
Noel Courage

Canadian drug patent enforcement

Noel Courage, Bereskin & Parr, describes the recent changes in Canada including eliminating the promise doctrine, extending drug patent terms, and improving drug patent enforcement.

Canadian patents have recently received a boost from the federal government and courts. Our top court recently removed the promise doctrine from patent utility law as a basis to challenge patents. New laws are going to beef up linkage regulations and create patent term extensions for drugs. Patent and design registrations are also being streamlined.

Promise doctrine eliminated as a ground of patent invalidity

The "promise doctrine" in the Canadian patent law of utility received a lot of press in the pharma industry. As the doctrine caught hold the past decade or so, Canadian utility became out of line with the law in the US and UK, where the utility standard is easily met. Under the promise doctrine, if any promises of utility in the patent specification were not met, then potentially the *entire* patent could be held invalid. This was an alarming proposition considering that brand name drug companies often make bold predictions that compounds will have a wide range of utilities to treat multiple diseases. Promise doctrine was primarily an issue in pharma patent cases, but Canadian utility had been used as a successful basis to invalidate claims in a mechanical patent case involving helicopter landing gear. There was no up-side for patent owners in the proliferation of the promise doctrine, and many were vexed by having to defend against promise doctrine. Eli Lilly went so far as to launch a failed North American Free Trade Agreement ("**NAFTA**") complaint against the Canadian government over Canadian utility after patents for the drugs atomoxetine and olanzapine were invalidated. A recent survey sponsored by the brand name pharma association in Canada, for what it's worth, alleged that the weakening patent environment in Canada was hitting Canadian R&D spending in the pocketbook.

Generic drug companies began to try to elevate every statement of advantage in a patent to a promise. Brand name companies downplayed their apparent promises. The case law on promise doctrine became conflicted, so Canadian patent attorneys scratched their heads as to the applicability and scope of the doctrine. Promise doctrine became a standard ground of attack for generic drug companies challenging patents. They won some cases and lost others, so it was certainly not open season on pharma patents in Canada. Examples of cases where brand-name drug company patents were found valid in spite of generic challenges based on promise doctrine include cases for clopidogrel sulfate[1] (the blockbuster drug Plavix) and celcoxib[2] (the blockbuster drug Celebrex). However, the uncertainty around promise doctrine needed to be resolved.

The promise doctrine ended up on the table at the Supreme Court of Canada[3], and the judgment was released in July 2017. There were two alleged promises made in the patent. One of the main issues was whether both promises had to be fully met in order for the patent to be valid. Note that the first promise, shown below, is about a chemical reaction (inhibiting proton/acid in the stomach), which is easy to demonstrate though a lab benchtop experiment. The second promise is more complex and harder to prove, that the drug works more effectively for a wider range of persons.

The Court identified the promises as follows:

> [9] … two promises of utility in the '653 patent: (1) use as a proton pump inhibitor; and (2) improved pharmacokinetic and metabolic properties which would give an improved therapeutic profile such as a lower degree of interindividual variation. In other words, the drug would (1) reduce the amount of acid in the stomach; and (2) work more effectively for a wider range of persons, having less variation in patient response.

The Supreme Court decided that it was enough for the patent to disclose something useful – all promises did not have to be kept. The patent was valid and enforceable. Once the first promise was met, the court did not have to look at second promise. This *directly overturned* the lower court which had decided that *all* promises must be

[1] *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186.
[2] *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250.
[3] *AstraZeneca Canada Inc. v. Apotex Inc.*, 2015 FCA 158.

Résumé

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met, and the second promise was not met in the patent, so it was invalid.

The Supreme Court called the promise doctrine "unsound", so it is now effectively dead. The bar for utility set by the Court is now that, "The invention must be capable of an actual relevant use and not be devoid of utility." A mere scintilla of utility will suffice.

This case provided clarity by snuffing out the promise doctrine and bringing Canada back more towards the lower standard in US and UK utility law. We have a lot more certainty now that technical legal attacks on the utility of a patent generally cannot invalidate the patent. This is a sensible result, since, in the real world, the patent covers a drug that is clearly very useful and valuable, or else a generic company would not be trying to copy it.

Drug linkage regulations being strengthened

The patent environment for innovative drug companies in Canada has the benefit of linkage regulations. These rules link generic drug regulatory approval to the *precondition* of first clearing certain brand name drug patent issues. The US has linkage regulations (Orange Book, ANDA proceedings etc), but the EU does not have such regulations. One can easily judge the importance of these linkage regulations to Canadian brand named pharma merely by how they have made the generic industry association apoplectic for over two decades. The newly-released revised draft linkage regulations are going to make them into an "action", determinative of patent infringement and validity issues, similar to the US ANDA Proceedings (currently, the Canadian linkage regulations are an "application", an affidavit-based process, that considers infringement and validity issues, but is *not* determinative)[4].

The revised system will have the benefit for both brand name and generic companies of reducing the multiplicity of litigation under the current system. Linkage proceedings will no longer be *followed by* patent infringement or impeachment actions, since they will now *incorporate* the actions. Early and active case management will be necessary to resolve these cases within the required 24 months.

Patent term extension

The Canadian government also just introduced draft regulations to implement up to two years of patent term extension[5]. This will be made available by way of a Supplementary Protection Certificate ("**SPC**"), *only* in the event that there is regulatory delay by Health Canada in review of a drug submission. The proposed Canadian SPC system is generally based on the European SPC system. It provides the same practical effect as a patent term extension, but the additional patent protection is effected by the SPC. The SPC is limited to the particular medicine that is an approved drug. For example, if the patent covers non-commercialized drugs, the non-commercialized drugs will not be protected further. The patent will have to pertain to a medicinal ingredient, or a combination, that was authorized after a cut-off date to be set by government. Drugs approved for sale in Canada prior to this cut-off date will not be eligible to apply for an SPC (i.e. currently-approved drugs will *not* be grandfathered into the SPC system). This improved patent protection term reinforces that it's still a good environment in Canada to do research and development and file patent applications.

Other changes in patent and design law

There are draft Patent Rules[6] and Design Rules[7] coming into force in the near future, which will bring the *Patent Law Treaty* and the *Hague Agreement* (industrial designs) into effect. The *Patent Law Treaty* amendments will streamline and harmonize certain Canadian filing formalities. The new rules will also have significant effects, such as on abandonment/reinstatement rights and introducing restoration of priority. The one-year grace period for late national phase entry as-of-right will continue to exist (ie. Up to 42 months from priority date), but will be significantly curtailed, requiring that the 30 month deadline was missed unintentionally. There will be three years to request examination (down from five months) and 4 months to respond to Office Actions (down from six months).

The Hague Agreement is an international industrial design filing system already implemented in the US and many other major countries. It allows filing of a single design application as a basis to protect design rights internationally. A major change coming to the Canadian design law is that the term will change from 10 years from issuance to 15 years from the application filing date. Novelty requirements are also being changed.

Overall, the net effect of the amendments is positive. The changes streamline many aspects of Canadian patenting, and certain types of patent and design rights are strengthened. This allows faster and more cost-effective IP registrations.

[4] Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017. Canada Gazette. Vol. 151, No. 28. July 15, 2017. http://www.canadagazette.gc.ca/rp-pr/p1/2017/2017-07-15/html/reg18-eng.php

[5] Certificate of Supplementary Protection Regulations. Canada Gazette. Vol. 151, No. 28 — July 15, 2017. http://www.canadagazette.gc.ca/rp-pr/p1/2017/2017-07-15/html/reg16-eng.php

[6] Proposed Patent Rules draft. http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04281.html

[7] Proposed Industrial Design Regulations draft. https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04255.html