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Canadian Patent Law in Review 2023: Notable Cases and Trends for 2024

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Happy New Year from the Cassels patent litigation team! We want to share this update on some of the most notable Canadian patent law developments from 2023 and projected trends that we expect to see develop in 2024.

The Proliferation of AI: What Does it Mean for Patents and Patent Litigation?

As we reported, the Canadian government tabled the *Artificial Intelligence and Data Act* (AIDA) as part of the *Digital Charter Implementation Act.* The AIDA provides a framework to regulate artificial intelligence (AI) in a way that will promote positive innovation. While the AIDA is still being discussed with industry stakeholders, its introduction confirms that the Canadian government is just as interested in AI and its potential as everyone else.

For stakeholders in the patent system, this raises questions about the proliferation of AI and its regulation. As we reported, the Federal Court of Canada recently published its own guidance on the use of artificial

intelligence in that court, including in cases involving patents.

Three key considerations for the future of AI and litigation relating to patents are:

1. *Ownership of inventions*. Generative and chat-based AI are used increasingly in the innovation process. Who owns the resulting inventions? The UK Supreme Court recently decided that an inventor under the UK *Patent Act* must be a natural person and cannot be an AI machine. Stay tuned for decisions in the Canadian courts as the role of AI in innovation becomes commonplace.

2. *Use of data in the creation process*. As jurisdictions, including Canada with the introduction of the AIDA, begin to regulate the use of data in creating, training, and maintaining AI systems, this may affect the patentability of inventions. If an invention is created using data that was not appropriately sourced, either by the inventor or by the AI utilized by the inventor, it may lead to a finding that the invention is not solely the work of the proposed inventor.

3. *Use of AI in the litigation process*. As parties, the Court and others become more familiar with the use of AI, and more comfortable with the necessary controls to ensure it is used appropriately, its role in the litigation process is sure to grow. The Federal Court's guidance is part of that development, but it is early days. The interaction between the efficiencies and other benefits that AI may be able to deliver, as compared to the risks of uncontrolled use, will be interesting to watch in 2024 and beyond.

With regulation looming and AI flourishing, there will likely be significant developments in the coming year. If you have questions, please reach out to the Cassels Intellectual Property and Information Technology and Data Privacy Groups.

Colour Selection Systems & Patentable Subject Matter: Canada (AG) v. Benjamin Moore & Co., 2023 FCA 168

In August 2023, the Federal Court of Appeal considered the test for assessing the patentability of computer-implemented inventions. In the decision below, the Federal Court had instructed the Commissioner of Patents to:

a. purposively construe the claim;

b. ask whether the construed claim as a whole consists of only a mere scientific principle or abstract theorem, or whether it comprises a practical application that employs a scientific principle or abstract theorem; and

c. if the construed claim comprises a practical application, assess the construed claim for the remaining patentability criteria: statutory categories and judicial exclusions, as well as novelty, obviousness, and utility.

The Federal Court of Appeal rejected that test. It agreed, and it is well established that, patent claims must be purposively construed. However, the Federal Court of Appeal rejected the balance of the proposed test finding that it was not supported by the current Canadian case law and dealt with issues that have yet to be considered. The Federal Court of Appeal also found the test to be contrary to the binding authority of *Amazon.com, Inc. v. Canada (AG)*, 2011 FCA 328.

The Federal Court of Appeal ordered that the patentability of the two applications at issue be redetermined in light of the current guidance in the Manual of Patent Office Practice (MOPOP), which includes Practice Notice PN2020-04:

a. purposively construe the claim;

b. once the subject-matter defined by a claim has been determined through purposive construction, then determine whether that subject-matter complies with all of the requirements of the *Patent Act*;

c. where a computer is an essential element of a claimed invention,

i. consider whether the computer cooperates together with other elements of the claimed invention and whether the actual invention has physical existence or manifests a discernible physical effect or change and relates to the manual or productive arts; and

ii. consider whether the computer is merely used in a well-known manner such that it is not sufficient to render a disembodied idea, scientific principle, or abstract theorem patentable subject-matter.

The Federal Court of Appeal reiterated that patentability is a highly fact specific exercise that must be considered with all relevant context, especially as computer technology becomes increasingly complex. The Court also cautioned against sweeping generalizations and extrapolating principles from prior decisions based on particular facts.

Inducement & The “Skinny Label”: Apotex Inc. v Janssen Inc., 2023 FCA 220

On November 9, 2023, the Federal Court of Appeal addressed the issue of induced patent infringement through a product monograph with a “skinny label” – one that omits any infringing uses found in the originator’s product monograph.

Apotex sought to market a generic version of Janssen's OPSUMIT (macitentan) medication to treat pulmonary arterial hypertension. Janssen had a patent claiming the use of macitentan in combination with a phosphodiesterase type-5 (PDE5) inhibitor. Accordingly, Apotex asserted that its product monograph for its proposed generic macitentan product referred only to macitentan monotherapy and did not mention the use of macitentan in combination with a PDE-5 inhibitor.

