-Pharm (lisinopril (ZESTRIL, PRINIVIL)), June 8, 2001

Prohibition proceeding discontinued on Nu-Pharm's withdrawal of its allegation. Prothonotary finds allegation was withdrawn following an unanticipated change of circumstances: Apotex refusal to supply pre-patent lisinopril. Prothonotary refuses solicitor-client costs, as no reprehensible, scandalous or outrageous conduct by Nu-Pharm. Applicants receive party-party costs.

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

Apotex v. Eli Lilly (nizatidine (AXID)), June 11, 2001

First claim under the damages provision of the *Regulations*. Judge refuses to strike Eli Lilly and Company as a party to the action. Judge refuses to strike claim in whole or in part against Lilly Canada. Complex issues of statutory interpretation arise that are better left to the Trial Judge. Eli Lilly has appealed.

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

SmithKline Beecham v. Apotex and The Minister of Health (paroxetine (PAXIL)), July 6, 2001

First proceeding under *Regulations* where generic succeeds on allegation of patent invalidity for lack of novelty. Previous patent had taught formulation of paroxetine by conventional methods of admixture such as blending, filling and compressing. Skilled person would, in every case and without possibility of error, have arrived at the formulation claimed. Logical first step to solve pink hue problem would be to turn to formulations disclosed by previous patent.

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

Apotex v. Janssen (cisapride (PREPULSID)), August 2, 2001

Court of Appeal dismisses Apotex' appeal of Order of prohibition. No error by Trial Judge in concluding that reaction employed to make Apotex product is an obvious chemical equivalent of reaction claimed in Janssen patent.

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

Merck v. Apotex (simvastatin (ZOCOR)), August 8, 2001

Consent Order directs Minister to verify that relevant portions of ANDS and DMF produced by Apotex correspond to documentation in Minister's file and Apotex to produce, and Minister to verify, any changes made to relevant portions of ANDS and DMF during the proceeding.

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

Other Decisions

Merck v. Apotex (enalapril (VASOTEC)), June 5, 2001

Judge fines Apotex \$250,000 for contempt of court for selling enalapril found to infringe Merck's patent, after Reasons finding infringement released, and by authorizing allowances to facilitate sales among third party vendors and purchasers after Order issued. Dr. Sherman, Chair of Apotex, fined \$4,500 for contempt for authorizing sales after Reasons released. Solicitor-clients costs to Merck. Apotex and Dr. Sherman have appealed. Merck has cross-appealed.

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

Novopharm v. AstraZeneca and The Registrar of Trade-marks (felodipine tablets (PLENDIL)), June 12, 2001

First successful pharmaceutical colour/shape opposition decision by applicant before Trial Division. Judge affirms rejection by Trade-marks Opposition Board of opposition to registration of trade-marks relating to appearance of felodipine tablets. Findings of Board that Novopharm's pleadings were deficient were reasonable. Drawings were adequate. Novopharm has appealed.

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

The Commissioner of Patents v. The President and Fellows of Harvard College (Harvard mouse), June 14, 2001

Supreme Court of Canada grants Commissioner of Patents leave to appeal the decision of Federal Court of Appeal, which ruled that higher life forms are patentable subject matter under the Canadian *Patent Act*.

Eli Lilly & Company and Eli Lilly Canada Inc v. Apotex Inc, Nu-Pharm Inc and Novopharm Limited (fluoxetine capsules (PROZAC)), June 21, 2001

Supreme Court of Canada denies Eli Lilly leave to appeal the decision of the Federal Court of Appeal, which dismissed Eli Lilly's appeal of Trial Judge's order. Trial Judge dismissed Eli Lilly's passing-off claim relating to appearance of PROZAC capsules.

Apotex v. The Minister of Health (Apo-X), June 27, 2001

AstraZeneca denied party/intervener status in Apotex' proceeding to require the Minister to process a submission for a NOC for a drug identified only as Apo-X. Evidence of AstraZeneca suggested that Apo-X might involve omeprazole or omeprazole magnesium, patented products of AstraZeneca. Judge also refuses to order Apotex to disclose whether Apo-X is an omeprazole or omeprazole magnesium product. AstraZeneca has appealed.

