



# IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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## AstraZeneca Seeks to Quash Issuance of NOC to Apotex for Apo-Omeprazole Capsules

AstraZeneca has initiated three judicial review applications arising out of the issuance of a Notice of Compliance (“NOC”) to Apotex for Apo-Omeprazole 20 mg and 40 mg capsules.

Two of the judicial review applications relate to the Minister of Health’s determination that AstraZeneca had not “marketed in Canada” LOSEC capsules for purposes of the *Patented Medicines (Notice of Compliance) Regulations* (“*Regulations*”). As a result, the Minister decided that a generic did not need to address certain patents listed by AstraZeneca on the Patent Register for omeprazole capsules. The applications for judicial review raise the issues of (1) what constitutes “marketing” for purposes of the *Regulations* and in particular, sections 5(1) and 5(1.1) (provisions that require generics to make allegations) and (2) the timing of the marketing so as to trigger the requirement to make an allegation under the *Regulations*.

The third application for judicial review arises out of the Minister’s decision not to require Apotex to make an allegation in respect of certain formulation patents. An earlier proceeding commenced by AstraZeneca regarding an allegation of non-infringement involving the formulation patents was dismissed by the Court. Subsequently, Apotex advised of a change in formulation from that disclosed in the earlier proceeding. Despite this change in formulation, the Minister decided that Apotex was not required to address the patents a second time.

The Minister’s position on both issues carries enormous implications for the administration of the *Regulations* as it suggests a generic may change formulations without having to provide a fresh allegation addressing the changed formulation. Further, the cases may determine what constitutes “marketing” under the *Regulations* and when such marketing must occur.

*Rx IP Update* will continue to update readers as these cases progress.

*J. Sheldon Hamilton*

## Government of Canada Reinstates Proposed Legislation to Facilitate Exports of Patented Medicines to Developing Countries

On February 12, 2004, the Government reinstated proposed legislation, whose stated purpose is “to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” The Bill takes the form of proposed amendments to the *Patent Act* and *Food and Drugs Act* and makes Canada the first country to seek to implement the August 30, 2003 decision of the World Trade Organization on the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health (Doha Declaration).

The Bill contains the same text as the Bill first tabled on November 6, 2003, which was cancelled when Parliament prorogued on November 12, 2003. It has been deemed read a second time and has been referred to the Standing Committee on Industry, Science and Technology.

[Industry Canada News Release](#) (February 12, 2004)

[Bill C-9](#) (*An Act to amend the Patent Act and the Food and Drugs Act*)

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## Patented Medicines Prices Review Board (PMPRB) News

The Patented Medicines Prices Review Board (PMPRB) has released guidelines relating to 2004 price increases. According to the guidelines, “allowable price increases for patented drug products in 2004 are based on the forecast increase in the Consumer Price Index of 2.2%. In some cases, the Guidelines allow a larger increase, but never more than 3.3%.”

[Guidelines](#)

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## Recent Court Decisions

### *Patented Medicines (Notice of Compliance) Regulations*

*Apotex v. The Minister of Health (simvastatin (ZOCOR))*, January 14, 2004

Judge dismisses Merck’s appeal of a Prothonotary’s Order, dismissing its motion for leave to intervene in Apotex’ application against the Minister effectively seeking to backdate the approvable date for its NOC for Apo-Simvastatin. The apparent purpose of the application is to enable Apotex to claim damages pursuant to section 8 of the *Regulations*. Judge finds that Apotex’ motives are irrelevant to the question of what is at issue in the proceeding. Merck has appealed.

[Full Judgment](#) (2004 FC 43)

*AstraZeneca v. Apotex (omeprazole (LOSEC))*, January 16, 2004

Judge allows AstraZeneca's motion to set aside a Prothonotary's decision, granting Apotex leave to file an affidavit, appending Apotex' revised product monograph as an exhibit. Judge finds that it was not in the interests of justice to allow a party to proceed this far into an application and then to change its litigation approach. AstraZeneca had filed their application record on the basis of the original product monograph.

