2018 Year in Review: Life Sciences

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2018 was another significant year for intellectual property in Canada with numerous court decisions and legislative changes. This article briefly summarizes some of the highlights in the life sciences realm, and provides outlooks on what is expected in 2019.

Utility and The Aftermath of *AstraZeneca*

Following the landmark decision in *AstraZeneca v Apotex,* 2017 SCC 36 ("*AstraZeneca*"), the lower courts have faithfully followed the Supreme Court decision in ending the often criticized Promise Doctrine, despite attempts by parties at disguising the Doctrine under other causes of action. Both the Federal Court and the Ontario Superior Court firmly stated in *Hospira Healthcare Corp v Kennedy Trust for Rheumatology Research*, 2018 FC 259 ("*Hospira*"), and *Apotex Inc v Abbott Laboratories Ltd*, 2018 ONSC 5199, that the Promise Doctrine allegations cannot be repackaged under the guise of insufficiency, overbreadth or misrepresentation. In *Hospira*, the Court noted that "it would be inconsistent to discard [the Promise] doctrine only to have it resurface under another principle without clear language to do so". A "scintilla" of utility as explained in *AstraZeneca* continues to be the Canadian standard. With such clear language, we are unlikely to see Promise Doctrine arguments play a significant role in future litigation.

CIPO Practice

Use claims can still be methods of medical treatment

Commissioner's Decision No. 1442, *Re Application No 2,416,408: Methods for therapy of neurodegenerative disease of the brain,*demonstrates a strict application of CIPO's 2015 practice notice on medical uses (PN 2015-01). The Commissioner refused application 2,416,408 on the basis of obviousness and being directed to a method of medical treatment. Interestingly, the claims rejected for encompassing a method of medical treatment were not method claims *per se*, but were written as use claims. Claim 12 reproduced below is a representative example:

> 12. Use of an adeno-associated virus (AAV) expression vector comprising a neurotrophin encoding transgene to ameliorate defective, diseased or damaged dopaminergic neurons in the brain of a mammal, wherein said AAV expression vector is for *in vivo* direct delivery into one or more delivery sites within a region of the brain containing targeted dopaminergic neurons, wherein each of said one or more delivery sites is within 500μm from a targeted neuron and no more than 10mm from another delivery site.

The Commissioner's decision noted that when determining whether a claim is directed to a medical use, the relevant inquiry is whether any one of the essential elements prevents, interferes with or requires the professional skill of a physician and not whether the claim is worded as a "use" claim. With this in mind, the Commissioner determined that the claims encompassed intracranially delivering the contemplated AAV expression, and that this entails a surgical step and the professional skills of a physician.

While it is common practice in Canada to circumvent the medical use prohibition using use claims, prudence must be taken to ensure the claims do not inadvertently encompass a medical method.

Late requests to amend priority date

Bayer Cropscience v Canada, 2018 FCA 77, involved a Canadian application that entered national phase from a PCT application on August 7, 2015. In its petition, Bayer requested a priority date of April 3, 2012 based on the date of the prior

US application. The US application was originally given a filing date of April 19, 2012, but this was later corrected.

Bayer's request was refused by the Canadian Patent Office, as the expiry of the 16-month period for requesting priority was August 19, 2013, and the request to the USPTO to amend the filing date of the priority document was not made until February 15, 2015. The Federal Court found that the Commissioner did not err in refusing to enter April 3, 2012 as the priority date, as the filing date of April 19, 2012 was constant throughout the 16-month period for both the corresponding US and PCT applications and correction was requested only after the expiry of the time period.

The Court held the Commissioner was under no duty to amend the priority date. Although there may have been a discrepancy between the factual filing date and the priority date, this inaccuracy was not the result of a mistake by the Commissioner. Accordingly, if a priority date of an earlier application needs to be corrected, an applicant should ensure the correction is made within the 16-month period following its priority date.

