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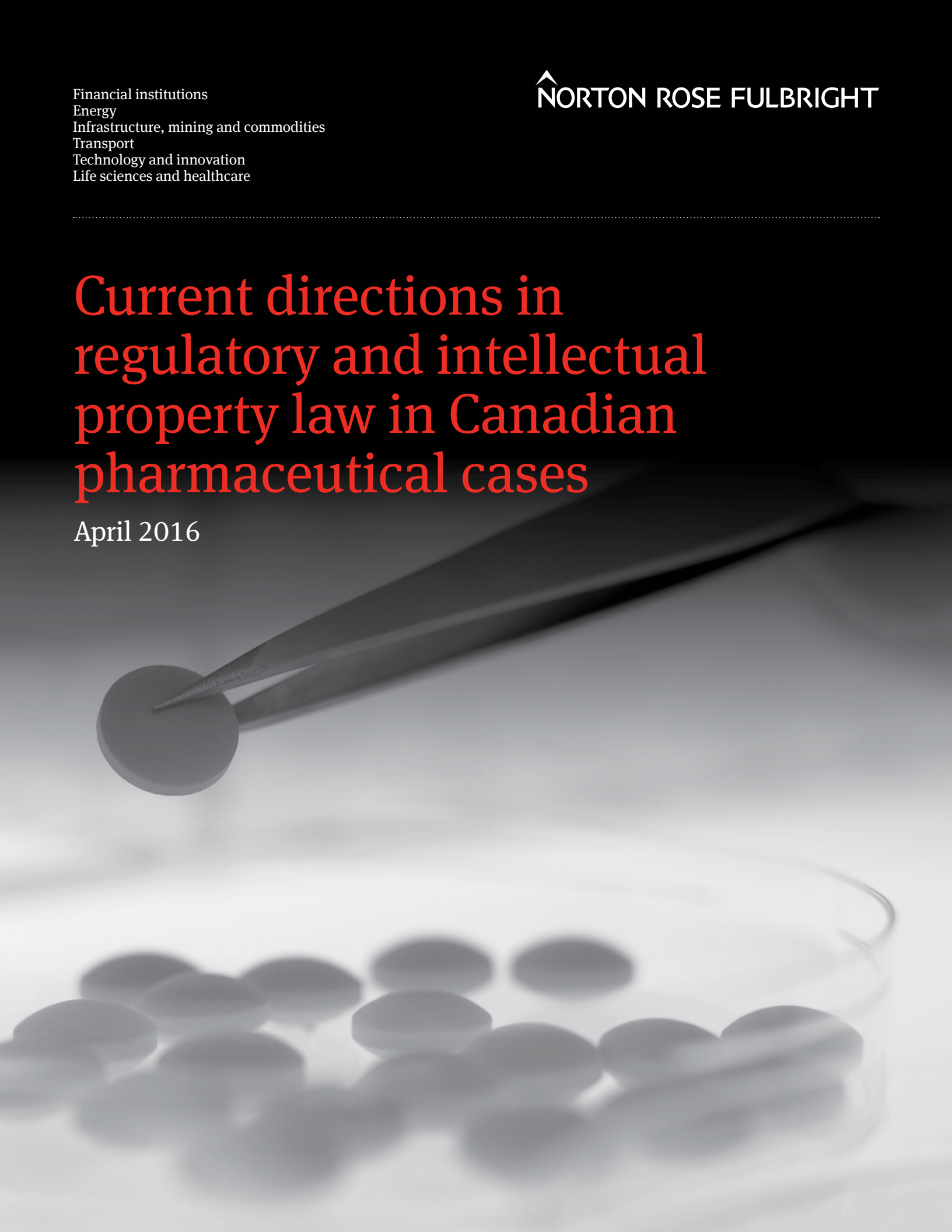
April 2016



Current directions in regulatory and intellectual property law in Canadian pharmaceutical cases

by Jordana Sanft, Tracey Stott, and Jillian Hyslop

Cases decided in 2015 resulted in developments on several fronts, including in regulatory matters, patent cases and class actions. We provide below an overview of some of the most notable Canadian decisions from 2015 that will continue to impact the legal landscape for the pharmaceutical industry in Canada over the coming year.