[Full Judgment](#) (2004 FC 71)

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*Pfizer v. Apotex (azithromycin dihydrate (ZITHROMAX))*, January 21, 2004

Judge dismisses application for an Order of prohibition relating to Apotex' azithromycin isopropanolate monohydrate clathrate. The patent at issue claims crystalline azithromycin dihydrate. Apotex alleged non-infringement on that basis that Apotex' tablets do not contain the dihydrate. Apotex refused to produce samples of its product.

Judge finds that Apotex was not required to produce samples in order to discharge its evidential burden; the common law presumption did not apply because "it is not manifestly beyond the power of Pfizer to determine on a balance of probabilities whether Apotex' product will contain the dihydrate" because Apotex disclosed a portion of its Abbreviated New Drug Submission (ANDS) which permitted Pfizer's expert to make azithromycin which was tested for the dihydrate; and the fact that samples were not produced was insufficient to form the basis of a successful application by Pfizer. On the merits, Judge finds that Pfizer has failed to show that Apotex would infringe by producing the dihydrate either as a by-product or final product.

Pfizer has filed a motion seeking to extend the time period in which to file a notice of appeal.

[Full Judgment](#) (2003 FC 1428)

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*Bristol-Myers Squibb v. Apotex (pravastatin (PRAVACHOL))*, January 27, 2004

Court of Appeal dismisses BMS' appeal of a judge's decision. The judge had dismissed BMS' motion for partial summary judgment with respect to Apotex' claim for profits in an action for damages or profits under section 8 of the *Regulations*.

[Court of Appeal Decision](#) (2004 FCA 43)

[Motions Judge's Decision](#) (2003 FCT 414)

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*AstraZeneca v. Apotex (omeprazole magnesium (LOSEC))*, January 30, 2004

Prothonotary dismisses Apotex' motion to strike affidavits on the basis that they contain hearsay evidence.

[Full Judgment](#) (2004 FC 166)

*Bayer v. Apotex* (**ciprofloxacin (CIPRO)**), February 2, 2004

Judge dismisses application for an Order of prohibition.

Judge finds that the requirement in section 5(3)(c)(i) that a submission for a NOC be issued prior to, or at the same time as, the service of a non-infringement Notice of Allegation (NOA) does not apply to a notifiable change.

Judge rejects Bayer's argument that Apotex' NOA does not "relate to" its ANDS and, as a result, Apotex has failed to comply with section 5(3)(c)(i), despite finding that "Bayer correctly states that Apotex' ANDS contains a previously-prohibited process, and does not contain the current Apotex process which is the subject of Apotex' NOA in the present proceedings."

Finally, Judge finds that Bayer has failed to demonstrate that Apotex' allegation of non-infringement is not justified. Bayer has appealed.

[Full Judgment](#) (2004 FC 177)

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*Apotex v. Pfizer* (**fluconazole (DIFLUCAN)**), February 4, 2004

In an action for damages pursuant to section 8 of the *Regulations*, Prothonotary refuses to grant leave to Pfizer to plead a limitations period defence, finding that the only limitation period that applies to Apotex' claim is six years, rather than the two year limitation period that Pfizer sought to plead.

[Full Judgment](#) (2004 FC 190)

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*Janssen-Ortho v. The Minister of Health* (**fentanyl transdermal patch (DURAGESIC)**), February 9, 2004

Court of Appeal dismisses Janssen-Ortho's appeal from an applications judge's decision. The judge had dismissed its application for judicial review of a Minister's decision to remove a patent from the Patent Register, finding 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*.

[Court of Appeal decision](#) (2004 FCA 62)

[Motions Judge's decision](#) (2003 FCT 286)

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## Other Decisions

*Eli Lilly v. Apotex* (**nizatidine (AXID)**), February 11, 2004

In a patent infringement action, Prothonotary denies Eli Lilly leave to amend its statement of claim to seek "an order declaring that Apotex is precluded from seeking relief or, in the alternative, permanently staying any claims for relief pursuant to Section 8 of the ...*Regulations* in respect of nizatidine" on the basis of "grave consequences" flowing from previous proceedings under the *Regulations*. Lilly alleges that in its first NOA, Apotex represented that it would rely upon Novopharm's compulsory licence to acquire only licensed nizatidine, thereby not infringing the plaintiffs' patent, and that contrary to its undertaking Apotex did not in fact sell licensed nizatidine. In the second case, the judge found the information supplied as to process by Apotex was "to say the least misleading." Prothonotary finds that "grave consequences" does not denote a cause of action, nor any form of legal or equitable relief other than that which is available for patent infringement.

