Big Changes in Canadian Patent Law

Compliance and Ethics

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Recently, through a combination of common law, legislative, and regulatory changes, Canadian patent law has undergone a number of fundamental shifts that are important patent owners in Canada. This article will highlight some of these changes and try to explain some of the context surrounding them, as well as the potential implications. However, at the time of writing, most of the changes were too recent (or not in force yet) to have had any judicial interpretation.

Promise Doctrine invalidated by the Supreme Court of Canada

For a number of years, Canada's utility requirement has been out of step with the rest of the world. The courts had adopted what became known as the "Promise Doctrine" to assess whether a patent had utility. The courts would first determine what they considered to be the promise of the patent, and then assess whether that promise had been demonstrated or soundly predicted as of the filing date of the patent. This led to much uncertainty, as it was not known what promise a patentee would be held to until the court issued its decision. Furthermore, if a patentee was relying on sound prediction of utility, the courts had held that an increased disclosure was required on the factual basis of the sound line of reasoning — from that factual basis to the prediction of utility.

However, in a recent unanimous decision, the Supreme Court of Canada (SCC) held that the so-called Promise Doctrine is not the correct approach for Canadian courts to use when assessing utility of a patent. The SCC then set out a new test to be used:

1. Courts must identify the subject-matter of the invention as claimed in the patent.
2. Courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e., an actual result)?

The SCC confirmed that a scintilla of utility will do, and that a single use related to the nature of the subject-matter of the patent is sufficient. Furthermore, this utility must be established by either demonstration or sound prediction as of the filing date. The SCC held that the application of the utility requirement in s. 2 is to be interpreted in line with its purpose — to prevent the patenting of fanciful, speculative, or inoperable inventions. Furthermore, a patentee is not required to disclose the utility of the invention in order to fulfill the requirements of s. 2.

The SCC held that the utility requirement in s. 2 of the Patent Act is a necessary pre-condition to patentability. However, the question was: Useful for what? The federal courts had answered this question with the Promise Doctrine. However, the SCC held that this doctrine was excessively onerous in two ways: (1) it determined the standard of utility by reference to the promises expressed in the patent; and (2) if there were multiple expressed promises, it required that all be fulfilled for a patent to be valid.

The SCC held that requiring all promises to be met is unfair. A single use makes the subject-matter of an invention useful. The Promise Doctrine risks an otherwise useful invention being deprived of patent protection because not every promised use was sufficiently demonstrated or soundly predicted by the filing date. The SCC held that such a result is punitive and has no basis in the Patent Act. In addition, the SCC held this requirement to be antagonistic to the bargain theory wherein patentees are asked to give fulsome disclosure in exchange for the limited patent monopoly.

The SCC held that the Promise Doctrine conflated the utility requirement of s. 2 with s. 27(3) of the Patent Act. Section 27(3) is the requirement to disclose the invention's operation or use, which is independent of s. 2. In considering the allegation that the Promise Doctrine prevents a patentee from overpromising, the SCC held that numerous other sections of the Patent Act address this mischief. In

particular, if the disclosure is not correct and full, or states an unsubstantiated use or operation of the invention, it may be found not to fulfill the requirements of s. 27(3); or if the overpromising in the specification amounts to an omission or addition that is willfully made for the purpose of misleading, it may result in the patent being void pursuant to s. 53.

While this new test appears to be more in line with international utility standards, it remains to be seen how this decision will be used to challenge the validity of patents and how it will be implemented by the courts. It appears that patent challengers will try to import the Promise Doctrine into insufficiency allegations made pursuant to s. 27(3). However, this new line of attack will have to be reconciled with the SCC's clear statements that the Promise Doctrine is antagonistic to the bargain theory of patents; that "the Promise Doctrine in its operation is inconsistent with the purpose of s. 27(3);" and that "it is not good law."

CETA: New linkage procedure

In October 2016, Canada signed the Comprehensive Economic and Trade Agreement (CETA) with Europe. The CETA provided two key benefits to innovative pharmaceutical companies in Canada: a right of appeal in Canadian linkage proceedings and a limited patent term restoration to make up for delays in receiving approval from Health Canada to sell the drug in Canada.

In Canada, generic drug approval is linked to preliminary clearance of certain patent rights.

However, when negotiating this treaty, the Canadian government also made a side deal with the Canadian Generic Pharmaceutical Association (CGPA) to revamp the Patented Medicines (Notice of Compliance) Regulations (the NOC Regulations) and end the practice of dual litigation. A draft of the revisions to the NOC Regulations has been pre-published in the *Canada Gazette*, with a 15-day comment period.