Validity

Anticipation and Obviousness

In *Teva Canada v Janssen,* 2018 FC 754, an action under section 8 of the *PM(NOC) Regulations*, Teva sought damages for losses suffered during the period Teva's generic drug bortezomib was kept off the market. Teva claimed that the patents at issue were invalid, while Janssen/Millennium defended and counter-claimed on the basis of infringement. The Federal Court found the claims in the patents were invalid and awarded Teva damages.

In his obviousness analysis, Justice Locke rejected arguments that the skilled person should be defined on a claim-by-claim basis if only a subset of the claims are asserted, and held that there cannot be different skilled persons for different claims.

With respect to the role of disclosure in claims construction, Justice Locke stated that even when claims are capable of only one interpretation, recourse to the disclosure is still necessary to confirm that interpretation. This is a departure from the Federal Court of Appeal's decision in *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119, in which the Court held recourse to the disclosure is unnecessary where the claims are plain and unambiguous. Justice Locke's approach is more in line with the Supreme Court's decision in *Whirlpool Corp. v Camco Inc.*, 2000 SCC 67, and resolves conflict created by the *Mylan* ruling.

In another decision involving obviousness, *Eli Lilly Canada v Apotex,* 2018 FC 736 ("*Lilly*"), Justice Manson confirmed that the test for obviousness set out by the Supreme Court of Canada in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 was not qualified by the 2017 Federal Court of Appeal decisions[1] *Ciba* and *Bristol-Myers Squibb,* where the FCA held that in some instances claims could be construed without deference to the "inventive concept".

In *Hospira*, the Court commented on both anticipation and obviousness-type double patenting. Regarding anticipation, the Court affirmed the principle that the disclosure requirement only requires that the public had the *opportunity* to access the information, not that the information was actually accessed. The Court also affirmed that anticipatory documents should be examined purposively as a skilled reader would read them.

Regarding obviousness-type double patenting, the Court differentiated it from a standard obviousness analysis. In particular, the Court explained that when considering double-patenting, only the earlier patent may be cited as rendering the patent at issue not patentably distinct. The only other prior art that may be considered is that which contributes to the common general knowledge of the skilled person. This decision is currently under appeal.

Infringement: Experimentation is not patent infringement

Apotex Inc v Shire, 2018 FC 637 ("*Apotex*"), another proceeding under the *PM(NOC) regulations,* involved Shire's ADHD drug Vyvanse® versus Apotex's generic lisdexamfetamine ("LDX"). The Court considered the scope of subsection 55.2(1) of the *Patent Act*, which states that it is not an infringement of a patent to make, construct, use or sell a patented invention for uses reasonably related to the development and submission of information required by law. Allegedly, Apotex had over 200 kilograms of LDX and had produced 3 million capsules. In absence of evidence to the contrary, Apotex successfully argued it had used and will be using the LDX product for experimental and regulatory purposes only and that "no use will result in a product that will be sold commercially." Thus, the Court held that Apotex's LDX materials were exempt from infringement.

Regulatory, Compliance and Legislative Changes

The Federal Court considers "Vanessa's Law"

As reported here, *Doshi v Canada AG*, 2018 FC 710 ("*Doshi*") was the first case calling upon a court to interpret and apply the *Protecting Canadians from Unsafe Drugs Act* (aka "Vanessa's Law"). Vanessa's Law added section 21.1(3) to *Food and Drugs Act* ("*FDA*"), which in essence allows the Minister of Health to disclose confidential business information about a therapeutic product in circumstances related to the protection or promotion of human health or public safety.

Dr. Peter Doshi filed requests under section 21.1(3) of the *FDA* for clinical trial data relating to various drugs including Gardasil®, Cervaris®, Tamiflu® and Relenza®, proposing to use the information for academic research. While Health Canada accepted Dr. Doshi was "a person who carries out functions relating to the protection or promotion of human health or the safety of the public", as stipulated under paragraph (c) of the section, it insisted he sign a confidentiality agreement. Dr. Doshi refused and sought judicial review.