Regulatory matters

Important cases relating to regulatory issues were decided in 2015, including a judicial review of an import ban imposed on Apotex and challenges to the jurisdiction of the Patented Medicine Prices Review Board ("Board") that remain to be determined in 2016.

Health Canada import ban quashed on products manufactured at facilities in India

In October 2015, the Federal Court released its decision quashing an import ban imposed by the Minister of Health ("Minister") on Apotex's products from two of its manufacturing facilities in India (*Apotex Inc. v. Canada (Health)*, 2015 FC 1161).

The Court found that the import ban was motivated by an improper purpose – media and political pressure following a U.S. FDA decision to impose a similar ban in the U.S. As a result, the Minister acted outside of her delegated authority and erred in her exercise of jurisdiction by imposing the ban and by releasing statements to the media. The Court also found that the Minister failed to provide Apotex with adequate procedural protections by (i) failing to provide any notice of the ban and (ii) denying Apotex the right to be heard prior to unilaterally imposing the ban.

Health Canada did not appeal the decision and in November 2015, the Minister and Health Canada retracted public statements regarding products made at Apotex's manufacturing facilities, as ordered by the Court.

Challenges to the Patented Medicines Prices Review Board's jurisdiction

Two significant challenges to the Board's jurisdiction occurred in 2015 and are ongoing in 2016.

Challenge to the Board's jurisdiction over generic products

In 2011 and 2012, the Board concluded that Sandoz and Ratiopharm (generic companies that sell patented products in Canada pursuant to a license or supply agreement) fell within the definition of a "patentee" under section 79(1) of the *Patent Act*. According to the Board, a person need not own a patent in order to be a "patentee" because the statutory definition includes persons "entitled to the benefit of the patent for that invention".

The generic companies brought an application for judicial review of the Board's decision. The Federal Court found that neither company had the exclusive benefits and rights acquired by patent holders, and as such were not "patentees" within the meaning of the *Patent Act*. As a result, the Board exceeded its jurisdiction by requiring price reporting from Sandoz and Ratiopharm. On November 6, 2015, the Federal Court of Appeal overturned this decision (*Attorney General of Canada v. Sandoz Canada Inc.*, 2015 FCA 249, reported here).

The Court of Appeal held that the Board's interpretation of "patentee" under section 79(1) was entitled to deference and affirmed the Board's finding that the legislative purpose of its enabling provisions is not merely to prevent patent holders from pricing their medicines excessively, but also includes protecting consumers against excessively priced patented medicines. The Court of Appeal also held that the Federal Court failed to appreciate that the mischief of excessive pricing could be caused by parties other than patent holders, and that the distinction between "generic" and "innovator" drug companies is not relevant to the Board's jurisdiction, as these terms are not present in the text of the legislation and are irrelevant to the question of whether the party is a "patentee" within the meaning of section 79(1).

The generic companies have filed for leave to appeal to the Supreme Court of Canada (court docket 36798).

Constitutional challenges to the Board's jurisdiction

In the above decision, the Federal Court of Appeal also upheld the Board's conclusion that the price reporting provisions of the *Patent Act* are constitutionally valid with respect to patent holders and to persons who exercise the right to sell patented medicines without owning the patent rights. The harm that the *Patent Act* seeks to prevent arises "by reason of the existence of the patent" and "nothing turns on the fact that the person exercising the selling rights does not hold the patent itself."

In another constitutional challenge to the Board's jurisdiction, Alexion filed a Notice of Application in the Federal Court alleging that the excessive price provisions of the *Patent Act* intrude on provincial jurisdiction over property and civil rights (court docket T-1537-15). Alexion's application was filed in response to the Board scheduling a nine-day hearing (starting June 27, 2016) to determine whether the pricing of Alexion's SOLIRIS® (eculizumab) was excessive. If Alexion's application is granted, the Board will have no jurisdiction to control prices of any patented drugs in Canada.

The Government filed a motion to dismiss the proceeding, arguing the constitutionality of the price control provisions is settled law. The motion was heard February 9, 2016, but no decision has issued.

Alexion has also filed for leave to intervene in the Sandoz and Ratiopharm application for leave to appeal to the Supreme Court of Canada.

Patent validity

The Federal Court of Appeal issued two notable decisions relating to utility in 2015, and the Supreme Court of Canada is again set to weigh in on the issue.

