Rx IP Update 2013: The Year in Review

A summary of developments in Canadian pharmaceutical law
# TABLE OF CONTENTS

1. Executive Summary ................................................................. 4

2. Introduction ........................................................................... 5

3. Substantive patent law issues.................................................. 5
   3.1. Utility ............................................................................. 5
   3.2. Obviousness ................................................................. 7
   3.3. Claims broader than the invention made or disclosed .......... 7
   3.4. Sufficiency of disclosure ................................................ 8
   3.5. Subject matter ............................................................ 8

4. The Patented Medicines (Notice of Compliance) Regulations .......... 9
   4.1. Decisions on the merits ................................................... 9
   4.2. “Procedural” decisions under PMNOC Regulations ................. 10
   4.3. Unjust Enrichment under the Patented Medicines (Notice of Compliance) Regulations ....................................................... 11
   4.4. Section 8 claims ............................................................ 12
   4.5. Patent eligibility cases .................................................... 14

5. Pharmaceutical patent infringement and impeachment actions .... 14
   5.1. Decisions on the merits ................................................... 16

6. Litigation Procedure ............................................................... 16

7. Other court proceedings ........................................................ 17

8. Patented Medicine Prices Review Board (PMPRB) ..................... 17
   8.1. Decisions ................................................................. 17
   8.2. NPDUIS reports ......................................................... 18

9. Data protection ........................................................................ 19

10. Additional regulatory developments/decisions ........................... 20
11. Health Canada news ................................................................. 22

12. Pharmaceutical Trade-marks decisions ......................................... 23

13. About our pharmaceutical practice group .................................... 23

   13.1. Regulatory and compliance .................................................. 23

   13.2. Litigation ............................................................................ 24

   13.3. Practitioners in our pharmaceutical practice group ................. 26

       13.3.1. Barristers and Solicitors, Patent and Trade-mark Agents ........... 26

       13.3.2. Patent and Trade-mark Agents ......................................... 26

   13.4. Recent rankings and recognition relating to our pharmaceutical practice ...... 26

   13.5. For more information .......................................................... 28

       13.5.1. Regulatory and compliance .............................................. 28

       13.5.2. Litigation ...................................................................... 28

       13.5.3. Prosecution contacts ...................................................... 29
1. Executive Summary

**Comprehensive Economic and Trade Agreement between Canada and Europe (CETA):** In October, Canada and the EU reached an agreement in principle regarding CETA. Canada agreed to (i) an innovator right of appeal under the *Patented Medicines (Notice of Compliance) (PMNOC) Regulations* and (ii) limited patent term restoration. The agreement still requires ratification and implementation into domestic laws.

**Patent law principles - Utility:** The Federal Court (*GLEEVEC*) and Federal Court of Appeal (*PLAVIX*) provided welcome guidance regarding the assessment of the promise of utility in a patent. [On January 30, 2014, the Supreme Court granted Apotex leave to appeal the PLAVIX decision].

**Patent law principles - Obviousness:** The Federal Court of Appeal in *PLAVIX* reversed the Federal Court's finding of obviousness – the invention was not “obvious to try” as its properties were unknown.

**PMNOC Regulations – VIAGRA SCC ruling:** The SCC clarified its 2012 ruling from *PMNOC Regulations* proceedings for Pfizer’s *VIAGRA*. Contrary to the initial ruling, Pfizer’s patent was neither invalid nor void; rather, consistent with the Regulations, Teva’s allegation of invalidity was justified and Pfizer’s application for an Order prohibiting the Minister from issuing a NOC to Teva was therefore dismissed.

**PMNOC Regulations statistics:** The patentee obtained an Order of prohibition for five patents in the Federal Court (one of which was affirmed by Federal Court of Appeal); the generic manufacturer successfully resisted Orders regarding seven patents.

**Unjust Enrichment under PMNOC Regulations proceedings:** The Ontario Court of Appeal confirmed that claims for unjust enrichment arising under the *PMNOC Regulations* are not recoverable, even when asserted in a court of general jurisdiction, and that the Regulations are intended to constitute a complete legislative code, including in respect of equitable remedies.

**Section 8 liability claims:** Apotex was successful regarding two section 8 claims (*azithromycin* and *pantoprazole*).

**Patent infringement actions:** The patentee (Lundbeck/escitalopram (*CIPRALEX*) and Novartis/ *imatinib* (*GLEEVEC*)) was successful in the two infringement/impeachment actions decided by the Federal Court this year. The patentee was also successful in the one Federal Court of Appeal decision on the merits (*PLAVIX*).

---

1 Nancy P. Pei, nppei@smart-biggar.ca. The assistance of Abigail Smith, student-at-law and Shirley Liang, summer student, Smart & Biggar, in the preparation of this paper is gratefully acknowledged.
**Patent Infringement Damages:** The Federal Court awarded Merck over $119 million in damages for losses resulting from Apotex’s infringement of its patent for lovastatin (MEVACOR). The Court confirmed that the existence of a non-infringing alternative is not relevant to assessing damages in Canada.

**Eli Lilly serves Notice of Arbitration under NAFTA:** In September, Eli Lilly filed a Notice of Arbitration under NAFTA Chapter 11 relating to its STRATTERA and ZYPREXA products, alleging that the judiciary’s application of the promise doctrine to Lilly’s patents for these products violates Canada’s obligations under both NAFTA and the Patent Cooperation Treaty.

**Patented Medicine Prices Review Board (PMPRB) decisions:** The PMPRB held that generic manufacturer Sandoz Canada Inc is a “patentee” falling within the Board’s jurisdiction for reporting purposes, based on its relationship with the patentee, Novartis AG. The Federal Court has heard Sandoz’s judicial review application (and separately, ratiopharm’s judicial review applications also relating to jurisdiction); decisions remain under reserve.

---

2. Introduction

This paper is largely based on Smart & Biggar/Fetherstonhaugh’s monthly newsletter, *Rx IP Update* and provides a summary of the key developments in patent and regulatory issues relating to pharmaceuticals and biologics in 2013. Developments are presented chronologically within each topic.

3. Substantive patent law issues

3.1. Utility

**Novartis successful in defending patent for imatinib mesylate (GLEEVEC).** On February 19, 2013, Justice Snider dismissed Teva and Apotex’s actions to impeach Novartis’s patent claiming imatinib mesylate (GLEEVEC) (“imatinib”). Snider J. found the promise of utility for each claim to be differentiated depending on the subject matter of the claim. For the compound claims, Snider J. held that the promise is that the compounds will selectively inhibit one of three types of kinases, which could be established with *in vitro* testing. In contrast, for the use claims the promise is that the compounds can be used to treat atherosclerosis and for the chemotherapy of tumours, requiring

---

2 The case briefs for *Rx IP Update* are prepared by Junyi Chen, Urszula Wojtyra, Tracey Stott, and Kyle Ferguson.

3 *Teva Canada Limited v Novartis AG, 2013 FC 141.*
in vivo efficacy. Snider J. assessed the soundness of the prediction by considering whether it was a reasonable theory or a reasonable hypothesis as of the relevant date. Further, she held that a sound prediction did not need disclosure of all of the test data in the patent: “[t]he fact that all of the Ciba-Geigy tests are not described in the patent is not, in my view, fatal to Novartis’s case. Applying the relevant jurisprudence to the ‘203 Patent now before me, the question is whether sufficient information was disclosed to allow the person of ordinary skill in the art to soundly predict that the compound of Claim 29 (imatinib) would be useful for the chemotherapy of tumours. I emphasize that the person to whom this question is relevant is a skilled person who would come to this exercise with … common general knowledge”.

**Eli Lilly denied leave to appeal regarding olanzapine patent.** On May 16, 2013, following a rare oral hearing, the Supreme Court of Canada denied Eli Lilly leave to appeal a Federal Court of Appeal decision upholding the decision of the Federal Court invalidating its olanzapine patent. Justice O’Reilly had found that the utility promised by the patent was neither demonstrated nor soundly predicted.

**Federal Court of Appeal reverses inutility findings re: PLAVIX patent.** On July 24, 2013, the Federal Court of Appeal overturned Justice Boivin’s finding that Sanofi’s patent claiming clopidrogel bisulfate (PLAVIX) lacked utility. On promise, the Court of Appeal held that the Court is to begin by determining if a skilled person would understand the patent to contain an explicit promise of a specific result. If so, the inventor will be held to that promise; if not, a mere scintilla of utility will do. The skilled person would understand that “alluding” to the possibility of potential use in humans was not a promise that this result had been or would be achieved. Justice Gauthier, concurring, cautioned that not all references to a “practical purpose” should be treated as a promise of a specific result. She distinguished the invention in the ’777 patent from a new use where there must be full disclosure of such utility.

