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CANADIAN PATENT LAW: 2016 YEAR IN REVIEW

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This article summarizes noteworthy Canadian patent law decisions and developments from 2016.

Notable Cases and Decisions

A wide variety of patent law issues were litigated and decided upon in 2016. For instance, the Supreme Court considered the law of utility, the Federal Court of Appeal changed the standard of review in appeals of decisions of Prothonotaries, and the Federal Court considered the situations in which a clinical trial may anticipate a claim. The following review focuses on 2016's most impactful decisions, with a primary focus on appellate decisions.

1. ***Esomeprazole – The Promise Doctrine is Argued before the Supreme Court***

The Supreme Court of Canada heard submissions on the controversial "promise" doctrine in 2016.[1] In recent years, Canadian courts have invalidated several patents on the basis of a failure to demonstrate or soundly predict a patent's "promised" utility as of the Canadian filing date. One such situation involved Astrazeneca's '653 Patent, which had been held invalid before the Federal Court and Federal Court of Appeal on the basis that not all of the promised utility was demonstrated or soundly predicted as of the filing date.

On November 8, Apotex, Astrazeneca and three interveners made oral arguments regarding the promise doctrine and the validity of Astrazeneca's '653 Patent. The oral and written arguments focused on whether the promise doctrine can be maintained under Canada's *Patent Act*, and, more broadly, the level of utility required in order to meet the section 2 "useful" requirement under the *Patent Act*. Submissions were also made as to whether the inventive concept of a given claim need be coterminous with the level of utility of the same claim. [2]

The Supreme Court reserved judgment. A decision can be expected in early-mid 2017.

2. ***Hospira – Housen Replaces Aqua-Gem in Appeals from Prothonotaries***

The Federal Court of Appeal's 1993 decision of *Canada v Aqua-Gem*[3] has long dictated the standard of review of discretionary orders made by Prothonotaries. *Aqua-Gem* held that discretionary orders of Prothonotaries ought not to be disturbed on appeal to a judge unless (a) they are clearly wrong; or (b) they raise questions vital to the final issue of the case. When either (a) or (b) was met, a *de novo* review was performed on the appeal.

Hospira[4] involved a five-membered panel (as opposed to the traditional three-membered panel) re-considering the *Aqua-Gem* standard. The Court in *Hospira* held that the standard enunciated in *Aqua-Gem* was wrong, and that the appropriate standard was that set out in the Supreme Court of Canada's *Housen* decision. [5] The *Housen* standard requires questions of law to be considered on a standard of correctness, and factual conclusions of a decision-maker to be given deference and evaluated on the standard of "palpable and overriding error". By adopting *Housen*, the standard of review for decisions of Prothonotaries now mirrors the standard of review applied by the Court of Appeal when considering decisions of Judges of the Federal Court.

3. ***Venlafaxine – Appeal of Liability Finding under Section 8 of the PM(NOC) Regulations***

Venlafaxine is a cautionary tale to litigants. In *Venlafaxine*, [6] the Federal Court of Appeal overturned a $92 million damages award made to Teva under section 8 of the *PM(NOC) Regulations*. A claim for damages requires proof that the person claiming damages "could have" and "would have" recovered the sought-after damages had the wrong not been committed. Key evidence relied on by Teva to establish that its supplier could have and would have supplied Teva with enough venlafaxine to supply the market at the relevant time was provided through hearsay.

The burden to prove its damages, including the "could have" and "would have" requirements, was said to fall squarely on Teva (the party seeking damages). It was thus confirmed that

section 8 actions are no different from normal damages cases in this regard. The only evidence that Teva put forward to prove that its supplier could have and would have provided Teva with enough venlafaxine to supply the market was the hearsay evidence from a former Teva executive. This hearsay evidence was relied on by the Trial Judge to find that Teva established its loss and was thus entitled to damages. The Federal Court of Appeal held that this reliance was improper, and sent the matter back to the Federal Court for redetermination.