Utility can be assessed on a claim-by-claim basis

The Federal Court of Appeal dismissed AstraZeneca's appeal of a Federal Court decision invalidating a patent relating to NEXIUM® (esomeprazole) for lack of demonstrated utility or sound prediction (*AstraZeneca v. Apotex*, 2015 FCA 158, reported here).

The Court held that the law is "well settled" that utility must be assessed on a claim-by-claim basis, and that although some "promises" may be "overarching" across claims, "promises" may also be limited to a subset of the claims. The Court also found AstraZeneca's argument that a promise of utility must be construed to be "virtually coterminous" with the inventive concept of the relevant claim to have no support in Federal Court jurisprudence. The Court of Appeal found that the Trial Judge properly construed the "promise" of the patent by considering the patent as a whole through the eyes of the skilled reader, and properly considered the difference between "goals" and "promises".

The Supreme Court of Canada granted AstraZeneca leave to appeal the decision on March 10, 2016 (reported here). Given that the Court of Appeal's decision contains an extensive discussion on the applicable standard for patent utility in Canada, including the "promise" doctrine, this is an opportunity for the Supreme Court to provide guidance on an issue that has been the subject of much debate in recent years.

Disclosure requirement relaxed

In June 2015, the Federal Court of Appeal upheld the Federal Court's decision granting a Prohibition Order to Allergan relating to LUMIGAN RC® (bimatoprost) (*Apotex Inc. v. Allergan Inc.*, 2015 FCA 137, reported here).

Apotex argued that the utility of the patent was not soundly predicted because the line of reasoning was not explicitly disclosed in the patent. The Court of Appeal disagreed and, citing its previous decision in *Eurocopter v. Bell Helicopter*, 2013 FCA 219, confirmed that the elements of sound prediction that would be self-evident to a skilled person need not be explicitly disclosed in the patent. Having determined that in this case the line of reasoning would have been self-evident to a skilled person, the Court dismissed Apotex's allegation.

Apotex's application for leave to appeal to the Supreme Court of Canada was dismissed (court docket 35184).

Patent Damages and Profits

The acceptance of a non-infringing alternative as a possible defence to infringement and an award of disgorgement of profits were two major developments in the law of damages in 2015.

Non-infringing alternative may be relevant in patent damages quantification

The Federal Court found Merck's patent relating to MEVACOR® (lovastatin) valid and infringed by Apotex. In the damages phase of the proceeding, the Federal Court held that the existence of a non-infringing alternative ("NIA") was not relevant to the computation of damages.

The Federal Court of Appeal held that the Canadian law of causation favours the consideration of NIA scenarios when assessing a patentee's lost profits, as failure to do so could, in some circumstances, overcompensate the patentee (*Apotex Inc. v. Merck & Co., Inc.*, 2015 FCA 171, reported here). The Court stated that "perfect compensation" requires consideration of any non-infringing products the infringer or any competitor could and would have sold "but for" the infringement, as well as the extent to which lawful competition would have reduced the patentee's sales and that "there is no reason in principle to ignore such conduct when assessing the patentee's lost sales".

The Court set out the four elements required to establish an NIA defence: (i) the alleged NIA is a true substitute and thus a real alternative; (ii) the NIA is economically viable; (iii) the infringer could have sold the NIA; and (iv) the infringer would actually have sold the NIA. The Federal Court of Appeal found that the evidence failed to establish that Apotex could and would have sold non-infringing lovastatin in place of infringing lovastatin.

Apotex's application for leave to appeal was dismissed on April 14, 2016.

Disgorgement of profits ordered in pharmaceutical patent case

In 2008, the Federal Court held Servier's patent relating to COVERSYL® (perindopril) valid and infringed by Apotex and Apotex Pharmachem, and awarded Servier an election of either its damages or the defendants' profits. Servier elected to take an accounting of the defendants' profits.

In 2015, the Court ordered Apotex to pay Servier a combined total of $61 million CAD, Apotex and Apotex Pharmachem's profit for making, using and selling perindopril tablets in Canada and for export sales to the U.K., Europe and Australia which infringed Servier's Canadian patent, plus interest (*Adir and Servier Canada Inc. v. Apotex Inc.*, 2015 FC 721, reported here). Norton Rose Fulbright Canada LLP represented Adir and Servier in both the liability phase and quantification phase of this action.

Apotex has appealed the decision (court docket A-315-15).

Developments under the PM(NOC) Regulations

Over twenty years after being introduced, the application of the *Patented Medicines* (*Notice of Compliance*) *Regulations* ("*Regulations*") continues to evolve. In 2015, decisions on patent listing eligibility resulted in changes to the *Regulations*, the first decision on a biologic under the *Regulations* was issued, and the approach to quantification under section 8 was confirmed.

Patent listing

Since 2006, paragraph 4(2)(a) of the *Regulations* has permitted a claim for the approved medicinal ingredient of a drug to support listing a patent on the Patent Register in respect of that drug. The Minister's established policy and practice applied paragraph 4(2)(a) to support the patent list eligibility of a patent claiming a single medicinal ingredient with respect to a combination drug.

Two decisions of the Federal Court of Appeal holding that listing patents claiming single medicinal ingredients on the Patent Register against combination drug products was inconsistent with paragraph 4(2) of the *Regulations* disturbed this established interpretation, by finding paragraph 4(2)(a) to require that a patent must claim all medicinal ingredients contained in the approved combination drug in order to be eligible for listing.

In response to these decisions, the *Regulations* were amended in June 2015 to, among other things, specifically allow for listing a patent for one medicinal ingredient against a product with additional medicinal ingredients (reported here).

Following the amendments, in July 2015 the Federal Court of Appeal again considered patent listing, and relaxed the "perfect match" requirement (*Eli Lilly Canada Inc. v. Canada (Attorney General)*, 2015 FCA 166, reported here). The patent at issue covered a fixed dose combination of spinosad and milbemycin oxime marketed by Eli Lily as TRIFEXIS®. The Minister's refusal to list the patent because it did not contain a claim for each medicinal ingredient in the approved product was upheld by the Federal Court.

The Court of Appeal reversed the decision. A majority of the Court held that the Federal Court misread the Court's previous decision (*Gilead Sciences Canada Inc v. Canada (Minister of Health)*, 2012 FCA 254) as requiring that each medicinal ingredient be spelled out in the claims of the listed patent. The majority held that the *Gilead* decision instead required only that each medicinal ingredient be claimed. In concurring reasons, Justice Dawson held that *Gilead* was wrongly decided and that this case was not distinguishable from *Gilead*.

First decision on a subsequent-entry biologic: NEUPOGEN® (filgrastim)

In November 2015, the Federal Court dismissed Amgen's application for a Prohibition Order relating to Amgen's NEUPOGEN® (filgrastim) in 300µg/0.5mL and 480µg/0.5mL strengths (*Amgen Canada Inc. v. Apotex Inc.*, 2015 FC 1261, reported here). The Court held that Apotex's allegations of inutility and lack of novelty were not justified; however, the obviousness allegation was. Apotex received an NOC for filgrastim in December 2015 for the 300µg/0.5mL strength.

Amgen is seeking an expedited appeal of the decision, and Apotex has brought a motion to dismiss the appeal (court file A-501-15).

In October 2015, Amgen commenced a second Application relating to filgrastim (480µg/0.8mL strength) in response to a second Notice of Allegation served by Apotex in August 2015. Amgen alleges that the second Notice of Allegation is an abuse of process. The hearing for this application has been set down for five days, beginning on June 5, 2017.

Section 8 of the Regulations

Supreme Court of Canada affirms section 8 damages quantification

In April 2015, the Supreme Court of Canada dismissed Sanofi-Aventis' appeal of the Federal Court of Appeal's decision on section 8 quantification relating to ALTACE® (ramipril) from the bench "substantially for the reasons of the majority of the Court of Appeal" (*Sanofi-Aventis v. Apotex Inc.*, 2015 SCC 20, reported here).

Innovative Medicines Canada (formerly Canada's Research-Based Pharmaceutical Companies (Rx&D)), represented by Norton Rose Fulbright Canada LLP, and Canadian Generic Pharmaceutical Association intervened in the case.

This hearing marked the Supreme Court of Canada's first consideration of section 8. As a result of the dismissal, the Federal Court of Appeal decision is the guiding law on section 8, and the quantification of section 8 damages remains a highly fact-specific inquiry.

Ontario Court of Appeal upholds dismissal of claim for unjust enrichment

In a decision upholding the Ontario Divisional Court decision striking Apotex's claim for unjust enrichment in a damages action under section 8 (*Apotex Inc. v. Eli Lilly and Company*, 2015 ONCA 305, reported here), the Ontario Court of Appeal confirmed once again that a "second person" claiming damages under section 8 cannot claim the profits of the "first person".