These draft revisions set out a new procedure under which Canadian linkage proceedings will be conducted. Instead of being an application to determine whether the generic company's allegations of invalidity and/ or non-infringement are justified, the court will now make an in rem determination of patent infringement and validity.

Numerous procedural changes are listed in the draft revisions. However, of critical importance is a provision that provides that if a company sends a notice of allegation (NOA) and the patentee does not start a proceeding in response, it will be precluded from doing so at a later time unless it can show that it had no reasonable basis upon which to bring the proceeding at the time of the NOA.

Furthermore, there are immediate disclosure requirements upon starting a proceeding. If requested, the patentee must produce laboratory notebooks, research reports, or other documents relevant to determining whether a particular property, advantage, or use asserted by the second person to be part of the invention was established as of the filing date of the application. The language in this provision appears to be based on the Promise Doctrine, which, as discussed above, is no longer good law in Canada. Thus, it may be subject to revision or interpretation by the courts.

There appear to be a number of gaps in the draft regulations. In particular, if a patent is invalidated, it is removed from the patent register. If the patentee is successful on appeal, the patent will be returned to the patent register. However, it appears that any company that files a submission that compares to the original innovator during the interim will not have to address the patent. There appears to be no mechanism in the regulations to force the generic company to pay for costs thrown

away if the generic company withdraws its NOA.

It is also not possible to add other patents to these proceedings. Thus, if an innovator has unlistable patents that are infringed, they are forced to start a second proceeding. In addition, damages claimed by the second person pursuant to section eight could potentially be greatly expanded. The federal courts were able to preview the draft revisions, and assured IP counsel at a town hall meeting that they will be doing their best to conduct proceedings pursuant to them within the 24-month stay period. However, actions are more taxing to case manage than applications, and take more hearing time, thus growing pains are likely to be expected. The Federal government has not added any further judges or prothonotaries to the court.

CETA: Patent term restoration

A draft of the Certificate of Supplementary Protection Regulations (CSP Regulations) has also been pre-published in the *Canada Gazette*. These regulations fill in certain blanks in the Patent Act amendments provided by bill C-30 which, as part of its amendments to the Canadian Patent Act, provides the skeleton of Canada's new, sui generis, patent term restoration, in the form of a Certificate of Supplementary Protection (CSP).

During the CSP's term, "the same rights, privileges, and liberties that are granted by the patent" are granted to the certificate's holder and their legal representatives with respect to the making, constructing, using, and selling of any drug that contains the medicinal ingredients set out in the certificate. In order to be eligible for a CSP, the patent must contain a claim to the medicinal ingredient or combination, a process to make that medicinal ingredient or combination, or the use of the medicinal ingredient or combination.

On payment of a prescribed fee, a patentee may apply to the Canadian Minister of Health for supplementary protection if all of a number of specific conditions are met, including that the patent must be in force, the authorization for sale is the first for the medicinal ingredient or combination, and no other CSP has been issued for the medicinal ingredient or combination. The CSP Regulations set out a number of conditions limiting what could be considered a variation of a medicinal ingredient, and thus ineligible for a CSP. These variations are particularly restrictive, and may result in only limited eligibility.

In addition, in order to be eligible for a CSP, the application for marketing approval in Canada must have been filed within a year of the filing of the first marketing approval in Europe, the United States, Australia, Switzerland, or Japan.

Furthermore, there will be no retroactive availability of a CSP. A person will only be able to apply for a CSP for a drug that is approved after the bill is proclaimed into force. This is expected to be around September 21, 2017. It will also not be an infringement to make, construct, use, or sell the medicinal ingredient or combination for the purposes of export.

The CSP's term will be calculated by "subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the authorization for sale set out in the certificate is issued" — to a maximum of two years.

This is the first time Canada has had such a mechanism available to innovators. It will be interesting to see how the details are enforced, and whether they will actually give effect to the CETA.

PMPRB Changes

The Patented Medicines Prices Review Board (PMPRB) is currently undergoing a significant consultation. It's in the early stages, however all signs point to major changes that will affect companies that sell patented medicines in Canada.

In addition, pursuant to bill C-30, the Patent Act will soon contain a definition of the word "medicine," and this definition will include a definition of the word "drug." Drug will mean a substance or mixture manufactured, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state or its symptoms; or restoring, correcting, or modifying organic functions, in human beings or in animals. This definition is similar to the PMPRB's current policy. However, it should help limit any attempt by the PMPRB to expand its jurisdiction.

Conclusions

These changes to Canadian patent law are likely going to result in a paradigm shift in patent litigation in Canada in the years to come, in particular for pharmaceutical and biotechnology companies. A great deal of new law needs to be interpreted and applied by the courts in order to see the full effect of these changes (and this paper only covers the highlights; a number of additional changes are forthcoming in the next few months). Furthermore, more changes could be coming due to the upcoming talks on renegotiating the North American Free Trade Agreement (NAFTA). Intellectual property issues were a large component of the original negotiations NAFTA, and could indeed appear as a priority again.