**Federal Court of Appeal considers disclosure requirement for sound prediction of utility for a mechanical invention.** On September 24, 2013, the Federal Court of Appeal affirmed the Federal Court’s ruling that all but one claim of a patent for helicopter landing gear failed for lack of sound prediction of utility. The Court stated that “where the sound prediction is based on … common general knowledge and on a line of reasoning … apparent to the skilled person …, the requirements of disclosure” for sound prediction “may readily be met by simply describing the invention in sufficient detail such that it can be practiced.”

---

4. **SUBSTANTIVE PATENT LAW ISSUES**

4. **Eli Lilly Canada Inc et al v Novopharm Limited**, [SCC Case No. 35067](#).

5. **Eli Lilly Canada Inc et al v Novopharm Limited**, [2012 FCA 232](#).

6. **Eli Lilly Canada Inc et al v Novopharm Limited**, [2011 FC 1288](#).

7. **Sanofi-aventis v Apotex Inc**, [2013 FCA 186](#); aff’g [2011 FC 1486](#).

8. **Bell Helicopter Textron Canada Limitée v Eurocopter**, [2013 FCA 219](#); aff’g [2012 FC 113](#).

9. A detailed discussion of this decision can be found in the [October 1, 2013 issue of IP Update — Canada](#).
3.2. Obviousness

**Federal Court of Appeal reverses obviousness findings re: PLAVIX patent.** The Federal Court of Appeal reviewed the Supreme Court’s determination in a prior proceeding under the PMNOC Regulations\(^{10}\) that the invention of the ‘777 patent was not obvious, in which the “key factor” was “the lack of knowledge of the properties of the enantiomers of the compounds” of the genus patent. The Trial Judge had found that the properties of the enantiomers were unpredictable, which the Court stated was “precisely what led the Supreme Court…to hold that it was not self-evident that what was being tried ought to work.” Thus, the Court reasoned that as the Trial Judge applied the Supreme Court’s test for obviousness to the same material facts, he ought to have come to the same conclusion – i.e., the invention was not “obvious to try”.\(^{11}\)

**AstraZeneca successful in obtaining prohibition Order against Ranbaxy for its generic esomeprazole product.** Justice O’Keefe applied the “obvious to try” test and concluded that it was not more or less self-evident to try to obtain the invention, a tableted enteric dosage formulation for esomeprazole, an acid-sensitive drug. O’Keefe J. noted that the prior art teaches away from the existence of the method employed or alternatively indicates that such a solution is extremely complex and technologically difficult. Furthermore, the experimentation required was prolonged, complex, and far from routine. Finally, on the issue of motivation, O’Keefe J. concluded that even if the prior art provided sufficient motivation, there remained a “lion in the path” significant enough to dissuade a person skilled in the art. Ranbaxy has appealed.\(^{12}\)

**Federal Court dismisses AstraZeneca's application for Order of prohibition for Teva's generic version of SEROQUEL XR.** On March 7, 2013, the Federal Court dismissed AstraZeneca’s applications for an Order prohibiting the Minister of Health from issuing an NOC to Teva for its generic sustained-release quetiapine product. The Federal Court held that the subject of the patent was “obvious to try,” concluding that “it was more or less self-evident to try to obtain a sustained release formulation of quetiapine using HPMC ... and that the person skilled in the art would have had a fair expectation of success.”\(^{13}\)

3.3. Claims broader than the invention made or disclosed

**Application for Order of prohibition denied for Pfizer's pregabalin (LYRICA).** Justice Hughes held that Pharmascience’s allegation that a claim of Pfizer’s patent for pregabalin (LYRICA) (claiming both the pregabalin enantiomer and its racemate for use in treating pain in a mammal), is invalid for

---

\(^{10}\) *Apotex Inc v Sanofi-Synthelabo Canada Inc, 2008 SCC 61.*

\(^{11}\) *Sanofi-aventis v Apotex Inc, 2013 FCA 186; rev'g 2011 FC 1486.*

\(^{12}\) *AstraZeneca Canada Inc v Ranbaxy Pharmaceuticals Canada Inc, 2013 FC 232.*

\(^{13}\) *AstraZeneca Canada Inc v Teva Canada Limited, 2013 FC 245 and 2013 FC 246.*
overbreadth was justified. Justice Hughes found (i) there was no reference to the racemate in the description, the inventor did not test or contemplate testing the racemate, and the skilled person would not infer that the racemate would be effective based on the disclosure of the patent and (ii) although the claim included both chronic and acute pain, the inventor’s evidence was that pregabalin is useful only for the treatment of chronic pain.

3.4. Sufficiency of disclosure

Novartis successful in defending patent for imatinib mesylate (GLEEVEC). In the GLEEVEC decision discussed above, on the issue of sufficiency, Snider J. applied the three-part test articulated in the recent Supreme Court VIAGRA decision: (1) what is the invention? (2) how does it work? (3) having only the specification, can a person of ordinary skill in the art produce the invention using only the instructions contained in the disclosure? Justice Snider found the patent sufficient: the invention was either a class of novel selective kinase inhibitors or two groups thereof; the patent adequately explained how that invention worked; and that the patent disclosure enabled the skilled person to produce the invention. Snider J. also noted that there is no best mode requirement for inventions that are not machines.

3.5. Subject matter

Patent “use” claims for ACLASTA held to be directed to methods of medical treatment. On September 25, 2013, Justice Hughes dismissed Novartis’ application for a prohibition Order regarding Cobalt in respect of zoledronic acid (Novartis’ ACLASTA) on the ground of unpatentable subject matter. Hughes J. found that each claim provides that: (i) zoledronate will be used for intermittent administration; and (ii) the period between the first and subsequent administration is about one year. The patent disclosure provided that the mode of administration and dosage may be selected by the attending physician taking into account the particulars of the patient and describing intermittent administration regimens. Each claim of the patent was thus directed to a method of medical treatment, and unpatentable. Novartis’s appeal was dismissed.

14 Pfizer Canada Inc v Pharmascience Inc, 2013 FC 120.

15 Teva Canada Limited v Novartis AG, 2013 FC 141.

16 Teva Canada Ltd v Pfizer Canada Inc, 2012 SCC 60.

17 Novartis Pharmaceuticals Canada Inc v Cobalt Pharmaceuticals Company, 2013 FC 985.

18 Novartis Pharmaceuticals Canada Inc v Cobalt Pharmaceuticals Company, 2014 FCA 17.
### 4. The *Patented Medicines (Notice of Compliance)* Regulations

#### 4.1. Decisions on the merits

**Table A: 2013 Prohibition application decisions on the merits**

<table>
<thead>
<tr>
<th>Decision</th>
<th>Medicine</th>
<th>Patent type</th>
<th>Issues</th>
<th>Successful party</th>
<th>Link to brief</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pfizer v Pharmascience,</em> 2013 FC 120</td>
<td>pregabalin (LYRICA)</td>
<td>use</td>
<td>validity (overbreadth; inutility; obviousness)</td>
<td>Generic (overbreadth; lack of sound prediction; actual inutility)</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>Novartis v Apotex; Novartis v Teva</em> 2013 FC 142</td>
<td>imatinib mesylate (GLEEVEC)</td>
<td>compound</td>
<td>validity (utility; sufficiency; claim breadth)</td>
<td>Patentee</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>AstraZeneca v Ranbaxy</em> 2013 FC 232 (appeal pending (A-121-13))</td>
<td>esomeprazole (NEXIUM)</td>
<td>formulation</td>
<td>validity (obviousness)</td>
<td>Patentee</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>AstraZeneca v Teva</em> 2013 FC 245 and 2013 FC 246</td>
<td>quetiapine (SEROQUEL XR)</td>
<td>formulation</td>
<td>validity (obviousness; ambiguity)</td>
<td>Generic (on obviousness; ambiguity not considered)</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>Novartis v Teva</em> 2013 FC 283 aff’d 2013 FCA 244</td>
<td>zoledronic acid IV (ZOMETA/ACLASTA)</td>
<td>compound (genus) compound (species)</td>
<td>genus - validity (obviousness, utility, sufficiency) species – validity (obviousness, utility, sufficiency)</td>
<td>genus – Generic (utility/sound prediction) species – Patentee</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>Bayer v Cobalt</em> 2013 FC 573</td>
<td>drospirenone (YASMIN)</td>
<td>product-by-process</td>
<td>non-infringement</td>
<td>Generic (non-infringement)</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>Hoffmann-La Roche v Apotex,</em> 2013 FC 718</td>
<td>valganciclovir (VALCYTE)</td>
<td>compound (prodrug)</td>
<td>validity (anticipation; obviousness; overbreadth, non-infringement)</td>
<td>Generic (anticipation; obviousness; non-infringement – claim 4 only)</td>
<td>Newsletter</td>
</tr>
<tr>
<td>Decision</td>
<td>Medicine</td>
<td>Patent type</td>
<td>Issues</td>
<td>Successful party</td>
<td>Link to brief</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>---------------------------</td>
<td>-------------</td>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td><em>Bayer v Cobalt, 2013 FC 1061</em> (appeal pending A-385-13)</td>
<td>drospirenone + ethinyl estradiol</td>
<td>composition use (YAZ)</td>
<td>composition: non-infringement, validity (obviousness; inutility; lack of sound prediction; overbreadth; insufficiency; ambiguity) use: non-infringement, validity (obviousness; double-patenting; inutility; lack of sound prediction; subject matter)</td>
<td>composition - Patentee use - Generic (non-infringement re: certain claims; unpatentable subject matter)</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>Gilead Sciences v Teva, 2013 FC 1270, 2013 FC 1272</em></td>
<td>tenofovir (TRUVADA, VIREAD, ATRIPLA)</td>
<td>compound (prodrug) salt</td>
<td>compound: validity (anticipation, obviousness) salt: validity (obviousness)</td>
<td>compound: patentee salt: generic (obviousness)</td>
<td>Newsletter</td>
</tr>
<tr>
<td><em>Bristol-Myers Squibb v Teva, 2013 FC 1271</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OVERALL:** Patentee successful regarding 5 patents in the Federal Court (one of which was affirmed by Federal Court of Appeal). Generic manufacturer successful regarding 7 patents in the Federal Court.

