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Canadian patent law 2024: a year in review.

Speakers: Andrea Berenbaum, Ryan De Vries, Michael Sgro

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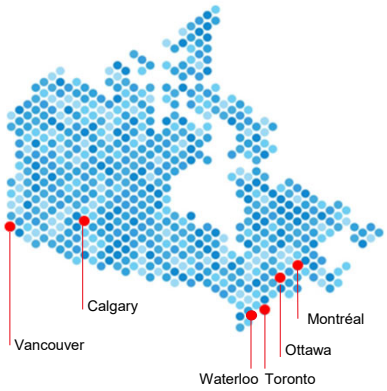

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1. Prosecution Update

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Prosecution – Patent Office IT System Update

Target date	Status	Milestones
July 17, 2024	Completed	Initial launch of MyCIPO Patents
July 17, 2024	Completed	Certified copies are available
July 24, 2024	Completed	Publication of Frequently asked questions – MyCIPO Patents page
August 1, 2024	Completed	Canadian Patent Database is available
...		
November 2024	Started	• Resumption of notice of allowance process ◦ We've started sending notices of allowance, beginning with a small volume that will increase over time. • CPD updates • Data corrections

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Prosecution – Patent Term Adjustment

“ ***Regulatory scenario***

In the regulatory scenario, the amendments come into force on January 1, 2025, and the date the first eligible patents may receive an additional term occurs on or after December 2, 2025.

...

from domestic clients. From FY 2024–2025 to FY 2033–2034, there are expected to be 1 129 applications for an additional term and 51 applications for reconsideration of an additional term. ”

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Prosecution – AI Inventors

"A preliminary analysis is provided below for the Applicant's consideration.

In brief, we are presently inclined to recommend to the Commissioner of Patents that the application be refused on the grounds that:

- The term "inventor" as used in the *Patent Act* and *Patent Rules* is limited to a natural person or persons and does not include an artificial intelligence system;
- The application does not name a natural person or persons as the inventor and therefore there can be no valid "inventor" or "inventor's legal representative" that filed the application in accordance with subsection 27(2) of the *Patent Act*; and
- Since no valid "inventor" can be identified, the requirements of subsection 54(1) of the *Patent Rules* also cannot be met." [1]

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2. Methods of Medical Treatment

Pharmascience Inc v Janssen Inc, 2024 FCA 23

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Methods of Medical Treatment

- Methods of medical treatment not considered patentable subject-matter in Canada
- Original decision based on a now-repealed section of the *Patent Act*
- Possible to obtain medical "use" claims, including the following forms:
  - Use of compound X for treatment of disease Y. [German-style]
  - Use of compound X in the preparation of a medicament for treatment of disease Y. [Swiss-style]
  - Compound X for use in the treatment of disease Y. [EPC 2000]
- In *Pharmascience v Janssen*, 2024 FCA 23 FCA considered distinctions between forms

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Methods of Medical Treatment

- Appeal from *Janssen Inc v Pharmascience Inc*, 2022 FC 1218
  - Actions pursuant to s 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*
  - Claims of CA 2,655,335 (the 335 Patent) were found not obvious or methods of medical treatment
  - Making, constructing, using, or selling of the drug at issue by Pharmascience in accordance with its Abbreviated New Drug Submissions would infringe the claims of the 335 Patent
  - Only ground of invalidity on appeal was whether the claims of the 335 Patent are invalid because they comprise unpatentable subject-matter (methods of medical treatment)

Pharmascience v Janssen, 2024 FCA 23

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Methods of Medical Treatment

- 335 Patent relates to paliperidone palmitate (Janssen's INVEGA SUSTENNA)
- Claims of 335 Patent relate to dosing regimens for paliperidone palmitate
  - **Claims 1-16** – prefilled syringes adapted for administration according to the claimed dosing regimens
  - **Claims 17-32** – use of a "dosage form" according to the claimed dosing regimens
  - **Claims 33-48** – use of paliperidone as paliperidone palmitate in the manufacture/preparation of a "medicament" adapted for administration according to the claimed dosing regimen
  - **Claims 49-63** – "dosage form" adapted for administration according to the claimed dosage regimens
- Federal Court distinguished between **"product" claims 1-16 and 33-63** and **"use" claims 17-32** stating "method of medical treatment analysis is only relevant in respect of claims 17-32"