4. ***Cialis – The Relevant Date for Obviousness-Type Double Patenting***

   Two Federal Court of Appeal decisions in 2016 dealt with the issue of obviousness-type double patenting. *Cialis Mylan*[7] and *Cialis Apotex*[8] were separate appeals, both pertaining to Lilly's '784 Patent covering its Cialis® product.

   In *Cialis Mylan* the FCA provided a review of the law concerning obviousness-type double patenting. Obviousness-type double patenting was distinguished from obviousness *per se*. Obviousness-type double patenting was said to only consider whether the patent at issue is obvious *vis-à-vis* a single, earlier granted patent based on a comparison of the claims of the two patents. There is no one-year grace period for obviousness-type double patenting. By contrast, obviousness *per se* involves a one year grace period for information disclosed by the patentee, and a consideration of the impugned patent as compared with the entire relevant art.

   Cialis Mylan and *Cialis Apotex* both addressed arguments from the generics that the relevant date for considering obviousness-type double patenting is the publication date of the second patent. This argument was rejected in both cases. The FCA did not go on to actually decide what the appropriate date is when considering obviousness-type double patenting.

5. ***Exjade – Claim Differentiation in Determining Utility***

   The FCA's *Exjade*[9] decision affirmed the *Celebrex*[10] principle that different claims can have different levels of utility. In *Exjade*, Teva was unsuccessful in appealing a decision of O'Reilly J.[11] in which it was found that certain claims of Novartis's '951 Patent met the *Patent Act*'s utility requirement and other claims did not on the basis that different claims in the '951 Patent contained different promises of utility.

   Teva's appeal hinged on an argument that there was a single promise of the patent that applied to every claim of the '951 Patent. However, the FCA found that the '951 Patent "expressly differentiates" between different classes of compounds (which were found in different claims). The principle of claim differentiation was applied such that the different claims were held to have different promises.

6. ***Aromasin – Granted NOCs on the Basis of Cross-referenced Drug Submissions***

   Aromasin[12] was a successful appeal by Teva of a Federal Court decision which held that Health Canada had been incorrect in granting Teva its NOC on the basis of a cross-referenced submission.

Aromasin involved an interesting fact situation. Pfizer held a listed patent in respect of Aromasin. The company "GMP" sought approval for a generic version of Aromasin and served a Notice of Allegation on Pfizer. Pfizer elected not to start a prohibition proceeding against GMP, and GMP was issued a NOC by the Minister of Health for generic Aromasin. Unbeknownst to Pfizer, Teva then filed an ANDS that was cross-referenced to GMP's submission, and which did not address Pfizer's listed patent. Nonetheless, the Minister granted Teva an NOC. Pfizer brought an application before the Federal Court, and it was found that the Minister's decision to grant Teva an NOC was incorrect.

The FCA held that the Federal Court erred by applying a correctness standard in evaluating the Minister's decision to grant Teva its NOC, and that a reasonableness standard should have been applied. The FCA could not conclude that the decision of the Minister to grant the NOC was unreasonable, and the Federal Court's decision to set aside the Minister's decision to issue the NOC was set aside.

7. ***Ethinylestradiol and Drospirenone – Clinical Trial Does Not Anticipate***

The decision of *Bayer v Apotex*[13] addressed the issue of anticipation via clinical trial. The patentee had conducted a phase III clinical trial for its YAZ and YASMIN products more than one year before the patent at issue was filed in Canada. The participants in the trial did not sign confidentiality agreements and no restriction was imposed on participants regarding the disclosure of information concerning the tablets. However, Fothergill J. of the Federal Court found that there was no anticipation. Fothergill J. found that even if some of the patented product was made public, it would have taken ingenuity to re-engineer the invention of the patent. Thus, there was no enabling disclosure to the public. Further, the clinical trial was found to constitute necessary public experimentation, and thus fell within the experimental use exception.