See also the Therapeutics Product Directorate’s annual statistical report relating to the administration of the *PMNOC Regulations* for 2012-2013.\(^9\) The report provides statistics relating to the maintenance of the Patent Register (including the number of patent lists filed by first persons, the number of patent lists accepted and rejected, and related litigation) and statistics relating to the number of notices of allegation served, prohibition applications initiated, and outcomes of the applications. The report also provides statistics on products added to the Register of Innovative Drugs (data protection) by product type.

### 4.2. “Procedural” decisions under *PMNOC Regulations*

**Supreme Court varies VIAGRA ruling, confirms that patent is neither invalid nor void.** The Supreme Court of Canada clarified its ruling in *Teva Canada Ltd v Pfizer Canada Inc*:\(^{20}\) the patent in issue is neither invalid nor void, rather, Teva established its allegation and therefore the Court dismissed Pfizer’s application for an Order of prohibition. The Court’s original reasons suggested that

---

\(^{19}\) Health Canada, “Therapeutic Products Directorate Statistical Report 2012/2013 for the *Patented Medicines (Notice of Compliance) Regulations* and Data Protection”.

\(^{20}\) *Teva Canada Ltd v Pfizer Canada Inc, 2012 SCC 60.*
that patent was void and invalid, a remedy not available under the *PMNOC Regulations*. This decision confirms that proceedings under the *Regulations* are distinct from the parties’ private rights of action.\(^{21}\)

**Application moot following withdrawal of notice of allegation (NOA).** Eli Lilly (“Lilly”) brought a prohibition application regarding two patents for Eli Lilly’s *injectable pemetrexed disodium* (ALIMTA). Lilly later accepted that one of the patents would not be infringed by Teva’s product and that no Order of prohibition could therefore be issued, rendering the application with respect to that patent moot. Regarding the second patent, Teva failed to file evidence and eventually withdrew its notice of allegation (NOA). Justice Barnes agreed with Teva that the application was moot, and he also rejected Lilly’s argument that, in light of withdrawal of its NOA, Teva must either cancel its submission to the Minister for an NOC or amend its submission to advise the Minister it will await expiry of the patent.\(^{22}\)

**Court of Appeal dismisses Apotex’s appeal of motion to set aside prohibition order regarding olanzapine.** On December 4, 2013, the Court of Appeal dismissed Apotex’s appeal of a Judge’s dismissal of its motion seeking to: (i) set aside a prohibition Order (which had been affirmed on appeal); and (ii) dismiss the application seeking the prohibition Order regarding the patent claiming *olanzapine* (Eli Lilly’s ZYPREXA).\(^{23}\) Apotex brought the motion on the basis that subsequent to the issuance of the Order of prohibition, the patent at issue was declared invalid. The Court of Appeal held, “[t]his Court has unequivocally held on several occasions that a finding that a patent is invalid does not enable the Court to reach back and retroactively dismiss an application for an order of prohibition granted earlier ...” and there was no basis to find that the decisions were “manifestly wrong.”

### 4.3. Unjust Enrichment under the Patented Medicines (Notice of Compliance) Regulations

**Ontario Court of Appeal affirms lower court’s rejection of claim for unjust enrichment under the *PMNOC Regulations*:** The Ontario Superior Court (Justice Quigley) dismissed a claim by Apotex for unjust enrichment under the *PMNOC Regulations*.\(^{24}\) The decision confirms that: (i) a claim for unjust enrichment (seeking disgorgement of revenues or profits) arising under the *Regulations* is not recoverable, even when the claim is asserted in a court of general jurisdiction; and, (ii) the *Regulations* are intended to constitute a complete legislative code, particularly with respect to the availability of equitable remedies beyond the legislative framework. On September 12, 2013, the Ontario Court of Appeal affirmed the decision,\(^{25}\) finding that the *Regulations* constitute “a valid juristic reason

\(^{21}\) *Teva Canada Ltd v Pfizer Canada Inc*, SCC Case No. 33951.

\(^{22}\) *Eli Lilly Canada Inc v Teva Canada Limited*, 2013 FC 28.

\(^{23}\) *Apotex Inc v Eli Lilly Canada*, 2013 FCA 282.

\(^{24}\) *Apotex Inc v Abbott Laboratories Limited*, 2013 ONSC 356.

\(^{25}\) *Apotex Inc v Abbott Laboratories Limited*, 2013 ONCA 555.
for the respondents’ profits and revenues” for the section 8 period, precluding Apotex’s claim for disgorgement.

**Ontario Divisional Court strikes stand-alone claim for unjust enrichment.** The Ontario Superior Court\(^{26}\) declined to strike claims for various remedies premised on Apotex’s delayed marketing of generic atomoxetine caused by Eli Lilly’s prohibition proceedings against Apotex for that product. Leave to appeal was granted regarding the claims for disgorgement of revenues or profits and damages or an accounting of profits.\(^{27}\) Apotex argued on the appeal that it was entitled to pursue a disgorgement claim on the basis of an independent cause of action. The Court allowed Eli Lilly’s appeal, citing Justice Quigley’s assertion (see above) that the PMNOC Regulations constitute a complete code and leaves no room for any stand-alone equitable remedies.\(^{28}\) [On January 27, 2014, the Ontario Court of Appeal granted Apotex leave to appeal].

### 4.4. Section 8 claims

**Apotex’s action for damages in Ontario Superior Court temporarily stayed pending outcome of appeals from section 8 damages decision in Federal Court.** In Ontario Superior Court proceedings for additional damages arising from Sanofi’s prohibition proceedings against Apotex for its Apo-Ramipril product, Sanofi brought a motion to strike or, in the alternative, a stay pending the outcome of Sanofi’s appeal from the Federal Court decision on section 8 damages and any appeal therefrom. Justice Stinson granted the stay, noting that there was substantial overlap between the issues and factual foundation of each proceeding, and that the outcome of the appeal is likely to resolve at least some of the issues raised in the present action.\(^{29}\)

**Federal Court of Appeal dismisses AstraZeneca’s appeal of decision allowing a section 8 claim regarding Apotex’s generic omeprazole product.** On March 11, 2013, the Federal Court of Appeal dismissed\(^{30}\) AstraZeneca’s appeal of Justice Hughes’s decision\(^{31}\) finding that Apotex is entitled to section 8 damages for its omeprazole capsule product. AstraZeneca challenged two aspects of the decision: i) whether it was relevant to the section 8 claim that AstraZeneca had sued Apotex for infringement of the patent in issue and the infringement trial had not yet been completed, and ii) whether it was relevant to the section 8 claim that during the period in which section 8 damages were claimed Apotex intended to manufacture its product at a manufacturing site other than the one mentioned in its pending regulatory submission. The Court of Appeal dismissed: (i) while a judge has

---

discretion to reduce damages under s. 8(5) based on an *ex turpi causa* argument which could include an infringement claim, it will be for the judge trying the infringement action to ensure that overall, taking both proceedings together, a party is compensated for its provable loss on proper principles (ii) nothing in the applicable regulatory regime precluded Apotex from manufacturing its product at either site.

**Apotex successful in establishing section 8 damages liability of Pfizer regarding azithromycin.**

On May 10, 2013, Justice O'Reilly allowed Apotex’s claim for relief under section 8 in a proceeding regarding **azithromycin** (Pfizer’s **ZITHROMAX**). Justice O'Reilly considered how proceedings under section 8 of the PMNOC Regulations “connect” with those under section 6. He found that the construction of the patent in the previous proceeding binds the judge hearing the section 8 action and that the notice of allegation (NOA) from the previous proceeding shapes the issues under section 8. To find otherwise would create a “duplicitous regulatory alternative to infringement and impeachment actions under the Patent Act, one completely disconnected from the rest of the scheme of the Regulations” and would “unfairly expose first persons to allegations that could not have been anticipated when making the decision whether to apply for an Order of prohibition.” He held that the NOA defines “the limits of what is relevant for purposes of” section 8. Pfizer has appealed.