[Full Judgment](#) (2004 FC 206)

*Alticor v. Nutravite* (**NUTRILITE and NUTRAVITE vitamins**), February 16, 2004

Judge dismisses trade-mark infringement action relating to use of NUTRAVITE in connection with vitamins, in view of registration for NUTRILITE registered for use in association with vitamin and mineral food supplements. Judge also dismisses claim for passing-off.

[Full Judgment](#) (2004 FC 235)

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## Trade-mark Opposition Board Decisions

**Opposition by Novopharm and Apotex to application no. 815,152 for the trade-mark Red-brown, Circular, Bi-convex Tablet Design owned by AstraZeneca (omeprazole magnesium (LOSEC))**

**Opposition by Apotex to application no. 815,153 for the trade-mark Red-brown Tablet Design owned by AstraZeneca (omeprazole magnesium (LOSEC))**

**Opposition by Novopharm to application no. 815,153 for the trade-mark Red-brown Tablet Design owned by AstraZeneca (omeprazole magnesium (LOSEC))**

**Opposition by Novopharm and Apotex to application no. 815,154 for the trade-mark Pink, Circular, Bi-convex Tablet Design owned by AstraZeneca (omeprazole magnesium (LOSEC))**

Board allows oppositions to applications for trade-marks relating to the appearance of LOSEC tablets, finding in all cases that “the applicant has not satisfied the burden on it to show that, on a balance of probabilities, the applied for ...trade-mark was distinctive of its wares as of the material date.” The evidence included AstraZeneca’s LOSEC packaging which contained a coloured picture of its tablet with the abbreviation TM/MC with the words, “If your omeprazole magnesium tablets look like that shown, it is your assurance that they come from Astra Pharma Inc.” Board member finds, “There is no evidence that doctors, pharmacists or patients interpret the wording on the packaging as meaning that red-brown, circular, bi-convex tablets of a certain size only come from one source and in the absence of such evidence I am not prepared to conclude that this would be the understanding.” Also, Board finds that the message may be interpreted as requiring that the markings be present in order to conclude that the product comes from Astra.

Due to the size of the PDF versions of these decisions, please email us at [rxip.update@smart-biggar.ca](mailto:rxip.update@smart-biggar.ca) if you wish to obtain a copy.

## New Court Proceedings

### *New NOC Proceedings*

**Medicine:** **omeprazole (LOSEC)**  
**Applicants:** AstraZeneca AB and AstraZeneca Canada Inc  
**Respondents:** Genpharm Inc and The Minister of Health  
**Date Commenced:** January 22, 2004  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,186,037. Genpharm alleges non-infringement and that the patent is not properly listed on the Patent Register.

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**Medicine:** **alendronate sodium (FOSAMAX)**  
**Applicants:** Merck & Co, Inc and Merck Frosst Canada & Co  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** January 23, 2004  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 2,018,477; 2,221,417; and 2,149,052. Novopharm alleges non-infringement and that certain claims should not be considered as being included on the Patent Register.

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**Medicine:** **sumatriptan succinate (IMITREX)**  
**Applicants:** GlaxoSmithKline Inc and Glaxo Group Limited  
**Respondents:** Apotex Inc and The Minister of Health  
**Date Commenced:** February 5, 2004  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,105,180. Apotex alleges invalidity.

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**Medicine:** **ondansetron hydrochloride dihydrate tablets (ZOFTRAN)**  
**Applicants:** GlaxoSmithKline Inc and Glaxo Group Limited  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** February 11, 2004  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 1,252,793; 1,319,323; and 2,019,944 and an Order confirming Novopharm's undertaking that it accepts that its NOC will not issue until the 793 patent expires. Novopharm alleges non-infringement with respect to the 323 and 944 patents.