Pharmascience v Janssen, 2024 FCA 23

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Methods of Medical Treatment

- The claimed dosing regimen for of paliperidone palmitate involves:
  - A first "loading dose" administered into deltoid muscle on Day 1 of treatment;
  - A second "loading dose" administered into deltoid muscle on Day 8 ± 2 days; and
  - "Maintenance doses" administered into deltoid or gluteal muscle monthly ± 7 days after second injection.
- For **"use" claims** Federal Court held professional skill and judgment would not be required to implement the claimed dosing regimens, as:
  - There are no choices in respect of possible ranges for the dosage amounts
  - Claim elements that involved choice (dosing windows around the Day 8 and monthly doses and injection sites for the maintenance dose) did not have clinical implications

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Methods of Medical Treatment

- On appeal, Pharmascience argued Federal Court erred in:
  - Excluding "product" claims from method of medical treatment analysis
  - Determining patentability on basis of dichotomy between fixed and variable dosing regimens

Pharmascience v Janssen, 2024 FCA 23

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Methods of Medical Treatment

- FCA affirmed claims drafted in EPC 2000 and Swiss styles were product claims and did not define methods of medical treatment – but did not accept Pharmascience's assertion that these claims were excluded from the method of medical treatment analysis

"[I]t did in fact consider these claims and it found that they related to a vendible product and were therefore patentable subject matter. In any case, the Federal Court's method of medical treatment analysis in relation to claims 17 to 32 of the 335 Patent would apply equally to the other claims."

Paragraph [43]

Pharmascience v Janssen, 2024 FCA 23

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Methods of Medical Treatment

"[W]hether or not a patent claim to a dosing regimen relates to a method of medical treatment cannot be based exclusively on whether its dosing and schedule is fixed or not. The proper inquiry remains whether use of the invention (i.e., how to use it, not whether to use it) requires the exercise of skill and judgment"

Paragraph [37] (emphasis in original)

- FCA held Federal Court properly recognized the above distinction
- FCA held no legal error in Federal Court conclusions relating to choices having no clinical implications not interfering with a physician's exercise of skill and judgement
- Pharmascience's application for leave to appeal to the Supreme Court of Canada granted

Pharmascience v Janssen, 2024 FCA 23

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3. Test for Inducing Infringement

Apotex Inc v Janssen Inc, 2024 FCA 9, aff'g 2022 FC 107
Pharmascience Inc v Janssen Inc, 2024 FCA 10, aff'g 2022 FC 62

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FCA Considers Test for Inducing Infringement

- Section 42 of the *Patent Act* provides a patentee with the "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used".
- Liability is not limited to direct infringement; a party may be liable for inducing infringement where it is established that:

1) The acts of infringement have been completed by a direct infringer;
2) The completion of the acts of infringement was 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 was knowingly exercised by the inducer; in other words, the inducer knew that this influence would result in the completion of the acts of infringement.

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FCA Considers Test for Inducing Infringement

- *Pharmascience Inc v Janssen Inc*, 2024 FCA 10 relates to an appeal from a trial decision finding that Pharmascience would induce infringement of a Janssen patent relating to dosing regimens for long-acting paliperidone palmitate depot formulations for treating schizophrenia.
- Pharmascience's appeal related only to the first prong.
  - Pharmascience argued that sale of a component of the claimed regimens by Janssen (an essential dose to the claimed regimens) includes an implied license to use the claimed dosing regimens.
- The FCA rejected the argument.
  - "*There appears to be no reason to conclude that either Janssen or its customers (a prescribing physician or a patient) would have understood that the purchase of paliperidone palmitate in a single dose from Janssen would include an implied licence to use the entire dosing regimen of the product in combination with other doses obtained from unlicensed sources […]*".

Paragraph [21]

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FCA Considers Test for Inducing Infringement

- *Apotex Inc v Janssen Inc*, 2024 FCA 9 relates to an appeal of a trial decision finding that Apotex would induce infringement the same Janssen patent.
- Apotex's appeal related to the second prong.
  - Apotex argued that its acts did not meet the high threshold—characterized as a "but for" test—for influence required by the second prong.
  - Apotex relied on the fact that its product monograph would essentially be a copy of Janssen's and thus the prescribing practices of physicians would not change if Apotex were allowed to market its generic product.
- The FCA rejected the argument—prescribing practices of physicians do not need to be altered because of Apotex's activities; "*what is required is that the ultimate act of direct infringement occur because of Apotex's activities*".