**Apotex denied leave to appeal decision upholding prohibition Order, addressing comity in PMNOC Regulations proceedings.** On May 9, 2013, the Supreme Court denied Apotex leave to appeal a decision of Federal Court of Appeal that dismissed Apotex's appeal of the Federal Court decision granting an Order prohibiting the Minister from issuing a notice of compliance (NOC) to Apotex for its ophthalmic drug combining **brimonidine** and **timolol** (Allergan’s **COMBIGAN**). The Federal Court issued a prohibition Order despite finding that Apotex’s allegation of obviousness was justified in order to allow the Court of Appeal to address issues of comity arising from a prior decision of the Federal Court relating to the same patent.

In dismissing the appeal, the Court of Appeal found that Apotex's allegation of obviousness was not justified, stating “although the prohibition order was issued by the Federal Court for the wrong reason, it was nevertheless properly issued.” Applying Justice Crampton's construction of the inventive concept, by which, absent some identified error, Justice Hughes was bound, the patent was not obvious: the improved safety profile associated with the combination of brimonidine and timolol would not have been expected by the skilled person.

**Apotex awarded section 8 damages regarding pantoprazole.** On December 11, 2013, Justice Phelan decided matters to guide Apotex’s compensation under section 8 for its **pantoprazole** product,

---

34. *Apotex Inc v Allergan Inc et al*, May 9, 2013 (*SCC Case No. 35184*).
including: the date Takeda would have launched an authorized generic; the date of subsequent generic entry; pricing of Apotex’s product; no “ramp-up” period, given that it had already experienced that period in the real world; and rebates that Apotex would have offered. Justice Phelan refused to deny Apotex damages on the basis that it had breached an undertaking in its notice of allegation (NOA) not to infringe the use patent relating to pantoprazole. A bare pleading in an NOA by itself did not constitute an enforceable undertaking. Both Takeda and Apotex have appealed.

4.5. Patent eligibility cases

Gilead denied leave to appeal decision determining that a patent claiming a combination of ingredients was not eligible for listing on the Patent Register. On March 22, 2013, the Supreme Court denied Gilead leave to appeal a Federal Court of Appeal decision that a patent containing claims for a formulation comprising tenofovir disoproxil fumarate, emtricitabine and a non-nucleoside reverse transcriptase inhibitor (NNRTI) and claims for a “chemically stable combination” of such ingredients was not eligible for listing on the Patent Register against its new drug submission for Gilead’s COMPLERA. The Minister held the patent was ineligible for listing as the patent referenced NNRTIs as a class without specifying rilpirivine, the NNRTI in COMPLERA. The Court of Appeal held that section 4(2)(a) of the PMNOC Regulations requires a “specific reference” to the medicinal ingredient rilpirivine.

5. Pharmaceutical patent infringement and impeachment action

Ontario Superior court refuses to strike Allergan’s infringement claim, not “quia timet”. Allergan is pursuing a claim in the Ontario Superior Court seeking a declaration that certain claims of two patents related to LATISSE (bimatoprost) are valid and infringed by Apotex. Justice Chiappetta refused to strike the claim in whole or in part: Allergan’s claim for infringement alleged sufficient material facts (for example, that Apotex continued to purchase and import raw bimatoprost, and to export topical bimatoprost solutions to the US) and although Apotex’s pursuit of regulatory approval “does not by itself support an action for patent infringement”, “the claim deemed true alleges that particular actions were taken for reasons not solely related to meeting the requirements of the regulatory scheme.” The pleadings were not quia timet, given that “the claims of past and continuing

37 Apotex Inc v Takeda Canada, 2013 FC 1237.
40 Gilead Sciences Canada Inc v Minister (Health), SCC Case No. 35123.
41 Gilead Sciences Canada Inc v Minister (Health), 2012 FCA 254.
infringement support the claim of future continuing infringement”, nor were they “scandalous, frivolous or an abuse of process.” Apotex’s request for further particulars was also refused.42

**Federal Court upholds Lundbeck’s escitalopram patent, grants injunction and accounting of profits.** On March 12, 2013, the Federal Court dismissed Apotex’s action to impeach the patent claiming escitalopram (CIPRALEX), declared the patent valid and infringed, and granted certain remedies to Lundbeck, including requiring Apotex Inc. and Apotex Pharmachem Inc. to pay profits of over $1.4 million and $300K, respectively, and a permanent injunction.43 The Court concluded that the inventive concept was the substance escitalopram, useful as an anti-depressant. In the Court’s view, the case for obviousness “boils down to whether or not it was ‘obvious to try’ certain techniques and whether at one point one might give up in frustration”. Regarding anticipation, the Court held that prior disclosure of citalopram did not teach how to resolve the enantiomers and did not disclose the therapeutic effects of escitalopram. The Court dismissed Apotex’s inutility argument in view of evidence that the pamoic salt of escitalopram was not toxic in rats, and Apotex’s lack of evidence of toxicity. Furthermore, the invention was properly disclosed. On the issue of sound prediction, the Court found that there was no explicit statement that escitalopram had greater therapeutic effect than the racemate, and Apotex’s experts did not explain why the skilled addressee would infer such a promise. Apotex’s appeal was discontinued.

**Apotex ordered to pay more than $119 million in damages to Merck for infringement of lovastatin patent.** In 2010, the Federal Court found that Apotex had infringed Merck’s product-by-process patent for lovastatin (MEVACOR), the patent was valid, and that Merck was entitled to damages rather than to an accounting of profits.44 On July 16, 2013, in the subsequent trial to determine the quantum of damages, Justice Snider awarded Merck over $119 million in damages made up of: (i) roughly $63M as lost profits to Merck Canada on lovastatin sales it would have made but for the infringement; (ii) roughly $51M as lost profits to Merck US on sales ofLovastatin it would have sold to Merck Canada but for the infringement; (iii) a reasonable royalty for post-expiry domestic sales of Apo-Lovastatin made before patent expiry; and (iv) a reasonable royalty for infringing export sales.45

Justice Snider rejected Apotex’s argument that Merck was entitled only to nominal damages (a reasonable royalty) in view of the availability of a non-infringing alternative (NIA), confirming that under Canadian law, the existence of an NIA alternative is not relevant to an assessment of damages. She further rejected Merck’s claim for recovery of “springboard damages”, finding that while the Patent Act does not preclude such recovery, Apotex had insufficient notice of the issue and the evidence was in any event inadequate. Apotex has appealed.46

---

42 Allergan Inc v Apotex Inc, 2013 ONSC 98.
43 Apotex Inc v H Lundbeck A/S, 2013 FC 192.
44 Merck & Co Inc v Apotex Inc, 2010 FC 1265, aff’d 2011 FCA 363.
45 Merck & Co Inc v Apotex Inc, 2013 FC 751.
5.1. Decisions on the merits

Table B: 2013 Infringement action decisions on the merits

<table>
<thead>
<tr>
<th>Decision</th>
<th>Medicine</th>
<th>Patent type</th>
<th>Issues</th>
<th>Successful party</th>
<th>Link to brief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apotex Inc v H Lundbeck A/S, 2013 FC 192</td>
<td>escitalopram (CIPRALEX)</td>
<td>compound</td>
<td>Validity (obviousness; utility; sufficiency)</td>
<td>Patentee</td>
<td>Newsletter</td>
</tr>
<tr>
<td>Teva Canada Limited v Novartis AG, 2013 FC 141</td>
<td>imatinib mesylate (GLEEVEC)</td>
<td>compound</td>
<td>Validity (utility; sufficiency), Infringement</td>
<td>Patentee</td>
<td>Newsletter</td>
</tr>
<tr>
<td>Sanofi-aventis v Apotex, 2013 FCA 186, rev’g 2011 FC 1486 [SCC leave granted in January 2014]</td>
<td>clopidogrel (PLAVIX)</td>
<td>compound</td>
<td>Validity (utility, obviousness)</td>
<td>Patentee</td>
<td>Newsletter</td>
</tr>
</tbody>
</table>

6. Litigation Procedure

Federal Court of Appeal dismisses Apotex’s appeals of Order requiring it to provide samples. On February 19, 2013, the Federal Court of Appeal dismissed three appeals and affirmed the Orders below requiring Apotex to provide samples of its raloxifene hydrochloride, escitalopram and esomeprazole magnesium for the purpose of conducting tests for litigation. The Court of Appeal noted that the use of the words “necessary or expedient” in Rule 249 was intended to give broad discretion to the Court and that Rule 249 requires the Court to balance the interests of the party requesting the inspection or samples, those of the party in possession of the samples, and those of the trier of fact. The Court of Appeal further noted that “in complex pharmaceutical patent cases like the present ones, the usual mechanisms of discovery may well not suffice and parties will often have to rely on Rule 249”.47

7. Other court proceedings

Subsection 53(2) of the Patent Act cannot be used alone to correct involuntary error. On September 30, 2013, the Federal Court dismissed Hoffmann-La Roche’s (“Roche”) judicial review application under subsection 53(2) of the Patent Act for a declaration amending a page from the disclosure of a patent, or in the alternative, for a declaration striking such language. Roche expressed the concern that the disclosure overstates the promised utility of all the claimed compounds. Roche was out of time to seek a reissue patent and found the disclaimer provision too drastic. Justice Roy found that subsection 53(2) cannot be used alone as a remedy to correct an involuntary error if the conditions of subsection 53(1) are not met.