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**Medicine:** **ondansetron hydrochloride injection (ZOFTRAN)**  
**Applicants:** GlaxoSmithKline Inc and Glaxo Group Limited  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** February 11, 2004  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 1,252,793; 1,319,323; and 2,019,944 and an Order confirming Novopharm's undertaking that it accepts that its NOC will not issue until the 793 patent expires. Novopharm alleges non-infringement with respect to the 323 and 944 patents.

**Medicine:** **bupropion hydrochloride tablets (WELLBUTRIN SR)**  
**Applicants:** Biovail Pharmaceuticals Canada, GlaxoSmithKline Inc and The Wellcome Foundation Limited  
**Respondents:** Novopharm Limited and The Minister of Health  
**Date Commenced:** February 12, 2004  
**Comment:** Application for Order of prohibition until expiry of Patents Nos. 1,321,754; 2,142,320; and 2,168,364. Novopharm alleges non-infringement and invalidity with respect to the 754 and 320 patents and non-infringement with respect to the 364 patent.

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**Medicine:** **sumatriptan succinate (IMITREX)**  
**Applicants:** GlaxoSmithKline Inc and Glaxo Group Limited  
**Respondents:** RhoxalPharma Inc and The Minister of Health  
**Date Commenced:** February 13, 2004  
**Comment:** Application for Order or prohibition until expiry of Patent No. 2,105,180. RhoxalPharma alleges non-infringement and invalidity.

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**Medicine:** **cyclosporine capsules (NEORAL)**  
**Applicant:** Novartis Pharmaceuticals Canada Inc  
**Respondents:** RhoxalPharma Inc and The Minister of Health  
**Date Commenced:** February 16, 2004  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,302,963. RhoxalPharma alleges non-infringement and that the patent is not properly listed on the Patent Register.

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**Medicine:** **azithromycin (ZITHROMAX)**  
**Applicants:** Pfizer Canada Inc and Pfizer Inc  
**Respondents:** RhoxalPharma Inc and The Minister of Health  
**Date Commenced:** February 17, 2004  
**Comment:** Application for Order of prohibition until expiry of Patent No. 2,148,071. RhoxalPharma alleges non-infringement, invalidity and that the patent is not properly listed on the Patent Register.

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### *Other New Proceedings*

**Medicine:** **omeprazole 20 mg and 40 mg capsules (LOSEC)**  
**Applicant:** AstraZeneca Canada Inc  
**Respondents:** The Minister of Health, The Attorney General of Canada and Apotex Inc  
**Date Commenced:** February 4, 2004  
**Comment:** Application for Order setting aside the decision of the Minister not to require Apotex to make an allegation in respect of one or more of Patents Nos. 1,292,693; 1,302,891; and 1,338,377; an Order quashing Apotex' NOC; and a declaration that Apotex is required to make an allegation with respect to these patents. For further information on this and the two following new applications, please see the article on page one of this issue of *Rx IP Update*.



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**Medicine:** omeprazole 20 mg and 40 mg capsules (LOSEC)  
**Applicant:** AstraZeneca Canada Inc  
**Respondents:** The Minister of Health and The Attorney General of Canada  
**Date Commenced:** February 4, 2004  
**Comment:** Application for Order setting aside the decision of the Minister to issue an NOC to Apotex without requiring Apotex to address Patents Nos. 2,284,470; 2,186,037; and 2,133,762; an Order quashing the NOC; and a declaration that Apotex is required to make an allegation in respect of these patents.

**Medicine:** omeprazole 20 mg capsules (LOSEC)  
**Applicant:** AstraZeneca Canada Inc  
**Respondents:** The Minister of Health and The Attorney General of Canada  
**Date Commenced:** February 4, 2004  
**Comment:** Application for Order setting aside the decision of the Minister not to require a second person to address either Patent No. 2,284,470 or 2,186,037 in respect of LOSEC 20 mg capsules and an Order compelling the Minister to require the second person to address these patents.

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