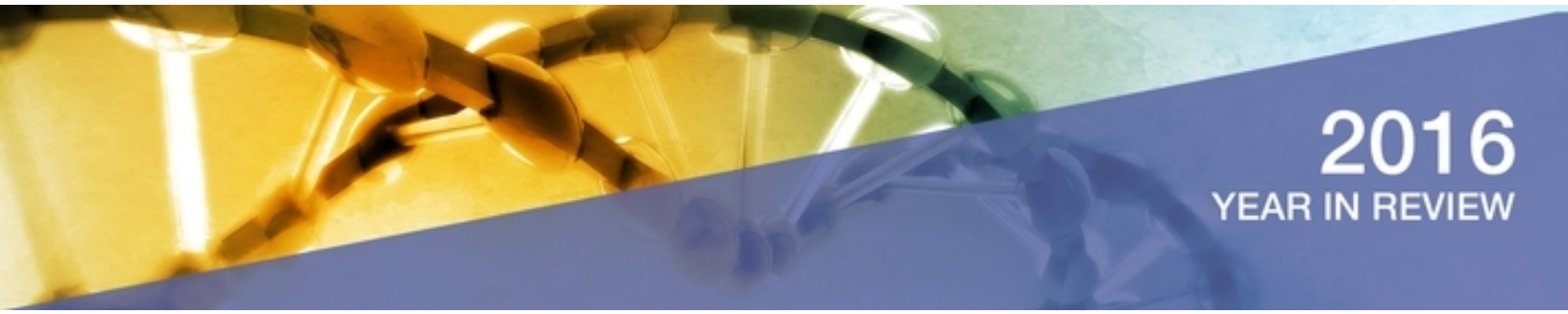

Life Sciences - 2016 Year in Review

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This article summarizes Canadian developments in the past year relating to the protection of Life Science innovations.

CETA signed - Patent term extensions and changes to the NOC Regulations on their way

In October 2016, following several years of negotiation, Canada and Europe signed off on the Comprehensive Economic and Trade Agreement ("CETA"). An implementation Bill (Bill C-30) was introduced into Canadian Parliament on October 31, 2016. It will go through readings in the House of Parliament before it is passed as a law and comes into force.

While CETA is a wide-ranging agreement, the most significant effects of Bill C-30 on the Life Sciences industry will likely be the introduction of patent term extensions for drug patents as well as changes to the *Patented Medicines (Notice of Compliance) Regulations* ("NOC Regulations").

In particular, the proposed Canadian Supplementary Protection Certificate (SPC) system will give a maximum of two years of additional patent rights for an approved drug and is based on the European SPC system. More details on the proposed Canadian system can be found here.

The current NOC Regulations set out summary proceedings by which a patent owner can apply to the Federal Court to keep a generic company's potentially infringing medicine off the market *before* the generic company receives Health Canada approval. As Noel Courage reported, Bill C-30 proposes providing the regulation-making authority with permission to replace the current summary NOC proceedings with full patent infringement and validity actions, thereby allowing final determinations on infringement and validity issues. Bill C-30 also proposes to provide brand-name companies with a right to appeal from unsuccessful applications under the NOC Regulations, something that they did not have if they list under the current Regulations. Details of the new regulations are not yet known.

US withdraws from the TPP

While the Trans-Pacific Partnership ("TPP") was signed on February 4, 2016, and corresponding changes to Canada's *Patent Act* with respect to patent term extensions and data protection provisions were expected, the United States withdrew from the agreement in January of this year. Without the US on board, the agreement as it stands cannot be ratified and it is unclear whether Canada will go ahead with implementing any of these changes.

Supreme Court and NAFTA to decide on the "promise" doctrine

Currently at issue before both the Supreme Court and NAFTA is the propriety of the so-called "promise of the patent" doctrine in Canada. Under this doctrine, if a patent sets out an explicit promise of utility, the patent will be void if it does not meet this promised utility. As a result, patents for drugs which clearly have significant utility and are commercially successful can be at risk of invalidation

when simple words or statements in the description are found by the court to amount to a promise of a particular utility. More details on the promise doctrine can be found here.