8. Patented Medicine Prices Review Board (PMPRB)

8.1. Decisions

Federal Court sets aside PMPRB decision regarding COPAXONE syringes for second time. In 2008, the Board ordered Teva Canada Innovation (“Teva”) to repay $2.4M to offset excess revenues for COPAXONE (glatiramer acetate) syringes. In 2009, the Federal Court set aside the decision and returned the matter to the Board for redetermination. In 2012, the Board ordered Teva to repay $2.8M for having sold COPAXONE at an “excessive price” between 2004 and 2010. The Federal Court again set aside the decision and sent it back for a second redetermination, holding that: (i) there was nothing unreasonable with the Board’s interpretation of the term “medicine” as found in section 85(1)(a) of the Patent Act; (ii) the Board offered no explanation as to why the removal of COPAXONE from the market was relevant; (iii) the Board was unreasonable in lessening the significance of the fact that the COPAXONE syringe was priced lower in Canada than elsewhere from 2004-2010 without explanation; and (iv) the decisive weight the Board gave to section 85(1)(d), changes in the Consumer Price Index, was an unreasonable interpretation of section 85(1) which treated the Guidelines as binding. On June 28, 2013, the Board issued a Notice of Hearing in the redetermination of the matter. The matter was heard in October, 2013.

Federal Court considers Board decisions re: ratio-Salbutamol HFA and Sandoz. On October 17, 2011, the Board issued an Order requiring ratiopharm (now Teva) to pay the Crown an amount of $65,898,842.76 to offset excess revenues for ratio-Salbutamol HFA from July 2002 to June 2010, after

48  F Hoffmann-La Roche AG v Commissioner of Patents, 2013 FC 1001.
49  Teva Neuroscience GP-SENC v Canada (Attorney General), 2009 FC 1155.
50  PMPRB-2010-D3-Copaxone decision and order.
51  Teva Canada Innovation v Canada (Attorney General), 2013 FC 448.
the determination by the Federal Court of ratiopharm's application for judicial review of the Board's May 27, 2011 decision in the excessive-pricing proceeding. ratiopharm sought judicial review of the October 17, 2011 Order in T-1825-11. In a related matter, the Board released its decision on June 30, 2011 requiring ratiopharm to provide (i) sales and pricing information for certain medicines it sold in Canada and (ii) revenue and R&D expenditures. Ratiopharm sought judicial review of the Board's June 30, 2011 decision in T-1252-11. The Federal Court heard all three judicial review applications in November, 2013, and a decision is under reserve.

On August 1, 2012, the PMPRB held that the generic manufacturer Sandoz Canada Inc. is a “patentee” and thus falls within the Board's jurisdiction for reporting purposes, on the basis of its relationship with the patentee, Novartis AG. Sandoz was therefore ordered to file information relating to Sandoz–Cyclosporine, − Famciclovir, − Azithromycin, − Estradiol and − Terbinafine. The Federal Court heard Sandoz’s judicial review application in November, 2013 and a decision is under reserve.

8.2. NPDUIS reports


1. Between 2008 and early 2011 (first quarter 2011), Canadian prices for many generic drugs decreased by up to 30%.
2. In early 2011, the mean foreign prices were 0.65 of corresponding Canadian prices. In other words, international generic price levels were 35% lower than in Canada. These levels are similar to those reported for 2007 and 2008.

In December 2013, the NDPUIS released two further reports. The Drivers of Prescription Drug Expenditures — A Methodological Report discusses the drivers of the two components of prescription drug expenditures: drug costs and dispensing fees. The New Drug Pipeline Monitor — December 2013 provides information on drugs currently under development that may have an impact on federal, provincial and territorial drug plan expenditures.

52 Court File No. T-1058-11, reported in the July 2011 issue of Rx IP Update; order and May 27, 2011 decision.
53 Order and June 30, 2011 decision; reported in the September 2011 issue of Rx IP Update.
54 PMPRB-10-D2-SANDOZ — Merits reasons and order.
55 Court File No. T-1616-12.
58 New Drug Pipeline Monitor — December 2013
**Rx IP UPDATE 2013: THE YEAR IN REVIEW**

---

**Patented Medicine Price Review Board's (PMPRB) 2012 Annual Report** On October 16, 2013, the PMPRB's 2012 Annual Report was tabled. The report contains compliance and enforcement statistics, including that 1,328 patented drug products for human use were under the PMPRB's jurisdiction in 2012 and that the Board approved 15 Voluntary Compliance Undertakings (to the end of May 2013) and completed two price hearings. The Board also reports that the sales of patented drug products in Canada decreased slightly from $13.1 billion to $12.8 billion in 2012 and that the R&D expenditures reported by patentees were $894.8 million in 2012, a decline of 9.8% over 2011. The Board has also published a summary of key information in the *Annual Report 2012: In Brief*.

**9. Data protection**

Federal Court of Appeal upholds Minister's decision denying data protection for THALOMID. Celgene challenged the Minister of Health's decision that THALOMID (thalidomide) was not entitled to data protection in view of prior approvals of thalidomide products in 1960 (KEVADON) and 1961 (TALIMOL). While the Federal Court granted Celgene's application, on February 15, 2013, the Federal Court of Appeal reversed in a split decision.

Supreme Court denies application for leave to appeal decision denying data protection for DEXILANT. On June 13, 2013, Takeda was denied leave to appeal the Federal Court of Appeal’s decision refusing to quash the Minister of Health’s refusal to grant data protection to DEXILANT (dexlansoprazole). Dexlansoprazole is an enantiomer of the previously approved racemate lansoprazole (PREVACID). The Minister held that dexlansoprazole was not eligible because it was a variation that is specifically excluded from the definition of “innovative drug” in the *Food and Drug Regulations*. The majority of the Federal Court of Appeal upheld the Federal Court’s decision, agreeing with the Minister’s interpretation.

---

59  *Communiqué. PMPRB, Annual Report 2012.*

60  *PMPRB, Annual Report 2012: In Brief.*

61  *Celgene Inc v The Minister of Health, 2012 FC 154.*

62  *Celgene Inc v The Minister of Health, 2013 FCA 43.*

63  *Takeda Canada Inc v Canada (Health), SCC Case No. 35276.*

64  *Section C.08.004.1.*

65  *Takeda Canada Inc v Canada (Minister of Helath), 2011 FC 1444.*

66  *Takeda Canada Inc v Canada (Health), 2013 FCA 13.*
10. Additional regulatory developments/decisions

Ontario Superior Court declines to strike claims against Attorney General of Canada for conduct in dealing with Apotex’s drug submissions. Apotex is suing the Attorney General of Canada based on its conduct in dealing with regulatory submissions filed by Apotex for 11 drug products. On February 11, 2013, Justice Frank struck the claim of unlawful discrimination on the basis that it had no reasonable prospect of success. However, references to bad faith, breach of statutory duty and discrimination were allowed to remain in the pleading as supporting the claim for misfeasance in public office. Further, it was not plain and obvious that the claims with respect to Apo-ASA, Apo-Lansoprazole, Apo-Pantoprazole and Apo-Omeprazole were barred by res judicata or were frivolous, vexatious or otherwise an abuse of process in light of the Federal Court of Appeal decision Apotex Inc v Canada (Health). Justice Frank declined to strike the claims for lost section 8 damages due to actions of the defendant delaying the issuance of NOCs. Finally, the Court declined to order particulars.

Report on the intellectual property regime in Canada. On May 1, 2012, the Standing Committee on Industry, Science and Technology adopted a motion to study the intellectual property regime in Canada and its contribution to advancing innovation. The Committee recently tabled its report, which includes a discussion of the Comprehensive Economic and Trade Agreement and intellectual property protection in the Canadian pharmaceutical industry. With respect to the pharmaceutical industry, the Committee recommend that the Government of Canada: (1) ensure that the regime appropriately balance encouraging investment in the development of new innovative drugs with ensuring access to affordable pharmaceuticals; and (2) undertake an independent, evidence-based review of challenges facing the brand-name pharmaceutical sector in Canada to determine the appropriate solutions. In June 2013, the Government of Canada stated in response that “the Government will ensure the patent regime continues to support a vibrant pharmaceutical industry, allows for timely access to new and innovative drugs, while also allowing for the timely entry of lower-priced generic drugs”, and that “engagement with the pharmaceutical sector will remain a key priority for the Government.”