Paragraph [23] (emphasis in original)

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4. Test for Ambiguity

Tekna Plasma Systems Inc v AP&C Advanced Powders & Coatings Inc, 2024 FC 871

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Test for Ambiguity

- Subsection 27(4) of the *Patent Act*:

> **Claims**
>
> **(4)** The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

- The claims must answer the question: What is the invention?

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Ambiguity - Tekna Plasma Systems Inc v AP&C Advanced Powders & Coatings Inc

- Patents directed to producing reactive metal powders with improved flowability, e.g., for additive manufacturing:
  - Claims to a "manufacturing process" comprising forming a surface layer that includes a native oxide layer and a depletion layer deeper and thicker than the native oxide layer.
  - Claims to an "atomization system" configured to control an atomizing gas in an atomizing mixture "to control formation of a depletion layer".
- "The term depletion layer is not one that is generally used in the field of powder manufacturing. … it is not a term of art but a "term of patent," coined by the inventors."

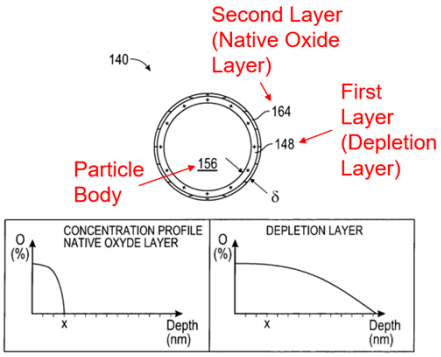

FIG. 3

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Ambiguity - Tekna Plasma Systems Inc v AP&C Advanced Powders & Coatings Inc

- "The scope of patent protection … must be reasonably predictable. …The scope of its prohibition should be made clear so that members of the public may know where they can go with impunity."

  Free World Trust v Électro Santé Inc, 2000 SCC 66 at para 41.

- "Although the claims must define the subject-matter distinctly and in explicit terms, they need not be perfect or a model of lucidity. They are addressed to a reader versed in the art who wants and tries to understand them in a purposive way and to give them a meaning that is fair to the inventor and the public. A lack of clarity or potential competing constructions is not alone fatal. *It is therefore a rare case where the Court will conclude that the claims of a patent cannot be meaningfully understood*." (Emphasis added)

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Ambiguity - Tekna Plasma Systems Inc v AP&C Advanced Powders & Coatings Inc

"despite the filing of numerous reports, none of the experts were able to clearly say how the POSITA would distinguish between the layers so as to confirm their existence and compare their depth and thickness. I agree with Tekna's observation in closing submissions that it is noteworthy that:

> ...after more than 3 years of litigation, very complex testing in specialized labs and universities, five experts in total, hundreds of pages of expert reports, and three weeks of evidence at trial, no one has been able to tell the Court (despite the Court asking the question on a few occasions) where the oxide layer and the alleged depletion layer are on any of the test results, and how thick these two layers are.

[Emphasis removed; Tekna Closing Argument, para 231.]"

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Ambiguity - Tekna Plasma Systems Inc v AP&C Advanced Powders & Coatings Inc

- "I conclude … it is impossible for the skilled reader to know or determine whether or not a powder particle has a depletion layer within the meaning of the patents' claims. Neither the claims nor the disclosure of the patents provide the reader with the ability to understand and assess whether a particle has a depletion layer, and thus whether a given process or system reads on the claims or not." (Emphasis added)

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5. Let's talk about "about"

Medexus Pharmaceuticals Inc v Accord Healthcare Inc, 2024 FC 424

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Claim construction: Let's talk about "about"

- Action for infringement of CA 2,659,662 (662 Patent)
- Accord received Health Canada approval to market syringes and injector devices pre-filled with a 50 mg/ml methotrexate solution based on plaintiffs' METOJECT products
- Accord conceded infringement of 662 Patent but argued Asserted Claims are invalid
- Federal Court ultimately found Asserted Claims invalid for obviousness – dismissed action for infringement and granted counterclaim for a declaration of invalidity
- Parties disagreed on construction of the term "about 50 mg/ml"