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

Hoechst Marion Roussel v. Canada (nicotine patches (NICODERM)), July 13, 2001

Hoechst seeks judicial review of interlocutory decision of Patented Medicines Prices Review Board (PMPRB) regarding jurisdiction of PMPRB in on-going proceedings regarding the pricing of NICODERM. Prothonotary refuses PMPRB Staff party/intervener status in the review application, although PMPRB itself granted limited intervener status. The PMPRB Staff and PMPRB have appealed.

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

Merck v. Nu-Pharm, Sherman and Benyak (enalapril maleate (VASOTEC)), July 13, 2001

In an action for infringement of the enalapril patent against Nu-Pharm, with counterclaim for invalidity, Prothonotary permits Merck to commence a third party claim against Apotex for declarations preventing Apotex and its alleged privy, Nu-Pharm, from attacking the patent, on the bases of estoppel and *res judicata*. Apotex had previously unsuccessfully attacked the validity of the enalapril patent. Apotex has appealed.

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

Apotex Inc v. The Wellcome Foundation Limited and Glaxo Wellcome Inc (trimethoprim-sulfamethoxazole (SEPTRA)), August 30, 2001

Supreme Court of Canada denies Apotex leave to appeal decision of Federal Court of Appeal, which dismissed Apotex' appeal of Trial Judge's order. Trial Judge ordered Apotex to pay GlaxoWellcome profits in the amount of \$23 million.

Legislative and Regulatory Updates

Bill S-17

Bill S-17 (*An Act to amend the Patent Act*) came into force on July 12, 2001 (S.C. 2001, c. 10). Consequently, a Canadian patent in force on July 12, 2001, maturing from an application filed in Canada before October 1, 1989, and which issued less than three years after filing, is subject to patent term extension, the extended term expiring twenty years after the date of filing in Canada.

Patented Medicines (Notice of Compliance) Regulations

On May 22, 2001, the Therapeutics Products Directorate issued a statement that the "filing date" referred to in s.4(4) would continue to be interpreted as the Canadian filing date and not the priority filing date. Accordingly, the policy of the Directorate is that a patent application must have a Canadian filing date pre-dating the filing date of a submission for a NOC, otherwise the patent list will be rejected and the patent not added to the patent register.

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	Cyclosporine oral solution (NEORAL)
Applicants:	Novartis Pharmaceuticals Canada Inc and Novartis AG
Respondents:	Apotex Inc and the Minister of Health
Date Commenced:	June 12, 2001
Comment:	Application for Order of prohibition until expiry of Patent No. 1,332,150. Apotex alleges non-infringement.

Medicine:	Paroxetine hydrochloride (PAXIL)
Applicants:	GlaxoSmithKline Inc and SmithKline Beecham PLC
Respondents:	Apotex Inc and the Minister of Health
Date Commenced:	June 15, 2001
Comment:	Application for Order of prohibition until expiry of Patent No. 2,214,575. Apotex alleges non-infringement, invalidity and improper listing on the patent register.

Medicine:	Ribavirin capsules and interferon alfa-2b solution for injection (REBETRON)
Applicant:	Schering Canada Inc
Respondent:	Attorney General of Canada
Date Commenced:	June 21, 2001
Comment:	Application for Order requiring the Minister of Health to add Patent Nos. 2,287,056 and 2,300,452 to the patent register on the basis of the patents' priority filing dates.

Medicine: **Azithromycin dihydrate tablets (ZITHROMAX)**
Applicant: Pfizer Canada Inc
Respondent: Attorney General of Canada
Date Commenced: June 21, 2001
Comment: Application for Order requiring the Minister of Health to add Patent No. 2,148,071 to the patent register on the basis of the patent's priority filing date.

Medicine: **Atorvastatin calcium tablets (LIPITOR)**
Applicant: Pfizer Canada Inc
Respondent: Attorney General of Canada
Date Commenced: June 22, 2001
Comment: Application for Order requiring the Minister of Health to add Patent No. 2,220,018 to the patent register on the basis of the patent's priority filing date.

Medicine: **Ketorolac tromethamine ophthalmic solution (ACULAR)**
Applicants: Syntex (USA) LLC, Hoffman-LaRoche Limited, Allergan, Inc and Allergan Inc
Respondents: Apotex Inc and the Minister of Health
Date Commenced: June 29, 2001
Comment: Application for Order requiring Apotex to comply with the Regulations by making a proper Notice of Allegation and for Order of prohibition until expiry of Patent No. 1,328,614.