In *AstraZeneca Canada Inc v. Apotex Inc*, 2014 FC 638, the trial judge found that AstraZeneca's Nexium® patent (Canadian Patent No. 2,139,653), if valid, would have been infringed by Apotex's sale of its generic esomeprazole drug. The judge however found that a "promise" of an improved therapeutic profile was unmet as of the filing date, and as a result, the patent was invalid. The Federal Court of Appeal affirmed the decision in 2015 FCA 158. The Supreme Court heard the appeal in November 2016 and a decision is expected in the first half of 2017. It is hoped that the Supreme Court will provide some much needed clarity with respect to the standard for utility in Canada.

Also expected in 2017 is a decision in the arbitration between Eli Lilly and the Government of Canada pursuant to NAFTA Chapter 11. In May 2016, a hearing took place in which Eli Lilly argued that the invalidation of Eli Lilly's patents for Strattera® and Z *yprexa*® in 2011 and 2012, respectively, on the basis of the promise doctrine, violated Canada's treaty obligations.

Both decisions are highly anticipated and the results will be followed closely.

Test for double patenting clarified (somewhat)

The Canadian prohibition on double patenting continues to trip up many foreign (and domestic) applicants filing patent applications in Canada. In Canada, double patenting bars the issuance of a second patent where the claims are co-terminous with ("same invention" double patenting) or do not exhibit inventive ingenuity over ("obviousness-type" double patenting), the claims of a first patent. There are no terminal disclaimers in Canada, so double patenting objections must be resolved by claim amendments and/or arguments that the later claims are inventive over the earlier claims.

In *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc*, 2016 FCA 119, a case relating to tadalafil (Eli Lilly's Cialis®), the Court clarified the test for obviousness-type double patenting. In particular, the Court emphasized that in the obviousness analysis for double patenting, the claims of the first patent and the second patent are to be compared to determine whether the claims of the second patent are inventive over those of the first patent. Ordinary rules of claim construction apply in the comparison, such that if the claims are unambiguous, it is improper to refer to the specification to vary the scope of the claims.

The Court declined to definitively decide the relevant date of obviousness-type double patenting. Of three possible dates (priority date of the first patent, priority date of the second patent, and publication date of the second patent), the Court only held that the publication date of the second patent was not the correct date. In a later decision (*Apotex Inc v Eli Lilly Canada Inc*, 2016 FCA 267), the Federal Court of Appeal maintained that the relevant date for assessing obviousness-type double-patenting is an open question.

Treatment of antibody claims by the Patent Office modernized

The Commissioner of Patent's decision *RE Chugai Seiyaku and Kabushiki Kaisha* (CD 1398) established that patent applicants can now claim humanized antibodies in cases where the antigen has been well characterized, even in the absence of complementarity determining region ("CDR") sequences or evidence that the human antibodies had been made as of the filing date. More details can be found here. This was welcome news for innovators who have long felt that Examiners were failing to take technological advances into account when examining antibody claims.

Following this decision, the Canadian Patent Office released new guidelines for the examination of antibody claims in January of this year (Manual of Patent Office Practice; Section 17.07; Antibodies - January 2017). The Guidelines confirm that monoclonal antibody claims may be enabled without a working example and that a humanized or chimeric antibody may be correctly and fully described through reference to the fully characterized antigen to which the antibody specifically binds.

Diagnostic claims remain under high scrutiny

As we reported last year, a practice notice was released by the Canadian Patent Office mid-2015 relating to the examination of medical diagnostic method claims. Throughout 2016, Canadian examiners continued to follow this guidance and have been placing diagnostic claims under high scrutiny. Until we have direction from the Court on the legitimacy of the Patent Office's practices with respect to diagnostics, we are working on a case-by-case basis to develop strategies for protecting diagnostic inventions in Canada.

We will continue to monitor and report on developments as they happen with respect to the protection of Life Science innovations in Canada. We expect that there will be a lot to report in our 2017 Year in Review.