Medexus v Accord, 2024 FC 424

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Claim construction: Let's talk about "about"

- Narrowest Asserted Claim of 662 Patent:

> *Use of methotrexate for the production of a subcutaneously administered medicament that is contained in a ready-made syringe for a single application and that is in a form suitable for patient self-administration, for the treatment of rheumatoid arthritis, wherein the methotrexate is present at a dosage of 5 to 40 mg in a pharmaceutically acceptable solvent selected from water, water for injection purposes, water comprising isotonization additives and sodium chloride, at a concentration of* ***about 50 mg/ml****.*

- Accord argued the term "about 50 mg/ml" is ambiguous

Medexus v Accord, 2024 FC 424

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Claim construction: Let's talk about "about"

- 662 Patent does not provide a definition for the term "about"
- No "compelling evidence" of what skilled person would expect boundaries of the claims to be
- Nevertheless, Accord found not to meet burden of establishing claims invalid for ambiguity

"*In conclusion, the defendants have not established that 'about' is incapable of understanding, nor have they established that 'about 50 mg/ml' cannot provide an unambiguous boundary defining the scope of the monopoly. The defendants have not established that claims 3, 20, and their dependent claims are invalid for ambiguity because the skilled person, with the assistance of the specification and a mind willing to understand, would be unable to construe the claim term 'about 50 mg/ml'.*"

Paragraph [256]

Medexus v Accord, 2024 FC 424

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Claim construction: Let's talk about "about"

- Objections to "about" common during prosecution of a Canadian patent application
- Such objections can often be overcome through argument and/or amendment
- Including "about" may prove important – consider attempting to retain

Medexus v Accord, 2024 FC 424

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6. Entitlement to Accounting of Profits

Rovi Guides, Inc v Videotron Ltd, 2022 FC 874, aff'd 2024 FCA 125
Rovi Guides, Inc v BCE Inc, 2022 FC 1388, aff'd 2024 FCA 126

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Entitlement to an Accounting of Profits

- The *Patent Act* provides multiple potential remedies for patent infringement, including:
  1) Reasonable compensation between publication and grant (subsection 55(2))
  2) Damages sustained by reason of the infringement (subsection 55(1))
  3) An accounting of the infringer's profits (paragraph 57(1)(b))
- An accounting of profits is ***an equitable remedy*** that may be awarded based on, for example:
  - (i) Whether there has been undue delay in commencing or prosecuting the litigation; (ii) the patentee's conduct; (iii) the infringer's conduct; (iv) whether the patentee practiced the invention of the patent in Canada; and (v) complexity of calculating an accounting of profits.

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Entitlement to an Accounting of Profits

- *Rovi Guides, Inc v Videotron Ltd*, 2022 FC 874 and *Rovi Guides, Inc v BCE Inc*, 2022 FC 1388 relate to allegations of infringement brought by Rovi Guides, Inc. and TiVo Solutions Inc.
  - The asserted claims from 4 patents were found invalid and/or not infringed.
- The Federal Court considered remedies and concluded that Rovi would not have been entitled to an accounting of profits, noting:
  - Rovi has a reputation of using hard-ball legal tactics to pressure third parties to license its portfolio and did not send a cease-and-desist letter.
  - Rovi was never prepared to disclose what that portfolio actually comprises or to reveal a list of patents it thought were infringed.
  - Rovi apparently deliberately delayed the prosecution of its patents—one of which granted more than 17 years after the filing date.

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Entitlement to an Accounting of Profits

- Rovi appealed both decisions: *Rovi Guides Inc v Videotron Ltd*, 2024 FCA 125 and *Rovi Guides Inc v Telus Corporation*, 2024 FCA 126.
- The FCA did not interfere with the Federal Court's findings regarding obviousness and/or anticipation but addressed the remedial analysis, clarifying that:
  - The Federal Court should have started from the premise that Rovi would be entitled to an accounting of profits unless there were sufficient compelling reasons to deny the remedy.
  - Rovi did not have an obligation to identify the claims that would be infringed.
  - There is nothing inappropriate *per se* in a party's staunch defence of its perceived patent rights and adopting a business model of licencing.
  - Rovi should not have been faulted for failing to send a cease-and-desist letter.