Further Reading

AstraZeneca Canada Inc. v. Apotex Inc., 2017 SCC 36.

October 17, 2003 letter from E. Fast, Minister of International Trade to J. Keon, President, CGPA.

Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017, C. Gaz. 2017.I.3336.

Certificate of Supplementary Protection Regulations, C. Gaz. 2017.I.3302.

Bill C-30, *An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its member states and to provide for certain other measures*, 1d Sess., 42nd Parl., 2017 (assented to 16 May, 2017).

Bill C-30, *supra*, s. 46(2) and s. 59 (what will be s. 79(1) and 104 of the Patent Act).

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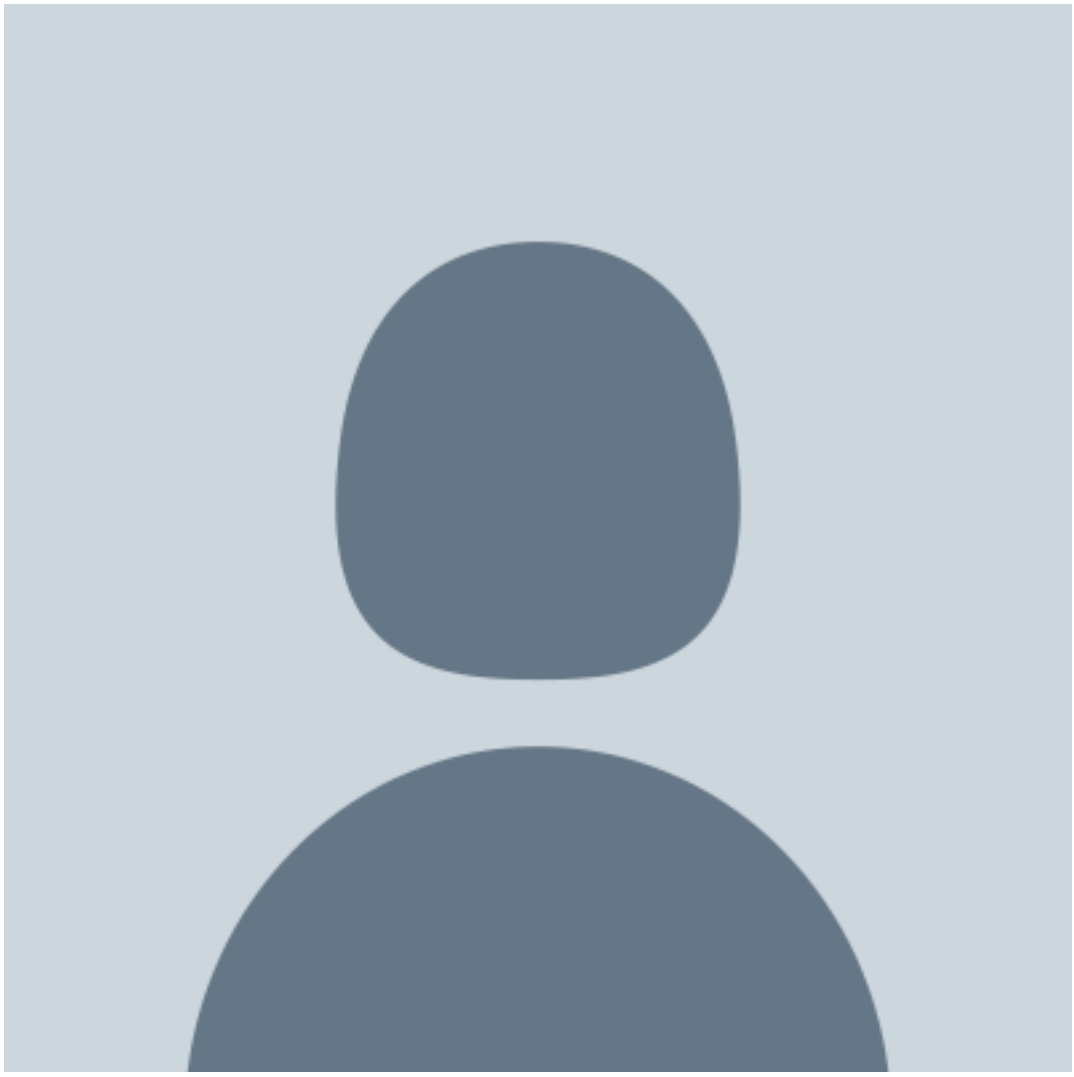

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