Despite Apotex's assertions that its product monograph did not refer to the patented combination therapy, the trial judge found, and the Court of Appeal affirmed, that:

- a majority of patients treated with OPSUMIT (macitentan) receive it in combination with a PDE5 inhibitor — it is the standard of care;
- the Apotex product monograph included data and other information relating to combination therapy, including from a key clinical study that showed the combination of macitentan with a PDE5 inhibitor was safe and effective;
- the small number of doctors who prescribe macitentan are very familiar with this key clinical study on the safety and efficacy of combination therapy
- those doctors would review the Apotex product monograph before deciding whether it was safe for their patients to receive Apotex's generic macitentan product; and
- read as a whole, the Apotex product monograph would direct doctors to prescribe Apotex's generic macitentan product in combination with a PDE5 inhibitor.

As a result, the trial judge concluded that the marketing and sale by Apotex of its generic macitentan product would induce infringement of Janssen's patent.

The Federal Court of Appeal affirmed the decision and confirmed that the test for inducing infringement has three prongs:

1. the act(s) of infringement were completed by the direct infringer;

2. the completion of the act(s) of infringement were influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place; and

3. the influence must knowingly be exercised by the inducer, i.e., the inducer knows that this influence will result in the completion of the act(s) of infringement.

On appeal, the parties agreed the first prong, direct infringement, was satisfied.

In considering the second prong of the test for induced infringement, the Federal Court of Appeal rejected Apotex's argument that express instruction in the product monograph was necessarily required to satisfy that prong. The various references and information from the Apotex product monograph directed to

combination treatment that were cited by the trial judge were sufficient to satisfy this part of the test.

The Federal Court of Appeal also held that, on the third prong of the test, a trial judge may infer the generic manufacturer's knowledge of its influence. Here, Apotex was knowingly seeking approval of a product available for combination therapy and knew the contents of its monograph. It was open to the trial judge to find Apotex knew or should have known its product monograph was not truly a "skinny label" and would affect doctors' prescribing decisions. This satisfied the third prong.

Andrew Skodyn*, the newest member of the Cassels Intellectual Property Group, was lead counsel to Janssen Inc. and Actelion Pharmaceuticals Ltd in this decision.*

Infringement Without an Injunction: AbbVie Corporation v. Jamp Pharma Corporation, 2023 FC 1520

At the end of 2023, the Federal Court released a decision holding that one of AbbVie's patents pertaining to HUMIRA (adalimumab) was valid and infringed, but decided not to grant the customary permanent injunction against JAMP. JAMP had been marketing SIMLANDI, a biosimilar version of AbbVie's HUMIRA (adalimumab), in Canada for over a year. A series of patent infringement actions and patent impeachment actions ensued between the parties.

JAMP conceded infringement of the relevant patent but argued against a permanent injunction because:

- the public interest did not support a permanent injunction — although AbbVie received approval for the specific formulation that was the subject of the patent in 2015 in the United States, it did not market that formulation to Canadian adults;
- JAMP's SIMLANDI product entered the Canadian marketplace in 2022 and was one of only two 100 mg/mL formulations available to adults and the only 80 mg/0.8 mL formulation;
- a reasonable, running royalty on future sales of SIMLANDI would adequately compensate AbbVie, especially considering AbbVie's existing licences for other adalimumab biosimilar products;
- SIMLANDI does not affect the sale of HUMIRA given the reimbursement policies of provincial drug plans and if SIMLANDI were removed from the market, patients would be switched to a different adalimumab biosimilar for which AbbVie is likely already receiving a royalty; and
- Canadian patients would be deprived of the only 80 mg/0.8 mL formulation available if SIMLANDI were removed from the market.

AbbVie argued that there was no equitable reason to deny a permanent injunction.

Ultimately, the Federal Court accepted JAMP's reasoning and described the case as "one of those rare

cases where I will not grant a permanent injunction given the public interest factor." Instead, the Federal Court ordered that AbbVie be compensated through a reasonable running royalty on future sales of SIMLANDI.

PMPRB Announces Next Steps in Guidelines Consultation Process

Pricing of patented medicines in Canada has been contentious. As we reported, the Patented Medicine Prices Review Board recently adopted its Amended Interim Guidance. First published on June 20, 2023, the Interim Guidance explains how the Board reviews the prices of patented medicines in Canada. It will be in force pending development and implementation of the long-awaited new guidelines.

On October 25, 2023, the Board announced the launch of the first phase of consultations on its new guidelines and invited stakeholders to participate in Policy Roundtable discussions. The consultations will focus on the following:

- Efficient Monitoring of Prices without Price Setting;
- Transition to PMPRB11 – New versus Existing Medicines;
- Price Reviews during Product Life Cycle;
- Investigations and Referral to Hearing;
- Relation to pan-Canadian Health Partners, Insurers (Private and Public) and Alignment with Broader Government Initiatives; and
- Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders.