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Entitlement to an Accounting of Profits

- The FCA also found that Federal Court's assessment of prosecution delays was made without evidence about normal practice and delays typically seen before the Patent Office, or Rovi's motives in prosecuting the patents the way it did.
- However, the FCA did not foreclose that prosecution delays could be relevant, stating:

> *"As for the length of time that it took Rovi to prosecute the Patents before the Patent Office, I would not completely foreclose the possibility that this sort of delay could be relevant to refusing an accounting of profits.* ***If there were ever a basis to determine that a plaintiff had unclean hands in seeking to extend the prosecution time to allow a defendant to accumulate profits that the plaintiff would then obtain****, such conduct could well be found to be so inequitable as to disentitle the plaintiff to an accounting of profits."*
>
> *Rovi Guides Inc v Videotron Ltd*, 2024 FCA 125 at paragraph [125]

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7. Use of a Patented Invention

Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd, 2024 FCA 67

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Use of a Patented Invention

- Section 42 of the *Patent Act:*

> **42** Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.
>
> R.S., 1985, c. P-4, s. 42; R.S., 1985, c. 33 (3rd Supp.), s. 16.

- What constitutes "use" of a patented invention?

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Use - Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd

- Patent directed to a system for liquifying natural gas prior to transpiration, using water-based liquefaction in shallow waters where large, oceangoing water-based liquefaction vessels cannot go.
- The invention claimed: A near-shore or at-shore floating LNG (FLNG) facility, comprising three key elements (1) a floating modular design, (2) an air-cooled liquefaction process, and (3) electric-driven compressors.

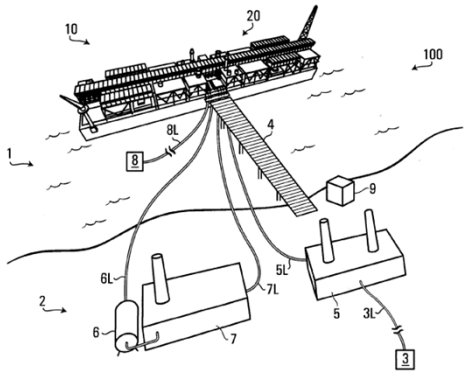

FIG. 1

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Use - Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd

- Respondent hired a third party to prepare a preliminary Front End Engineering Design ("pre-FEED") study for an LNG facility.

> "[12] From approximately February 2019 to May 2020, the Consortium showed a high-level summary of the pre-FEED study to potential investors, LNG off-takers (companies that use or re-sell LNG) and large-scale industry contractors, and allowed four of these third parties to see the pre-FEED study itself. None of the third parties participated further with the respondents in respect to its pre-FEED study or the FLNG facility design it contained."

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Use - Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd

> "[16] In their Amended Statement of Claim, the appellants did not advance a *quia timet* cause of action, which patent-holders can bring to prevent a party from engaging, on an imminent basis, in activity that would raise a strong possibility of infringement: see e.g. *AstraZeneca Canada Inc. v. Novopharm Limited*, 2010 FCA 112, 405 N.R. 95 at paras. 6–7 and the cases cited therein. As such, the appellants' action alleges no forward-looking infringement or threat of infringement.
>
> ...
>
> [18] The appellants acknowledged that the respondents did not make, construct, or sell the invention claimed in the 085 Patent, and that the claimed system, method, or apparatus does not exist anywhere in Canada. They also acknowledged that the only question of fact and law is whether the respondents have "used" the invention claimed in the 085 Patent."

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Use - Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd

- Characterization of Appellant's position:
  - The Supreme Court of Canada decision in *Monsanto Canada Inc. v. Schmeiser, 2004 SCC 34*, [2004] 1 S.C.R. 902, establishes that an invention is used if its purpose or advantage is exploited for commercial benefit.

> "the appellants observed that the respondents used the pre-FEED study to effectively "scoop" them by securing one of the few viable sites for an FLNG development on British Columbia's coast."

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Use - Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd

- The scope of the monopoly is defined by the patent claims:

> "[50] Accordingly, the Supreme Court's purposive inquiry in *Monsanto* indicates that what is "used" under section 42 is the claimed invention. In the case of a patent for an apparatus, the claimed invention is the apparatus described in the claims, not its goal, purpose or advantage, however these might be defined."

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Use - Steelhead LNG (ASLNG) Ltd v ARC Resources Ltd

"[67] The question is not whether commercial benefit is relevant to the analysis. The question is whether a commercial benefit is realized in the context of a defendant's commercial activities involving the patented object. The term "patented object" does not designate the purpose, goal or advantage of an invention. It designates the "subject-matter of the invention" or the "invention" itself as defined in the patent claims. Since these include, as an essential element, a water-based apparatus comprising a hull, an AER system and storage tanks, and because this apparatus did not and does not exist in Canada, the respondents realized no commercial benefit in the context of commercial activities involving the patented object."

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8. Patented Medicine Prices Review Board (PMPRB or Board)

Galderma Canada Inc v Canada (Attorney General), 2024 FCA 208

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Patented Medicine Prices Review Board

- Quasi-judicial body established by the *Patent Act*
- Regulates "excessive" pricing of patented medicines
- Has jurisdiction where invention "pertains to" a medicine

> *"an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine"*
>
> *Patent Act*, s 79(2)

Galderma v Canada, 2024 FCA 208

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Patented Medicine Prices Review Board

- Adapalene is a retinoid used to treat acne
- Galderma markets two products containing adapalene:
  - DIFFERIN [0.1% adapalene] – two patents, latest expiring in 2009
  - DIFFERIN XP [0.3% adapalene] – CA 2,478,237 (237 Patent) lapsed on March 14, 2016
- Galderma ceased providing information to the Board about DIFFERIN after patents expired

Galderma v Canada, 2024 FCA 208

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Patented Medicine Prices Review Board

- Board – December 19, 2016 decision:
  - 237 Patent capable of being "used for" DIFFERIN
  - Ordered Galderma to provide pricing information for DIFFERIN from 2010 - 2016
- Galderma sought judicial review:
  - 2017 FC 1023 – Federal Court quashed Board's decision
  - 2019 FCA 196 – FCA overturned decision and remitted back to Board for redetermination on whether the invention of the 237 Patent (use of a 0.3% concentration of adapalene for treatment of dermatological disorders) pertains to DIFFERIN

- DIFFERIN [0.1% adapalene] – two patents, latest expiring in 2009
- DIFFERIN XP [0.3% adapalene] – 237 Patent lapsed on March 14, 2016

Galderma v Canada, 2024 FCA 208

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Patented Medicine Prices Review Board

- Board – May 7, 2020 redetermination decision:
  - Given the clinical similarities, 237 Patent pertains to DIFFERIN
  - Ordered Galderma to provide pricing information for DIFFERIN from 2010 - 2016
- Galderma sought judicial review

- DIFFERIN [0.1% adapalene] – two patents, latest expiring in 2009
- DIFFERIN XP [0.3% adapalene] – 237 Patent lapsed on March 14, 2016

Galderma v Canada, 2024 FCA 208

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Patented Medicine Prices Review Board

- *Galderma Canada Inc v Canada (Attorney General)*, 2024 FC 46
  - Federal Court dismissed application for judicial review

"The Board was directed to consider the kind of clinical similarities that would support a finding that the invention of a patent was intended or capable of being used for that medicine. The Board found significant clinical similarities between Differin XP and Differin, and reasonably concluded that the invention of the 237 Patent pertained to, or could be used for, Differin."

Paragraph [64]

- Galderma appealed

- DIFFERIN [0.1% adapalene] – two patents, latest expiring in 2009
- DIFFERIN XP [0.3% adapalene] – 237 Patent lapsed on March 14, 2016

Galderma v Canada, 2024 FCA 208

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Patented Medicine Prices Review Board

- FCA granted appeal, set aside Board's Order
  - 237 Patent did not pertain to DIFFERIN
  - DIFFERIN was an unpatented medicine; the 237 Patent did not cover it

"The [Board] regulates the pricing of medicines under the market power given by a patent—namely, patented medicines. The Board does not regulate the pricing of unpatented medicines. After all, it's right in the Board's name: the Board is the 'Patented Medicine Prices Review Board', not the 'Patented and Unpatented Medicine Prices Review Board' or the 'All Medicine Prices Review Board'."