The *Bayer v Apotex* line of cases produced a second interesting decision in 2016. As of the date of the *Bayer v Apotex* decision, Apotex and Cobalt had already entered the YAZ and YASMIN markets (which were covered by the patent at issue in the above-discussed action) by virtue of successful non-infringement allegations made in applications under the *PM(NOC) Regulations*. Bayer then succeeded in the infringement aspect of *Bayer v Apotex*, and thus became entitled to damages from Apotex and Cobalt. While the typical case is that a successful patentee has the right to choose between damages or, if allowed by the Court, an accounting of profits, the infringer Apotex actually asked for the reverse: it sought the right to choose between paying Bayer its damages or an accounting of profits. Apotex's position was that it only gained market entry by virtue of the *Regulations*, and thus that it should not be exposed to a claim for damages. This argument was rejected by the Court, who found that ability to to elect was Bayer's by right as enshrined in section 55(1) of the *Patent Act*. [14]

8. ***Viagra – Striking of Requested Relief in Provincial Court following Patent Invalidity***

Viagra was a motion to strike elements of a claim made by Apotex. [15] Apotex commenced a proceeding against Pfizer in the Ontario Superior Court seeking damages for being kept off the market by virtue of Pfizer's '446 Patent covering Viagra®. Briefly, Apotex had been unsuccessful in an application under the *PM(NOC) Regulations*, but then succeeded in having

the ‘446 Patent impeached in an action. Apotex thus had no recourse to section 8 of the *Regulations*, and went to the Ontario Courts to claim various relief.

Apotex’s claim is for relief on the basis of: a) section 8; b) unjust enrichment; c) section 7 of the *Trade-marks Act*; d) public and private nuisance; e) conspiracy; f) the principle in *Ashby v White*; and g) the English and Ontario *Statute of Monopolies*. Pfizer sought to strike all of the requested relief except for the *Statute of Monopolies* claim.

Pfizer only succeeded in striking the claims under section 8 of the *Regulations* and *Ashby v White*. As an overarching theme, Pfizer argued that the *PM(NOC) Regulations* constitute a “complete code” that barred other common law relief. Lederman J. rejected the notion that this conclusively disposed of matters and allowed the issues to proceed to trial.

This is one of several damages cases brought by Apotex in the Ontario Courts. While there have been numerous decisions on pleadings motions in these cases (such as this motion to strike), the cases will begin to go to trial in 2017 or 2018. Whether Apotex and other generics can expand the scope of damages that they are entitled to through recourse to the Provincial Courts is something to monitor.

Patent Agent Privilege Comes Into Force

As of June 24, 2016, certain communications between patent agents and their clients will enjoy the same protection of privilege as traditional solicitor-client communications. Pursuant to amendments to the Canadian *Patent Act*, communications made with the expectation of confidentiality and for the purpose of seeking or giving advice between a patent agent and his/her client are protected from forced disclosure within or outside a legal proceeding. Such privilege, which belongs to the client, may only be waived, impliedly or expressly, by the client.

Previously under Canadian law, privilege did not extend to non-lawyer agents for the simple reason that they are not members of the legal profession. This lack of privilege applied not only to communications of domestic agents, but also foreign agents where the agent’s communications were relevant to a legal proceeding in Canada and notwithstanding that privilege applied to the communications in the foreign agent’s jurisdiction. Under the new law, not only will Canadian agent-client communications be protected, but also the communications of foreign agents will be protected where privilege applies to the communications in the foreign agent’s jurisdiction.

A key requirement for privilege to apply is that the patent agent-client communication must have been made for “the purpose of seeking or giving advice with respect to any matter relating to the protection of an invention”. This requirement has yet to be interpreted by the Courts, so there is some uncertainty as to its scope. On one hand, communications related to activities such as the drafting of a patent application, or the preparation of responses to office actions, very likely fall within the scope of the new privilege. On the other hand, situations that stray closer to contentious matters may be less clear.