Medicine: **Naproxen slow-release tablets (NAPROSYN SR)**
Plaintiff: Apotex Inc
Defendants: Syntex Pharmaceuticals International Limited and Hoffmann-LaRoche Limited
Date Commenced: June 29, 2001
Comment: Action for damages suffered by reason of commencement of prohibition proceedings or profits, including claim for damages for unjust enrichment.

Medicine: **Lovastatin tablets (MEVACOR)**
Plaintiff: Apotex Inc
Defendants: Merck & Co, Inc and Merck Frosst Canada & Co
Date Commenced: June 29, 2001
Comment: Action for damages suffered by reason of commencement of prohibition proceedings or profits, including claim for damages for unjust enrichment.

Medicine: **Sodium monensin controlled release capsule (RUMENSIN)**
Applicant: Eli Lilly Canada Inc
Respondent: Attorney General of Canada
Date Commenced: July 20, 2001
Comment: Application for Order requiring the Minister of Health to add Patent No. 2,065,084 to the patent register on the basis that "a claim to the medicine itself or the use of the medicine" includes a formulation of active ingredient and inactive ingredients. Veterinary product.

Other New Proceedings

Medicine: **Meloxicam (MOBICOX)**
Applicant: Boehringer Ingelheim (Canada) Ltd
Respondents: Minister of Health (and Pharmacia Canada Inc for first application only)
Date Commenced: June 5, 2001; June 25, 2001; July 31, 2001
Comment: Three applications for review of Access to Information Act decisions to disclose the Mobicox NDS, information Re: Mobicox product monograph and other related documents.

Medicine: **Ranitidine hydrochloride Form 1**
Plaintiff: Brantford Chemicals Inc
Defendant: Pharmascience Inc
Date Commenced: June 13, 2001
Comment: Action for infringement of Patent No. 2,120,874.

Medicine: **Gemfibrozil (LOPID)**
Plaintiff: Plantex USA, Inc
Defendant: Apotex Inc
Date Commenced: June 13, 2001
Comment: Ontario Court action in contract seeking money judgment under a supply contract.

Medicine: **Cyclosporine capsules (NEORAL)**
Plaintiffs: Novartis AG and Novartis Pharmaceuticals Canada Inc
Defendant: RhoxalPharma Inc
Date Commenced: June 28, 2001
Comment: Action for infringement (imminent sales) and validity of Patent No. 1,308,656.

Medicine: **Butorphanol tartrate nasal spray (STADOL NS)**
Plaintiffs: Bristol-Myers Squibb Company, Bristol-Myers Squibb Canada Inc and The University of Kentucky Research Foundation
Defendant: Apotex Inc
Date Commenced: July 18, 2001
Comment: Action for infringement and validity of Patent No. 1,183,778.

Medicine: **Influenza Virus Vaccine**
Applicant: Aventis Pasteur Limited
Respondent: Attorney General of Canada
Date Commenced: July 24, 2001
Comment: Application for review of Access to Information Act decision to disclose documentation Re: contracts for supply of vaccine from 1993 - 1999.

Medicine: **Fenofibrate (LIPIDIL MICRO)**
Plaintiffs: Fournier Pharma Inc and Fournier Industrie et Santé
Respondent: Novopharm Ltd
Date Commenced: July 27, 2001
Comment: Action for infringement of Patent No. 1,322,529.

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:	Unidentified
Applicant:	Genpharm Inc
Respondent:	Minister of National Health
Date Commenced:	August 3, 2001
Comment:	Application for Order requiring Minister to reconsider rejection of ANDS.

Medicine:	Ticlopidine hydrochloride
Plaintiff:	Apotex Inc
Defendant:	Pharmascience Inc
Date Commenced:	August 13, 2001
Comment:	Action for infringement of Patent No. 2,100,836.

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
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Pharmaceutical Practice Group

James D. Kokonis, Q.C.	A. David Morrow	Michael E. Wheeler
John R. Morrissey	John Bochnovic	Joy D. Morrow
Gunars A. Gaikis	Michael D. Manson	Tokuo Hiramata
J. Christopher Robinson	Steven B. Garland	J. Sheldon Hamilton
David E. Schwartz	Brian G. Kingwell	Yoon Kang
Hans Koenig	Nancy P. Pei	Thuy H. Nguyen
Filko Prugo	Daphne C. Ripley	

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