Justice Grammond held that although Health Canada may impose a confidentiality agreement under section 21.1(3), in this instance it was unreasonable. Justice Grammond noted that one of the main purposes of Vanessa's Law is to improve clinical trial transparency, and held that Health Canada's adoption of a confidentiality policy contradicted the intentions of parliament. Justice Grammond also found that preventing Dr. Doshi from quoting from the clinical trial reports was a breach of his freedom of expression under section 2(b) of the *Canadian Charter of Rights and Freedoms*.

Doshi is the first case interpreting Vanessa's Law, and provides insight into the powers of Health Canada under the law. Brand owners and clinical trial sponsors must be aware that otherwise confidential information related to new drugs, medical devices, and clinical trial results may be publicly disclosed under Vanessa's Law. We expect future judicial review on Vanessa's Law and will continue to provide timely updates as they occur.

Health Canada Guidance Document on PM(NOC) Regulations

In May 2018, Health Canada released a guidance document focusing on the amendments to the *PM(NOC) Regulations* implemented in September 2017, which are summarized in our 2017 year in review. The guidance document provides clarity on many amendments, including directions on how to provide litigation information to Health Canada, and how to renounce the 24-month stay imposed on second persons when an infringement action under the *PM(NOC) Regulations* is brought.

Certificate of Supplementary Protection: Canada's Patent Term Adjustment for Drugs

A summary of eligibility and requirements for the Certificate of Supplementary Protection (CSP) for patent term restoration of pharmaceutical products, which came into force in Canada in September 2017, can be found here.

More than one year into the legislative change, the CSP program has certainly been well used. A total of 32 applications have been filed since implementation, with 31 of them being for human use and only one for veterinary. Eighteen CSPs have been issued, while five have been refused and the remainder still pending. Biologics are well represented on the Register of CSP populating 50% of the all applications, including the highly anticipated first-in-market CAR T therapy tisagenlecleucel (Kymriah®) from Novartis, and the high potential autoimmune disorder products brodalumab from Valeant (Siliq®) and guselkumab (Tremfya®) from Janssen.

Despite the more stringent timing requirement of a maximum 12-months between the issuance of Notice of Compliance and the filing of the CSP application after the transition period ended on September 21, 2018, eight new applications were filed between October and now. We are likely to see more use of the CSP program in 2019 and we except to get more clarity on what is required for CSP protection.

United States-Mexico-Canada Agreement (USMCA)

The new USMCA draft published in October 2018 brought some good news for patentees. A more comprehensive review can be found here. Also referred to as "NAFTA 2.0", the agreement is indicative that there will likely be a new patent term adjustment for future applications in Canada to compensate for Patent Office delays. Moreover, a longer period of ten years of data exclusivity for biologics is anticipated, bringing Canada more in line with the US practice where biologics enjoy a 12-year data exclusivity period.

Issues such as patentable subject matter, grace periods for prior disclosure, data protection for agricultural chemical products and non-biologic pharmaceutical products, and patent term adjustment for regulatory delays (i.e. CSP) will likely not change.

As it currently stands, the USMCA remains a draft agreement that each national government has to approve and eventually implement. The fate of these changes remain uncertain. We look forward to any developments in 2019.

PMPRB Proposed Amendments Still Under Consideration

In late 2017, amendments to the current Patented Medicine Prices Review Board (PMPRB) Regulations had been proposed. Several controversial proposed amendments include the PMPRB having access to confidential pricing agreements between pharmaceutical companies and provincial formularies, and the removal of the United States from the list of current comparator countries. The proposed amendments are still pending.

The Bereskin & Parr team will continue to bring you timely and comprehensive updates to new developments in the life sciences and patent space. 2019 is gearing up to be an exciting year as we await appeal results on several decisions rendered in 2018, and legislative updates on both the USMCA and the PMPRB regulations.

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[1] *Ciba Specialty Chemicals Water Treatments Ltd v SNF Inc*, 2017 FCA 225, and *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA.