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2020: A year of clarity for Canadian life sciences and software patents

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Two industries in which patents play an undeniable strategic role are life sciences and software. Canada has historically been a strategic jurisdiction for litigating life sciences patents, as launching a generic or biosimilar medicine requires that patents be addressed before product approval. Conversely, companies have often forgone protection and enforcement of software patents in Canada, due in part to barriers to approval of these patents either by our patent office or ultimately by the courts.

In 2020, Osler's patent litigation team helped to advance the law pertaining to life sciences and software patents in critical ways, providing guidance regarding patentability of contentious subject-matter as well as litigation strategy. This progress is owed largely to the efforts of Canada's Federal Court and Federal Court of Appeal, which worked through the pandemic to hear important patent cases using Zoom and the Federal Court's e-Trial platform.

A high bar for validity of patents directed to optimized use of known drugs

It is not uncommon for pharmaceutical patentees to attempt to extend patent protection for a drug by pursuing patents on optimized usage of the drug, even after the drug's use has been established. In *Eli Lilly v Mylan,* the Federal Court[1] invalidated such a patent, which was directed to low doses of tadalafil, the active ingredient in Eli Lilly's blockbuster drug CIALIS® that is used to treat erectile dysfunction.

Eli Lilly had sued multiple generic companies, including Mylan, for infringement of its low-dose patent. Mylan and other defendants alleged that Eli Lilly's patent was invalid in view of a prior tadalafil patent that already taught that the drug was useful to treat erectile dysfunction at a broad range of doses. Mylan alleged that the low doses were not "new" because the earlier patent taught that the doses worked. Mylan further alleged that the doses were "obvious" because there was no invention in the doses, given prior tadalafil patents and the routine nature of dose selection. Mylan and the other defendants won. Osler successfully represented Mylan in this action.

Patentees often point to the unexpected advantages of optimized medical uses and the high cost and risk associated with pre-clinical and clinical testing necessary to arrive at the

optimized use. Eli Lilly pursued these approaches, asserting before the Court that low doses had the unexpected advantage of reducing certain side effects of the drug, and that the work required to arrive at the doses was fraught with obstacles that would have caused others to abandon it altogether. The Court was not persuaded by Eli Lilly's arguments, instead finding that the patent did not disclose doses that were peculiarly advantageous and, in any event, that selecting doses was a routine part of drug development.

The decision in *Eli Lilly v Mylan* provides useful guidance for pharmaceutical use patents. Where the invention is routine optimization of an existing drug with already known uses, a high bar will be set when determining the patent's validity, and it may be difficult to sustain. The court's approach helps clarify the balancing of two important interests: rewarding innovation for new drugs, but also enabling affordable access by limiting monopoly protection to only those innovations worthy of protection.

Preservation of first-mover advantage in pharmaceutical litigation

Preserving the balance between drug innovation and access to generic alternatives can also involve incentivizing generic and biosimilar drug manufacturers to challenge weak or invalid patents. Such challenges facilitate competition that can lower drug prices once a drug's valid patents expire. However, such patent challenges are risky and the litigation is expensive. Generic challengers who are leading (and shouldering the financial cost of) the litigation taking on these types of patents lack the incentive to do so if their success will only be met with a flood of competition from other generic companies.

In May 2020, the Federal Court of Appeal addressed this issue,[2] overturning a decision of the Federal Court[3] that had allowed the trials of other generic drug manufacturers, which had started months later, to be heard at the same time as earliest (or first-moving) generic drug manufacturers. The result is that "first-mover position" is now preserved in drug patent litigation under Canada's *Patented Medicines (Notice of Compliance) Regulations* (the Regulations). Osler successfully represented the appellant, Teva, on the appeal.

The appeals concerned four generic drug manufacturers, each seeking approval for a drug product containing rivaroxaban. Teva and Apotex commenced their patent challenges within a month of each other. Taro Pharmaceuticals and Sandoz Canada commenced theirs several months later.

