Protecting Life Science Innovations in Canada – A Year in Review

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In this article, we highlight some recent Canadian developments from last year that have particular relevance for the life sciences industry.

Legislation and Treaties

Canada has committed to a number of significant legislative changes expected to come into effect in the next few years.

Trade Treaties

The past year in Canadian life sciences has seen a lot of treaty talk. Not much action has happened yet. We are still waiting for word on if and how the newly-elected federal government will implement the *Canada-Europe Free Trade Agreement*. The agreement was originally reached in 2013 by a prior federal government.

In 2015, the prior federal government agreed to the *Trans-Pacific Partnership*, and the newly-elected federal government said that it intends to follow through with implementation of this treaty.

The potential for up to two years of Canadian patent term extension is the main issue that is of interest for life sciences patent owners in these two treaties. The treaties may also cause amendments to Canada's linkage regulations (generally similar to US ANDA litigation) in order to prevent a multiplicity of proceedings and to give brand name companies appeal rights comparable to those of generics.

Patent, Design, Trademark and Plant Breeders' Rights Amendments (IP Treaties)

The plant breeders' rights (PBR) amendments came into effect in 2015, bringing many changes as Canada harmonizes its PBR system with the 1991 UPOV Treaty. For example, the term of rights was extended from 18 years to 25 years for trees and vines, with a 20 year term for all other varieties. There is a new one year grace period to file after sales in Canada, getting rid of the absolute novelty requirement (there has always been, and remains, a longer grace period for sales outside Canada).

We are still waiting for the Canadian Intellectual Property Office (CIPO) to implement significant amendments for patents, designs and trademarks that were passed in 2014. Consultations are expected to begin late 2016. The expected dates for implementation have been pushed back to 2017-18. The patent and design amendments are not specific to life science patents. The amendments implement the *Patent Law Treaty* and the design *Hague Treaty* that will respectively impact all patents and designs. The trademark amendments will have significant impact for life science trademarks owners by implementing the *Madrid Protocol*, among other

changes. Among the many changes, use will no longer be required for registration, so companies will have to file quickly to get ahead of competitors and trademark squatters.

Prior Art Issues

Obvious to Try Test

A common issue that patentees address in respect of a life sciences invention is whether the invention was "obvious to try". The Federal Court of Appeal in *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC*, 2015 FC 178; 2015 FCA 286 confirmed the Supreme Court of Canada's test from *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61, that it must be "more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough". This overturned a trial Court decision that would have made it easier to challenge patents by setting the test at, "whether the skilled person had good reason to pursue predictable solutions or solutions that provide a 'fair expectation of success.'" Maintaining the "self-evident' test is significant in life sciences where slight changes or improvements can result in significant unexpected advances.

Amount of Support and Disclosure Required in Patent Application

Utility Disclosure Requirement

Also relevant to life sciences is the requirement for explicit disclosure of utility in a patent. This requirement stems from the Supreme Court of Canada's 2002 decision relating to AZT in *Apotex v. Wellcome Foundation Ltd*. 2002 SCC 77, which set out the requirements for a *sound prediction* of utility of a patent (as opposed to *demonstrated* utility via experiments etc.). Since then, there have been numerous decisions that question what is meant by proper disclosure for utility and when such disclosure is required. In *Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc*., 2015 FC 1156, the Court confirmed that for a new composition, there is no requirement to specifically disclose the utility in the application. A specific utility must, however, be disclosed in patents claiming a new use of a known compound.

Sufficiency of Disclosure Requirement

Canadian courts have also been grappling with the analysis of what is required for an application to sufficiently disclose the invention under Subsection 27(3) of the Canadian *Patent Act*. In this regard, *Gilead*, discussed above, stated that a disclosure is sufficient where common general knowledge and routine experimentation can make the invention work. However, in *Gilead*, even though there was evidence of a wealth of literature being available to the skilled person, the Court held that routine trial and error experimentation can become undue experimentation where there is an excess of choice. The Court ultimately found that the disclosure was not sufficient for that reason. Accordingly, caution should still be taken so that there is enough information in the patent specification such that the skilled person would not be left with an "excess of choice", particularly for important steps in the synthesis of new chemical compounds or other compositions of matter.

Subject Matter

Methods of Medical Treatment

The Federal Court provided some clarity in relation to patents directed to drug dosage claims in the late 2014 decision in *AbbVie Biotechnology Ltd. v. Canada (Attorney General)* 2014 FC 1251, confirming that certain claims to specific dosages or dosing schedules are patentable. This improved the landscape for dosage claims, and CIPO issued a revised practice notice taking the case into account (*Revised Examination Practice Respecting Medical Uses – PN 2015-01*) as well as associated examples. The new guidelines focus the analysis on whether the invention is directed at what to use for treatment, which is patentable, versus how to use for treatment, which may be unpatentable if it interferes with or requires professional skill of a physician. These new guidelines and

examples provide more certainty in the prosecution of medical use inventions and should help expedite patent prosecution in this area.

Diagnostics - New Canadian Patent Office Guidance

Examination of certain life sciences diagnostic inventions were on hold as Examiners awaited further guidance. There was no Canadian court decision on diagnostic subject matter eligibility, but a business method subject matter decision influenced subject matter analysis by CIPO in other fields, such as diagnostics. A new practice notice was finally released, called *Examination Practice Respecting Medical Diagnostic Methods – PN 2015-02*. Examination is now ongoing for such inventions, and CIPO is parsing diagnostics claims more carefully on subject matter eligibility. We are working on strategies to address these guidelines and continue to protect diagnostic inventions. It remains to be seen how these new guidelines will affect life sciences patent applications in Canada.

We will continue to monitor the changes on the horizon in relation to the treaties and case law specific to life sciences. We will provide updates on the progress of life science inventions through the Canadian Patent Office in light of the new patent office guidelines. Stay tuned for 2016…

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