A second stage of consultation will follow in 2024 and aim to develop the new guidelines.

Please reach out to any member of our life sciences team if you would like to discuss the upcoming consultations and development of the new guidelines.

Import, Export, and Possession as Infringement: Deeproot Green Infrastructure, LLC v GreenBlue Urban North America Inc., 2023 FCA 185

The Federal Court of Appeal was asked to consider whether Greenblue complied with a permanent injunction against infringing DeepRoot's patents. At trial, the Court found DeepRoot's patents valid and infringed, and ordered a permanent injunction against Greenblue. Greenblue then purported to sell a "design-around" product with one added component to avoid the injunction. When Deeproot learned of Greenblue's continued import, export, and possession of the product, Deeproot started a proceeding against Greenblue and moved for an order that Greenblue was in contempt of the injunction.

The Federal Court dismissed the contempt motion and the Federal Court of Appeal affirmed. Interestingly, the Federal Court of Appeal discussed the role of import, export, and possession of the product as acts of infringement.

A Federal Court injunction for patent infringement is usually only enforceable in Canada and prevents an infringer from interfering with a patentee's exclusive rights — the making, constructing and using the invention and selling it to others to be used. Here, Greenblue was importing the product from the United Kingdom, possessing it in Canada, and then exporting it for sale in the United States. The Federal Court of Appeal held, based on the evidence before them, that none of Greenblue's acts constituted patent infringement beyond a reasonable doubt (as required to establish contempt). Greenblue did not make the product available for sale to Canadians and the Canadian jurisdiction over patents is limited to the Canadian borders and the subject matter of the injunction.

Striking Inadmissible Expert Evidence: McCain Foods Limited v J.R. Simplot Company, 2023 FC 1480

Expert evidence is crucial in patent actions. The Federal Court has recognized its obligations as a gatekeeper to the admission of expert evidence. Early assessments of expert evidence serve to reduce costs and provide certainty.

Recently, the Federal Court confirmed that case management judges are permitted to strike inadmissible expert evidence on a pre-trial motion. However, the Court also found that this discretion should be exercised with restraint and the decision to strike expert evidence should usually be left to the trial judge.

Here, the Case Management Judge held that the expert evidence in question should not be struck by the Case Management Judge on a pre-trial motion. Although the Case Management Judge found the proffered expert evidence to be unusual and validly criticized by the moving party, he ultimately held its admissibility should be dealt with by to the trial judge.

Mark Davis *and* Kassandra Shortt*, members of the Cassels Intellectual Property Group, were counsel to McCain Foods Ltd. in this decision.*

FCA Confirms the Importance of Counsel's Role in Maintaining the Independence of Experts

As we reported, expert evidence in patent cases was also at issue in *dTechs EPM Ltd. v. British Columbia Hydro and Power Authority*, 2023 FCA 115. The Federal Court of Appeal confirmed that counsel can work

closely with experts to prepare their reports, provided that the reports present the experts' substantive and objective opinion.

At trial, dTechs EPM Ltd. (dTechs) claimed that British Columbia Hydro and Power Authority (BC Hydro) infringed the method claims of Canadian Patent No. 2,549,087 (087 Patent). It also alleged that Awesense Wireless Inc. (Awesense) indirectly infringed the 087 Patent through inducement or common design. Each party entered expert evidence on consent and did not challenge the admissibility of the others' expert reports. The parties did, however, contest the appropriate weight the Court should give the other's expert evidence. The Federal Court dismissed dTechs' infringement claim and declared the claims at issue to be invalid for anticipation and obviousness. dTechs appealed the decision.

Following trial, dTechs received a working agreement for BC Hydro's expert and invoices for his work. dTechs was allowed to introduce these documents as new evidence in the appeal, where they argued it evidenced that BC Hydro's expert did not author his reports and was therefore neither independent nor unbiased.

The Federal Court of Appeal concluded that, although the new evidence might have impacted the weight afforded to BC Hydro's expert, it could have affected the Federal Court's finding on the validity of only one claim. The validity of that claim was sent for redetermination by the Federal Court.

In the process, the Federal Court of Appeal clarified that while counsel in a patent case must ensure that the independence and credibility of an expert is respected throughout the preparation of an expert report, counsel's involvement in preparing reports that reflect the substantive opinion of the expert that prepared them does not necessarily mean that the resulting report does not reflect the opinion of the expert. Furthermore, opposing counsel may cross-examine the expert at trial to test the expert's opinion and reveal any overstep by counsel in preparing the report.

How to Stay Tuned for More in 2024

Issues relating to AI, patentability, expert evidence, the test for infringement, and the enforcement of patent rights will all remain front and center in 2024. Our patent litigation team will remain an active voice in evolution of Canadian patent law.

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