At issue was whether the trials for the later challengers, Taro and Sandoz, should be heard at the same time as the trials for the first-movers, Teva and Apotex. The addition of Taro and Sandoz to the first trial would have eliminated Teva's and Apotex's opportunity (if successful) to benefit from being the first to launch their rivaroxaban drug product in Canada, with the potential to occupy a larger share of the market.

The Court of Appeal held that the late-movers should not be added to the early-mover trials. A prohibition on joinder in the Regulations forbids trials involving different generic drug manufacturers to be heard concurrently even in respect of common issues. This prohibition is important. While first-movers can enter the market if they win at trial, late-movers must separately resolve their litigation under the Regulations, which typically means absent a settlement, they are unlikely to benefit from a first-mover's decision until it becomes final and unappealable (which can take months or years).

This decision preserves the incentive for generic and biosimilar manufacturers to make the commercial investment and absorb the litigation costs to be first-movers under the Regulations. The first generic or biosimilar drug manufacturer to commence a patent

challenge will be protected from late-movers seeking to "piggy-back" on their efforts. This preserves a legitimate opportunity for first-movers to get to market first and enjoy a period with limited competition, thereby creating a reward for the risk they assume when successfully challenging weak drug patents.

A clearer path to software patent approval

Software companies have historically faced considerable uncertainty when applying for Canadian patents, not knowing in advance whether they will be able to obtain a patent and the associated protections on the inventions they create. This uncertainty has been exacerbated over the past decade, as the Canadian Intellectual Property Office (CIPO) has been applying a policy of routinely denying patents for computer-implemented inventions based on a forensic and subjective assessment of the problem and solution addressed by the patent. Patents directed to solving "computer problems," such as chip control software that enables faster computer processing, have been considered more worthy of protection than patents that solve business or other types of problems, such as management of risk in an investment portfolio.

CIPO's approach created confusion regarding the availability of Canadian software patents, leading companies to forgo Canadian patent protection even when such protection could provide meaningful mitigation of business risk. Although copyright in software provides some residual protection against copying of source code, unlike patents, copyright does not provide broad protection over core software functionality. Thus, the previous challenges to obtaining the functional protection of a patent have had a negative commercial impact on companies in Canada.

On August 21, 2020, the Federal Court issued its decision in *Choueifaty,*[4] providing much-needed clarity for industry. The Court allowed an appeal from a decision of the Commissioner of Patents rejecting a patent application in relation to a new computer-implemented method for selecting and managing investment portfolio assets. The Court scrutinized and rejected the Commissioner's "problem-solution" approach, re-emphasizing that patent claims must be interpreted in the same way for all purposes, including assessing subject-matter eligibility.

The *Choueifaty* case was not appealed. The Court's decision, which emphasizes the primacy of language that patent applicants choose to define their proposed monopoly, should enhance business certainty for both patent applicants and third-parties that seek clarity regarding the scope of patents in their fields of business. CIPO has now begun the process of rewriting its administrative policy arising from the case, including providing new guidance on computer-implemented inventions, as well as medical diagnostic methods and medical uses.[5]

Amid the global pandemic, many of the most important innovations have arisen in the life sciences and software fields, from new disease test kits and anti-viral medicines to software that enables socially distant connectivity. The past year provided clarity regarding when innovations in these fields merit patent protection and how patent litigation is likely to unfold. Guidance from the Court's recent patent decisions should shape companies' Canadian patent strategy, both during the pandemic and beyond.

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[1] *Eli Lilly Canada Inc et al.* (Eli Lilly) *v Mylan Pharmaceuticals ULC* (Mylan), 2020 FC 816. Eli Lilly

appealed the Federal Court's decision on September 30, 2020.

[2] *Teva Canada Limited* (Teva) *v Bayer Inc et al.* (Bayer) and *Apotex Inc.* (Apotex) *v Bayer*, 2020 FCA 86.

[3] *Bayer v Teva et al.*, 2019 FC 1039.

[4] *Yves Choueifaty v Attorney General of Canada*, 2020 FC 837.

[5] CIPO Practice Guidance available at: http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04860.html.