The new agent privilege provisions apply retroactively to communications made before June 24, 2016, provided that the communications have remained confidential through to June 24, 2016. If the communications are sought in connection with any litigation, the new provisions will only apply to actions or proceedings commenced on or following June 24, 2016.

Patent Act Changes on the Horizon as a Result of CETA

On October 31, 2016, the Canadian Parliament introduced draft legislation that would significantly change the way pharmaceutical patent disputes are litigated, and that would provide a framework for patent term extensions in certain situations for pharmaceutical patents. The draft legislation, which may receive final approval in 2017, is further to the *Comprehensive Economic and Trade Agreement* between Canada and the European Union ("CETA").

In particular:

i. Change in how pharmaceutical patent disputes are litigated: presently, innovators who are unsuccessful in enforcing their patent rights pursuant to the procedures of the *PM(NOC) Regulations* do not have any right of appeal, whereas unsuccessful generics do have a right of appeal. The draft legislation resulting from CETA contemplates replacement of the summary-type procedures of the *PM(NOC) Regulations* with full patent infringement actions that would involve full trials with live witnesses, final judgments on infringement and validity, and two-way rights of appeal. Specific details regarding the new procedures have yet to be disclosed; and

ii. Patent term extensions in certain situations for pharmaceutical patents: presently, regulatory-related delays suffered by an innovator seeking regulatory approval for a patented pharmaceutical product cannot be compensated for by way of any patent term extension. The draft legislation resulting from CETA contemplates providing patent term extension in certain situations by providing for the grant of a "certificate of supplementary protection". The maximum patent term extension pursuant to a certificate is two years. Only one certificate is available for a "medicinal ingredient" or combination of ingredients, and protection against accused infringers during the term of the certificate is limited to preventing making, using or selling of such ingredient(s).

Final Competition Bureau IPEGs Published

As a result of consultations conducted by the Canadian Competition Bureau (the "Bureau"), the Bureau published in 2016 a final version of its Intellectual Property Enforcement Guidelines ("IPEGs"). The IPEGs address how the Bureau may approach, among other things, the conduct of patent assertion entities (PAEs), conduct concerning standard essential patents (SEPs), patent settlements, and product switching.

a. ***Patent assertion entities***

The Bureau's focus *vis-à-vis* PAEs will be on whether demand letters alleging infringement "included representations that were false or misleading in a material respect", including the "general impression created by the notice, as well as its literal meaning". For example, if a demand letter states that others have already paid the PAE licensing fees, and that the PAE would sue the accused infringer if the demanded licensing fee was not paid immediately, but one or both of these claims were found to not be true (e.g., no prior fees have been paid, or the PAE has no intention of commencing suit), then the Bureau would be concerned that the letter contains false or misleading representations. The representations would be "material" if they "would affect the likelihood of the recipients taking some significant action in response to the claims, up to and including acceding to the demand". A wide range of remedies is available in the event of a breach, including monetary penalties in less serious cases and criminal sanctions in more serious cases.

In relation to the assignment of patent rights from a practicing entity to a PAE for enforcement

purposes (e.g., privateering), the Bureau does not consider such activity to be anti-competitive.

b. ***Standard essential patents***

The final IPEGs address the following issues vis-à-vis standard essential patents:

i. Price fixing: provided there is no price fixing among IP owners or product makers, exercise of buyer power among potential licensees, foreclosure of innovative technologies, or restriction of access to a standard, competition issues appear unlikely to arise;
ii. Patent ambush: failure by a party to disclose patents relevant to a standard and then later assertion by the party of those patents may be found to be anti-competitive unless a "legitimate business justification" exists for the failure to disclose the patents during the standard setting process;
iii. Reneging on a licensing commitment: reneging on a licensing commitment agreed to during a standard-setting process may be found to be an abuse of dominant position unless a "legitimate business justification" exists, such as a "credible efficiency or pro-competitive rationale for the conduct … which relates to and counterbalances the anti-competitive effects and/or subjective intent of the acts"; and
iv. Seeking of injunctions: patent holders that seek injunctions after committing to license their patents on fair, reasonable and non-discriminatory ("FRAND") terms may also be found to be an abuse of dominant position, though an injunction may be appropriate "when a prospective licensee constructively refuses to negotiate" (e.g., insisting on non-FRAND terms) or "when a prospective licensee has no ability to pay damages" (e.g., licensee is in bankruptcy).