Novartis’ judicial review of Minister’s decisions under Access to Information Act dismissed. Novartis brought three judicial review applications appealing the Minister of Health’s decisions to disclose Novartis’ internally generated “narratives” regarding suspected adverse events. In a single set of reasons, Justice Hughes dismissed Novartis’ applications, finding that Novartis had not discharged

67 Apotex Inc v Canada (Health), 2011 FCA 86.
its burden of proving that the “narratives” were exempt from disclosure under either section 20(1)(b) or (c) of the Access to Information Act.\footnote{Novartis Consumer Health Canada Inc v Health Canada, 2013 FC 508.}

**Eli Lilly serves second Notice of Intent to submit claim to arbitration and Notice of Arbitration under NAFTA for STRATTERA and ZYPREXA.** On November 7, 2012 Eli Lilly served the Government of Canada with a Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter 11 relating to STRATTERA (atomoxetine).\footnote{Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven} On June 13, 2013, Eli Lilly filed a second Notice of Intent relating to both its STRATTERA and ZYPREXA (olanzapine) products.\footnote{Second Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven (Strattera and Zyprexa).} On September 12, 2013, Eli Lilly filed its Notice of Arbitration, asserting the judiciary’s application of the promise doctrine to Eli Lilly’s patents contravenes Canada’s obligations under NAFTA and the Patent Cooperation Treaty.\footnote{Notice of Arbitration} Eli Lilly seeks damages arising from its loss of the ZYPREXA and STRATTERA patents and/or its inability to enforce either patent.

**Ontario Court of Appeal upholds injunction preventing online prescription drug retailer selling drugs in the United States from operating call and processing facilities in Ontario.** The Ontario College of Pharmacists sought and obtained an injunction preventing, \textit{inter alia}, Global Pharmacy Canada and RX Processing Services Inc. from selling by retail prescription drugs from any location in Ontario and to cease using the designated terms “pharmacy”, “drug” or “drugs” in relation to their business.\footnote{Ontario College of Pharmacists v 1724665 Ontario Inc (Global Pharmacy Canada), 2012 ONSC 4295.} The corporate defendants take customer orders, process payments, and ensure that orders are filled in India and shipped to customers in the United States. Although the drugs never enter Canada, the Ontario Court of Appeal upheld the lower Court’s determination that their sale takes place in Ontario. It further found that the College properly exercised its jurisdiction over the sales; the connection between Ontario and the parties sufficed.\footnote{Ontario College of Pharmacists v 1724665 Ontario Inc (Global Pharmacy Canada), 2013 ONCA 381.}

**Comprehensive Economic and Trade Agreement between Canada and Europe to result in greater protection for pharmaceutical patentees.** As reported in the October 30, 2013 \textit{IP Update — Canada},\footnote{October 2013 Issue of RxIP Update} the Canadian government tabled a Technical Summary report on October 29, 2013 which contained details concerning the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU). An agreement in principle was reached on October 18, 2013.\footnote{Technical Summary of Final Negotiated Outcomes: Canada-European Union Comprehensive Economic and Trade Agreement} The EU had requested (i) an innovator right of appeal under the PMNOC Regulations, (ii) patent term restoration, and (iii) an extended data protection term. Canada agreed to (i) and (ii) for a limited term. CETA is
neither published nor finalized, so these commitments may be subject to change. Further, ratification is not expected until 2015 and further statutory and regulatory amendments will be required to implement the CETA commitments into domestic law.

**Supreme Court upholds validity of Ontario Regulations prohibiting prescription “private label products”**. On November 22, 2013, the Supreme Court of Canada upheld\(^{79}\) the validity of Ontario Regulations that essentially ban the sale of “private label products” in the public and private markets in Ontario by preventing such products from being listed on the Formulary\(^{80}\) or designated as interchangeable with the brand-name products.\(^{81}\)

**Federal Court agrees with Apotex; Minister’s interpretation of “identical medicinal ingredients” was unreasonable**. On December 23, 2013 Justice Kane allowed Apotex’s judicial review application of Health Canada’s decision to refuse to review the Abbreviated New Drug Submissions (ANDS) of Apotex’s *Apo-Telmisartan*. Apotex seeks to market its generic version of *telmisartan* (MICARDIS). The Therapeutic Products Directorate (TPD) determined that Apotex’s finished product differs from the Canadian Reference Product (CRP) MICARDIS because in the CRP the medicinal ingredient is telmisartan-sodium, whereas Apo-Telmisartan contains telmisartan-potassium. The Minister took the position that the medicinal ingredient found in the finished product or dosage form must be identical to the CRP. Apotex argued that the starting ingredient was identical insofar as it was telmisartan. With respect to whether there was a breach of procedural fairness, Justice Kane found that “[a]lthough there were some irregularities in the approval process and the application of the Reconsideration Policy, these irregularities, on their own or cumulatively, do not result in a breach of procedural fairness.” Justice Kane however found that the Minister’s decision regarding the interpretation of the phrase “identical medicinal ingredients” in the definition of “pharmaceutical equivalent” in section C.08.001.1 of the *Food and Drug Regulations* was unreasonable. The decision of the Minister not to accept the ANDS for review was therefore quashed and sent back for reconsideration.

11. Health Canada news

**New public database of clinical trials**. On May 29, 2013, the Minister of Health announced several new government initiatives designed to assist Canadians in finding and understanding information about clinical trials, including: (i) a public database of Health Canada-authorized drug clinical trials; (ii) new standards for research ethics boards that oversee clinical trials; (iii) updated guidance on the inclusion of women in clinical trials; and; (iv) a document for patients considering participating in

---

79 *Katz Group Canada Inc v Ontario (Health and Long-Term Care)*, 2013 SCC 64.

80 *Ontario Drug Benefit Act Regulation*, O. Reg. 201/96, section 12.02.

trials. The database was implemented in May, and publishes certain information regarding Clinical Trial Applications for which Health Canada provided a No-Objection Letter. The database includes information for trials that were authorized as of April 1, 2013.


12. Pharmaceutical Trade-marks decisions

Trade-mark Opposition Board rejects Pfizer’s application to register trade-mark for VIAGRA based on tablet shape and colour. Pfizer applied to register a trade-mark for VIAGRA, which consisted of the colour blue applied to a particular shape of tablet, in 2005 based on proposed use in association with “a pharmaceutical preparation for the treatment of sexual dysfunction.” The Canadian Generic Pharmaceutical Association opposed the application. The Board rejected Pfizer’s application on the ground of lack of distinctiveness. Specifically, the Board found that Pfizer had not established that the trade-mark was distinctive to physicians or pharmacists as of the relevant date. Pfizer has sought judicial review.

13. About our pharmaceutical practice group

13.1. Regulatory and compliance

Our pharmaceutical regulatory and compliance group has extensive experience understanding and managing issues that arise at the pharmaceutical/biologic patent-regulatory interface. We recognize

---

82 Announcement.
83 Notice.
84 Draft Revised Guidance Document.
85 Pfizer Products Inc (Re), 2013 TMQB 27.
the importance of coordinating patent prosecution and enforcement with regulatory and market status of pharmaceutical and biologic drug products. Drawing on the experience of our professionals with patent prosecution experience, litigation experience, and our professionals that have specific expertise in regulatory areas, we provide an integrated team approach and a level of technical depth and support that is unparalleled in Canada.

Our expertise includes the following:

**Patented Medicine Prices Review Board (PMPRB).** We provide assistance in preparing materials and appearing before the PMPRB, including on questions of jurisdiction and reporting requirements, such as sales and pricing data.

**Patent listing: The Office of Patented Medicines and Liaison (OPML).** It is our practice to work with our clients in prosecuting the most appropriate claim set for the purposes of enforcement in Canada, including taking into consideration patent listing requirements. We can assist in the preparation and/or review of patent listing forms, and in instances where the OPML does object to listing a patent on the Patent Register, we have successfully addressed objections through written and/or personal appearances before the Office.

**Data protection.** Data protection is a key factor that we consider in advising our clients. We can also assist in ensuring that an “innovative drug” is properly identified as such by the OPML and thus subject to the data protection provisions of the *Food and Drug Regulations*. As with patent listing, we can assist through written or personal appearance before the OPML.

**Access to Information (ATI) requests.** We have significant experience in providing assistance in responding to ATI requests received by provincial and federal agencies, and we have a team of professionals and paraprofessionals that have handled numerous such requests in a timely and cost efficient manner.

**Applications for judicial review.** Should it be necessary, we can also pursue a judicial review of any administrative decision noted above (e.g. PMPRB, OPML), before the Federal Court and appellate courts.

### 13.2. Litigation

The realm of pharmaceuticals is the most commonly contested area of intellectual property law in Canada, and it is often the most challenging. With generic and subsequent entry biologic manufacturers relentlessly attempting to gain early entry into the marketplace, the stakes for innovative companies are extremely high. Smart & Biggar’s pharmaceutical litigation group calls upon decades of extensive and in-depth experience to keep your pharmaceutical IP rights where they belong: in your hands.

Our group has vast experience in all areas of pharmaceutical litigation, including:

- applications under the *PMNOC Regulations*
• defending actions for damages under section 8 of the PMNOC Regulations
• patent infringement actions
• defending patent impeachment actions
• judicial review applications relating to patent listing and other decisions by the Minister of Health
• appeals of Patent Appeal Board decisions
• appeals of decisions under access to information legislation

**Technical expertise.** Our pharmaceutical litigation group offers unrivalled experience in the legal aspects of operating within the pharmaceutical industry. Nearly all of our practitioners hold a graduate or undergraduate degree in the fields of chemistry, pharmacy, biochemistry or chemical engineering, and some are also licensed pharmacists. We have successfully assisted with obtaining and asserting IP rights for some of the most successful drug products in Canada, including for patents covering active ingredients, synthetic processes, novel crystalline forms, formulations, salts and enantiomers.

**Legal expertise.** The practitioners of our pharmaceutical litigation practice group are among the most prominent and experienced in Canada. Our combined decades of experience appearing before all levels of the provincial and federal court systems, including the Federal Court of Appeal and the Supreme Court of Canada, has afforded us expertise in an array of disciplines that is unmatched by our peers.

We regularly handle cases covering many aspects of pharmaceutical IP law, including complex patent infringement and validity actions, judicial reviews, and litigation under the access to information legislation. We have also acted as counsel for innovative companies in over 170 proceedings under the PMNOC Regulations. The cases we handle are frequently multijurisdictional, and we represent our clients not only in the Canadian aspects of the dispute but also in coordinating litigation strategies worldwide.

Outside the courtroom, we understand the importance that life cycle management plays in securing the strongest possible protection for our clients’ products. Our chemical and biotechnology practice group operates integrally within our litigation team, which gives us a unique perspective on the interplay between establishing and enforcing patent rights. Our added in-depth knowledge of the related regulatory, data protection and pricing regimes permits us to provide our clients with practical and strategic advice that extends well beyond the specific litigation matter at hand.

Our monthly newsletter, *Rx IP Update*, keeps our clients abreast of the latest developments in Canadian pharmaceutical IP and regulatory law. We also frequently present both in-house and external seminars to clients on the fundamentals of the various regimes as well as important developments. Many of our professionals are called upon frequently to offer their expertise through written articles or speaking engagements. In short, we devote considerable resources to ensuring that our clients receive the benefit of our unparalleled experience and expertise in intellectual property law in Canada.
13.3. Practitioners in our pharmaceutical practice group

13.3.1. Barristers and Solicitors, Patent and Trade-mark Agents

Ofﬁces: O=Ottawa, T=Toronto, M=Montreal, V=Vancouver

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Education and Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gunars A. Gaiks</td>
<td>T B.Sc.Phm. (Pharmacy, Univ. of Toronto), J.D. (Osgoode Hall, York Univ.)</td>
<td></td>
</tr>
<tr>
<td>J. Christopher Robinson</td>
<td>V B.Sc. (Biology, Univ. of Calgary), M.Sc. (Genetics, Univ. of Calgary), LL.B. (Univ of Calgary)</td>
<td></td>
</tr>
<tr>
<td>Steven B. Garland</td>
<td>O B.Eng (Chemical-Biochemical, Univ. of Western Ontario), LL.B. (Univ of Ottawa)</td>
<td></td>
</tr>
<tr>
<td>J. Sheldon Hamilton</td>
<td>T B.A.Sc. (Chemical Engineering, Univ. of Toronto), LL.B. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>David E. Schwartz</td>
<td>O B.Sc. (Genetics, Univ. of Alberta), LL.B. (Univ. of Alberta)</td>
<td></td>
</tr>
<tr>
<td>Yoon Kang</td>
<td>T B.Sc. (Microbiology/Genetics, Univ of Toronto), M.Sc. (Mol. Bio. and Med. Genetics, Univ of Toronto), LL.B. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Nancy P. Pei</td>
<td>T B.Sc. (Pharmacy, Univ of Toronto), LL.B. (Univ. of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Mark G. Biernacki</td>
<td>T B.A.Sc. (Mechanical Engineering, Univ of Toronto), LL.B. (Osgoode Hall, York Univ.)</td>
<td></td>
</tr>
<tr>
<td>Jeremy E. Want</td>
<td>O B.Sc. (Chemistry, Univ of Western Ontario), LL.B. (Univ of Manitoba)</td>
<td></td>
</tr>
<tr>
<td>Collin B. Ingram</td>
<td>O B.A.Sc. (Electrical Engineering, Queen’s Univ.), LL.B. (Univ of Ottawa)</td>
<td></td>
</tr>
<tr>
<td>Daphne C. Laison</td>
<td>O B.Sc. (Chemistry, Queen’s Univ.), M.Sc. (Chemistry, Queen’s Univ.), LL.B. (Univ of Windsor)</td>
<td></td>
</tr>
<tr>
<td>Sanjay D. Goorachurn</td>
<td>M B.Sc. (Chemistry, Univ of Manitoba), LL.B. (Univ of Manitoba)</td>
<td></td>
</tr>
<tr>
<td>Sally A. Hemming</td>
<td>T B.Sc. (Biochemistry, Univ of Victoria), Ph.D. (Biochemistry, McMaster Univ.), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Y. Lynn Ing</td>
<td>T B.Sc. (Biochemistry, McMaster Univ.), Ph.D. (Biochemistry, Univ of Toronto), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Heather E. Robertson</td>
<td>T B.Sc. (Microbiology, Univ of Manitoba), LL.B. (Queen’s Univ)</td>
<td></td>
</tr>
<tr>
<td>Daniel M. Anthony</td>
<td>O B.Sc. (Cell Biology and Genetics, Univ of British Columbia), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Junyi Chen</td>
<td>T B.A. (Chemistry, Lawrence Univ.), M.Sc. (Chemistry, Yale Univ.), Ph.D. (Chemistry, Yale Univ.), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Andrew Mandlsohn</td>
<td>T B.Sc. (Pharmacy, Massachusetts College of Pharmacy), J.D. (Suffolk Univ. Law School)</td>
<td></td>
</tr>
<tr>
<td>Kathy Rzeszutek</td>
<td>V B.Sc. (Chemistry, Univ of Manitoba), Ph.D. (Chemistry, Univ of Manitoba), J.D. (Univ of British Columbia)</td>
<td></td>
</tr>
<tr>
<td>Jeffrey E. Coles</td>
<td>O B.Sc. (Biochemistry and Microbiology, Dalhousie Univ.), M.Sc. (Oncology, Univ of Alberta), LL.B. (Univ of Alberta)</td>
<td></td>
</tr>
<tr>
<td>Daniel S. Davies</td>
<td>O B.A.Sc. (Electrical Engineering, Univ of Ottawa), LL.B. (Univ of Ottawa)</td>
<td></td>
</tr>
<tr>
<td>Glen S. Kurokawa</td>
<td>O B.Sc. (Chemistry/Biochemistry, Univ of British Columbia), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Lisa M. Thorne</td>
<td>V B.Sc. (Chemistry, Queen’s Univ.), M.Sc. (Chemistry, Queen’s Univ.), LL.B. (Univ of British Columbia)</td>
<td></td>
</tr>
<tr>
<td>Urszula Wojtyra</td>
<td>T B.Sc. (Applied Biochemistry, Univ of Guelph), M.Sc. (Biochemistry, Univ of Toronto), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Mark Pidkowich</td>
<td>V B.Sc. (Biology, Univ of Saskatchewan), Ph.D. (Genetics, Univ of British Columbia), J.D. (Univ of British Columbia)</td>
<td></td>
</tr>
<tr>
<td>Tracey L. Stott</td>
<td>T B.Sc. (Chemistry, Dalhousie Univ.), Ph.D. (Chemistry, Univ of British Columbia), LL.B. (Univ of British Columbia)</td>
<td></td>
</tr>
<tr>
<td>Jayda A. Sutton</td>
<td>T B.Sc. (Biology, Queen’s Univ.), M.Sc. (Pathology and Molecular Medicine, Queen’s Univ.), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Hongbin Li (李洪滨)</td>
<td>O B.Sc. (Chem, Wuhan Univ), M.Sc. (Biophysics, Peking Univ), M.Sc. (Med. Info Sci, Univ of Calif, San Francisco), J.D. (Univ of Alberta)</td>
<td></td>
</tr>
<tr>
<td>Cameron P. Weir</td>
<td>T B.Sc. (Life Sciences, Queens Univ), M.Sc. (Pharmacology and Therapeutics, McGill Univ), J.D. (Queen’s Univ)</td>
<td></td>
</tr>
<tr>
<td>Kyle A. Ferguson</td>
<td>T B.Sc. (Pharmacology, Univ of British Columbia), M.Sc. (Reprod./Developmental Sc, Univ of British Columbia), J.D. (Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Eve Heafey</td>
<td>O L.L.B. (Univ of Ottawa), M.Sc. (Nanochemistry, Univ of Ottawa), LL.M. (P Law, Univ of Ottawa), J.D. (Univ of Ottawa)</td>
<td></td>
</tr>
<tr>
<td>Mark S. Wilke</td>
<td>V B.Sc. (Biochemistry, Univ of Guelph), Ph.D. (Structural Biology, Univ of British Columbia), J.D. (Univ of British Columbia)</td>
<td></td>
</tr>
</tbody>
</table>