Paragraph [4]

- DIFFERIN [0.1% adapalene] – two patents, latest expiring in 2009
- DIFFERIN XP [0.3% adapalene] – 237 Patent lapsed on March 14, 2016

Galderma v Canada, 2024 FCA 208

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Patented Medicine Prices Review Board

- Galderma no longer "patentee" for DIFFERIN as after patent expiry no longer entitled to benefit of invention (lower 0.1% concentration of adapalene in DIFFERIN)
- 237 Patent is a "use patent" covering use of 0.3% adapalene – invention of 237 Patent cannot be "intended or capable of being used" for DIFFERIN or for "the preparation or production of DIFFERIN" as DIFFERIN does not embody that use
- Board does not have the power to review unpatented medicines – even if a patented medicine might be used in its place or if it shares some unpatented properties of the patented medicine
- Attorney General would need leave from the Supreme Court of Canada to appeal

- DIFFERIN [0.1% adapalene] – two patents, latest expiring in 2009
- DIFFERIN XP [0.3% adapalene] – 237 Patent lapsed on March 14, 2016

Galderma v Canada, 2024 FCA 208

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9. Federal Court Considers "Due Care"

Taillefer v Canada (Attorney General), 2024 FC 259, aff'd 2025 FCA 28
Matco Tools Corporation v Canada (Attorney General), 2025 FC 118

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Federal Court Considers "Due Care"

- Amendments to the *Patent Act* and *Rules* made in 2019 to bring the Patent Law Treaty into force in Canada introduced the requirement to show due care to reinstate an application or patent that is deemed abandoned or expired for failure to pay a maintenance fee.
- The applicant or patentee has ***two*** opportunities to convince the Commissioner of Patents that the failure to pay a maintenance fee and late fee by the deadline occurred in spite of the due care required by the circumstances having been taken.
  - An applicant or patentee can seek judicial review of a negative decision by the Commissioner.
- CIPO has posted over 300 determinations related to due care.
  - Fewer than 15% of the determinations conclude that due care was taken.

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Federal Court Considers "Due Care"

- *Taillefer v Canada (Attorney General)*, 2024 FC 259 is the first decision by the Federal Court on an application for judicial review of a decision by the Commissioner.
- The 2020 maintenance fee and late fee were not paid by the deadline after correspondence related to the 2020 maintenance fee deadline was caught by the Patentee's spam filter.
  - The Patentee and their Canadian agent had communicated by email for close to 10 years.
- The Commissioner refused to reverse the deemed expiry, focusing on the facts that:
  - It was not shown that steps were taken to ensure email remained an effective form of communication.
  - The agent did not appear to have or rely on a back up mechanism to contact the Patentee.
  - It was not shown that the Patentee was monitoring/tracking maintenance fee payments.

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Federal Court Considers "Due Care"

- The Federal Court dismissed the application for judicial review and affirmed the standard applied by the Commissioner:

> "*whether the patentee took all measures that a reasonably prudent patentee would have taken, given the particular set of circumstances to avoid the failure – and despite taking those measures – the failure nevertheless occurred*"
>
> Paragraph [25]

- The Federal Court also clarified that the guidance relied upon by CIPO does not create a clear and unqualified framework for the handling of reinstatement requests.
  - Fitting a fact scenario into one of the circumstances CIPO indicates may result in a finding of due care is ***not*** necessarily sufficient.
- Appeal dismissed: *Taillefer v Canada (Attorney General)*, 2025 FCA 28

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Federal Court Considers "Due Care" - Again

- The Federal Court has since released a second decision considering the due care standard (*Matco Tools Corporation v Canada (Attorney General)*, 2025 FC 118).
- The Federal Court affirmed the standard set out in *Taillefer* but also set out a two-stage framework that provides an applicant or patentee an opportunity to show that the due care required by the circumstances was taken:
  1) Prior to the original maintenance fee deadline; and/or
  2) After receiving notice from the CIPO that a maintenance fee was missed.
- Provided that due care was taken at ***either time***, an application should be reinstated or the deemed expiry of a patent reversed.
- The Attorney General has appealed (Court File No. A-42-25).

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Q&A

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Thank you!

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