c. ***Patent litigation settlements***

Generally, settlement agreements that involve a generic launching before or upon patent expiry will not be seen as anti-competitive, though the Bureau may review the agreement if it includes a provision whereby a payment is made by the innovator to the generic. For there to be consequences in such a situation, the Bureau would need to establish that the agreement in question has had, is having or is likely to have the effect of substantially preventing or lessening competition. For example, if the payment was significantly large enough to have affected the generic's entry into the market (taking into account market value of goods, litigation costs and the innovator's section 8 damages exposure), and there were no countervailing or counterbalancing factors (e.g., notwithstanding the lessening of competition, did product selection, output or quality improve? Were there any pro-competitive rationales for the conduct?), then remedies such as prohibition orders or monetary penalties may be sought.

Criminal investigations are unlikely, unless the exclusion of the generic applies post-patent expiry, unrelated products are involved in the agreement, the parties recognize the patent rights are not enforceable (due to, e.g., invalidity or non-infringement), or the agreement is a sham.

d. ***Product switching***

Soft product switches, i.e., where an innovator's first product's patent protection is about to expire and the innovator stops promoting the first product in favour of promoting a second product that has several more years of patent protection, likely do not raise any competition law issues.

Such soft product switches are in contrast to hard product switches where the first product is completely removed from the market by the innovator and healthcare professionals have no choice but to use the second product.

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1. Discussed here: https://gowlingwlg.com/en/canada/insights-resources/supreme-court-of-canada-to-consider-law-of-utility-in-esomeprazole-appeal
2. The parties' factums and the archived webcast of the hearing can be found on the SCC website (case number 36654). Factums can be found here: http://www.scc-csc.ca/case-dossier/info/af-ma-eng.aspx?cas=36654
3. [1993] 2 F.C. 425
4. *Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, 2016 FCA 215
5. *Housen v. Nikolaisen*, 2002 SCC 33
6. *Pfizer v Teva*, 2016 FCA 161, discussed here: https://gowlingwlg.com/en/canada/insights-resources/federal-court-of-appeal-affirms-application-of-principles-of-causation-burden-of-proof-and-laws-of-evidence-to-section-8-proceedings
7. 2016 FCA 119, discussed here: https://gowlingwlg.com/en/canada/insights-resources/eli-lilly's-cialis®-patent-withstands-double-patenting-and-utility-challenges-on-appeal
8. 2016 FCA 267
9. *Teva v Novartis*¸2016 FCA 230
10. *Mylan v Pfizer*, 2014 FCA 250
11. Discussed here: https://gowlingwlg.com/en/canada/insights-resources/federal-court-affirms-principle-of-claim-differentiation-in-evaluating-utility
12. *Teva v Pfizer*, 2016 FCA 248, discussed here: https://gowlingwlg.com/en/canada/insights-resources/federal-court-of-appeal-grants-minister-of-health-the-right-to-be-wrong
13. 2016 FC 1013, discussed here: https://gowlingwlg.com/en/canada/insights-resources/patent-survives-anticipation-attack-based-on-use-in-phase-iii-clinical-trial
14. *Bayer v Apotex*, 2016 FC 1192, discussed here: https://gowlingwlg.com/en/canada/insights-resources/challenge-to-patentee's-right-to-elect-between-damages-and-accounting-of-profits-rejected
15. *Apotex v Pfizer Ireland Pharmaceuticals*, 2016 ONSC 4966, discussed here: https://gowlingwlg.com/en/global/insights-resources/portions-of-apotex's-requested-relief-for-being-kept-off-the-viagra®-market-struck?lang=en-CA