13.3.2. Patent and Trade-mark Agents

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Education and Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thuy H. Nguyen</td>
<td>O B.Sc. (Biochemistry, Univ of Toronto), Ph.D. (Biochemistry, Univ of Toronto)</td>
<td></td>
</tr>
<tr>
<td>Sohrab Sabet</td>
<td>O B.Sc. (Chemistry, Univ of Strathclyde), M.Sc. (Analytical Chem., Univ of Strathclyde), Ph.D. (Atomic Spectroscopy, Univ of Strathclyde)</td>
<td></td>
</tr>
<tr>
<td>Christian Bérubé</td>
<td>O B.Sc. (Chemistry, Univ of Ottawa), M.Sc. (Inorganic Chemistry, Univ of Ottawa)</td>
<td></td>
</tr>
<tr>
<td>Andréanne Auger</td>
<td>M B.Sc. (Biochemistry, McGill Univ), M.Sc. (Biochemistry/Molecular Bio, Dalhousie Univ), Ph.D. (Molecular/Cellular Biology, Univ Laval)</td>
<td></td>
</tr>
<tr>
<td>George Elvira</td>
<td>M B.Sc. (Biochemistry, Univ de Montréal), M.Sc. (Biochemistry, Univ de Montréal), Ph.D. (Biochemistry, Univ de Montréal)</td>
<td></td>
</tr>
<tr>
<td>Lei Liu (刘磊)</td>
<td>O B.Sc. (Biological Science, Peking Univ), Ph.D. (Biochemistry, Queen’s Univ)</td>
<td></td>
</tr>
</tbody>
</table>

13.4. Recent rankings and recognition relating to our pharmaceutical practice

Our pharmaceutical litigation group has been recognized in a number of national and international legal directories and surveys, including:
2013 LMG Life Sciences Awards. Smart & Biggar/Fetherstonhaugh was honoured to be named the Canadian Non-contentious Patent Firm of the Year.

Benchmark Canada 2014. Seven of our lawyers were recognized in the Guide, including four members of our pharmaceutical practice group: Gunars A. Gaikis, Steven B. Garland and J. Sheldon Hamilton were named, and Colin B. Ingram was listed as a future star.

2013 LEXPERT® Guide to the Leading US/Canada Cross-Border Litigation Lawyers in Canada. Three of our lawyers appear in the area of IP litigation, including Gunars A. Gaikis and Steven B. Garland of our pharmaceutical practice group. No other Canadian firm has more litigators selected within the field of cross-border IP litigation.

The Best Lawyers in Canada, 2013 Edition. Three lawyers in our pharmaceutical practice group were named Lawyer of the Year in their respective jurisdictions:

- Gunars A. Gaikis, 2013 Toronto Biotechnology Law Lawyer of the Year
- J. Christopher Robinson, 2013 Vancouver Intellectual Property Law Lawyer of the Year
- Steven B. Garland, 2013 Ottawa Intellectual Property Law Lawyer of the Year

The International Who’s Who of Life Sciences Lawyers 2013. Three members of our pharmaceutical practice group were selected to appear in the Guide: Gunars A. Gaikis, Steven B. Garland and J. Christopher Robinson.

LMG Life Sciences 2013. Six of our lawyers were named a Life Science Star in the area of Intellectual Property, all members of our pharmaceutical practice group: Gunars A. Gaikis, Steven B. Garland, J. Sheldon Hamilton, Yoon Kang, Nancy P. Pei and David E. Schwartz. No other Canadian firm has more lawyers listed in this area.

The 2014 LEXPERT®/American Lawyer Guide to the Leading 500 Lawyers in Canada. Four of our lawyers (including Gunars A. Gaikis and Steven B. Garland of our pharmaceutical practice group) were recognized by the Guide in the areas of intellectual property and intellectual property litigation. No other firm in Canada has more lawyers named in both areas.

Managing Intellectual Property’s 2013 North America Awards. Our firm was honoured as having successfully handled the Canadian Trade Mark Milestone Case of the Year — Federal Court of Appeal’s decision in Marlboro Canada v Phillip Morris, 2012 FCA 201.

Who’s Who Legal: Canada 2013. Nine of our lawyers were selected in the areas of Patents, Trademarks and Life Sciences (including pharmaceutical practice group members John Bochnovic, Gunars A. Gaikis, Steven B. Garland, J. Sheldon Hamilton and J. Christopher Robinson.

2013 LMG Life Sciences Awards. David E. Schwartz, a member of our pharmaceutical practice group was named Canadian Non-contentious Patent Attorney of the Year.
Chambers Global – The World’s Leading Lawyers for Business, 2013 Edition. Smart & Biggar/Fetherstonhaugh was named a Band 1 firm in Canada — the highest ranking given by the Guide. Additionally, five of our lawyers were recognized in the areas of intellectual property and intellectual property: litigation (including pharmaceutical practice group members John Bochnovic, Gunars A. Gaikis and Steven B. Garland).

2013 Benchmark Canada Awards. Steven B. Garland, of our pharmaceutical practice group was named Canada’s Trademark Litigator of the Year.

The International Who’s Who of Patent Lawyers 2013. Five of our lawyers were selected, more than any other firm in Canada (including four members of our pharmaceutical practice group, John Bochnovic, Gunars A. Gaikis, Steven B. Garland and J. Sheldon Hamilton).

13.5. For more information

For more information on how Smart & Biggar/Fetherstonhaugh can help you make the most of your pharmaceutical intellectual property portfolio, please contact:

13.5.1. Regulatory and compliance

Nancy P. Pei, Partner, Toronto
Barrister and Solicitor, Patent and Trade-mark Agent
nppei@smart-biggar.ca | Phone: 416.593.5514

Daphne C. Lainson, Partner, Ottawa
Barrister and Solicitor, Patent and Trade-mark Agent
dclainson@smart-biggar.ca | Phone: 613.232.2486

13.5.2. Litigation

Gunars A. Gaikis, Partner, Toronto
Barrister and Solicitor, Patent and Trade-mark Agent
ggaikis@smart-biggar.ca | Phone: 416.593.5514

Steven B. Garland, Partner, Ottawa
Barrister and Solicitor, Patent and Trade-mark Agent
sbgarland@smart-biggar.ca | Phone: 613.232.2486

J. Sheldon Hamilton, Partner, Toronto
Barrister and Solicitor, Patent and Trade-mark Agent
jshamilton@smart-biggar.ca | Phone: 416.593.5514

Yoon Kang, Partner, Toronto
Barrister and Solicitor, Patent and Trade-mark Agent
ykang@smart-biggar.ca | Phone: 416.593.5514
Nancy P. Pei, Partner, Toronto  
Barrister and Solicitor, Patent and Trade-mark Agent  
nppei@smart-biggar.ca | Phone: 416.593.5514

Jeremy E. Want, Partner, Ottawa  
Barrister and Solicitor, Patent and Trade-mark Agent  
jwwant@smart-biggar.ca | Phone: 613.232.2486

Colin B. Ingram, Partner, Ottawa  
Barrister and Solicitor, Patent and Trade-mark Agent  
cbingram@smart-biggar.ca | Phone: 613.232.2486

13.5.3. Prosecution Contacts

J. Christopher Robinson, Partner, Vancouver  
Barrister and Solicitor, Patent and Trade-mark Agent  
jcrobinson@smart-biggar.ca | Phone: 604.682.7780

Yoon Kang, Partner, Toronto  
Barrister and Solicitor, Patent and Trade-mark Agent  
ykang@smart-biggar.ca | Phone: 416.593.5514

David E. Schwartz, Partner, Ottawa  
Barrister and Solicitor, Patent and Trade-mark Agent  
deschwartz@smart-biggar.ca | Phone: 613.232.2486

Daphne C. Lainson, Partner, Ottawa  
Barrister and Solicitor, Patent and Trade-mark Agent  
dclainson@smart-biggar.ca | Phone: 613.232.2486

Thuy H. Nguyen, Partner, Ottawa  
Patent Agent  
thnguyen@smart-biggar.ca | Phone: 613.232.2486