The Court held that regardless of whether the Regulations constitute a complete code, or whether the absence of a juristic reason exists – two grounds upon which courts have previously dismissed claims for unjust enrichment under section 8 – Apotex's claim for unjust enrichment is flawed and must fail because "[p]ut simply, Apotex was never deprived of the portion of Lilly's revenues represented by its monopolistic profits because Apotex would never have earned those profits."

Apotex's application for leave to appeal to the Supreme Court of Canada was also dismissed (court docket 36538).

Class actions and the patent regime in Canada

In December 2015, the British Columbia Court of Appeal issued an important decision in *Britton Low v. Pfizer Canada Inc. et al.*, 2015 BCCA 506 (reported here) describing the interaction between consumer common law claims and the patent regime in Canada. Norton Rose Fulbright Canada LLP represented Pfizer in this proceeding.

The Court found that a proposed consumer class action based on alleged breaches of the *Patent Act* and the *Regulations* could not proceed because the patent regime conferred no rights on consumers, nor did the regime intend to allow consumers to make claims. As a result, the pleaded tort and equitable claims based on alleged breaches of the *Patent Act* and the *Regulations* did not disclose a cause of action at law. Where Parliament has comprehensively legislated in a particular area, as it has in respect to patents, the Court found that it was reasonable to infer that Parliament did not intend recovery to extend beyond that which is embodied in the regime and the Court should not upset the balance struck by expanding the scope of available remedies.

The Plaintiff has filed for leave to appeal to the Supreme Court of Canada (court docket 36848).

Practical litigation matters

The Courts provided some guidance on conducting experimental testing and on instructing experts in 2015.

Probative value of pre-trial testing

The Federal Court of Canada considered the probative value of secret testing conducted prior to trial in *Gilead Sciences, Inc. v. Idenix Pharmaceuticals, Inc.*, 2015 FC 1156, an action relating to Gilead's SOVALDI® (sofosbuvir).

Idenix conducted two sets of testing prior to trial: the first set were performed without informing Gilead and subsequently Gilead was invited to attend a second set. Given that the first experiments were conducted in secret behind the cloak of litigation privilege, and only later was Gilead informed of the testing and invited to observe, the Court gave little weight to the results of the second set of experiments.

The Court also disagreed with Idenix's assertion that Gilead should have undertaken its own testing, and held that there was no reason for Gilead to incur the expense, when Idenix could have provided a better solution by simply being transparent in its own process. The Court stated that Idenix should have offered to retain an outside testing agency mutually agreed upon by the parties, or it could have been transparent in the development of its testing protocols and by permitting Gilead to participate fully in all of the testing, at Idenix's cost.

The Court ultimately found Idenix's patent invalid for lack of demonstrated utility and sound prediction, and insufficiency, and dismissed Idenix's counterclaim for infringement of its patent and for impeachment of Gilead's patent. Norton Rose Fulbright Canada LLP represented Gilead in this action.

Idenix has appealed the decision (court docket A-483-15).

"Blinding" experts

Several recent decision from the Federal Court of Appeal and the Federal Court have dealt with the issue of "blinding" experts to certain aspects of the case, particularly on the issues of construction and obviousness.

With respect to claim construction, the expert is instructed to provide their opinion before receiving information regarding the allegedly infringing product. This occurred in *Teva Canada Innovation v Apotex Inc*, 2014 FC 1070 (relating to AZILECT® (rasagiline), reported here).

"Blinding" and obviousness was considered in *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638 (relating to NEXIUM® (esomeprazole)), *Takeda Canada Inc. v Canada (Health), 2015 FC 570* (relating to OMNARIS® (ciclesonide), reported here), *Eli Lilly Canada Inc. v. Apotex Inc*, 2015 FC 875 (relating to CIALIS® (tadalafil)), and *E Mishan & Sons, Inc v Supertek Canada Inc*, 2015 FCA 163. Generally, the expert is asked to provide an opinion on potential solutions to the problem the patent seeks to solve without knowledge of the contents of the patent.

For both construction and obviousness, courts have in some circumstances preferred the evidence of blinded experts, although it does not appear to be the deciding factor.

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