
Jordana Sanft
416-596-1083
jsanft@litigate.com


Jim Lepore
416-865-2881
jlepore@litigate.com

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Close Only Counts in Horseshoes: Federal Court of Appeal Reins in the PMPRB

The Federal Court of Appeal's decision in *Galderma Canada Inc v Canada (Attorney General)* ("*Galderma FCA*") arose from what seemed like a straightforward production order, but ended up providing clear guidance on the jurisdiction of Canada's Patent Medicine Prices Review Board (PMPRB). The key takeaway: the PMPRB's jurisdiction extends only to *patented* medicines, not *all* medicines.

By way of brief background, *Galderma FCA* generally concerns the Galderma's products containing adapalene, which are used for the treatment of dermatological disorders (*e.g.*, acne). Galderma offers a 0.1% adapalene product under the brand name Differin and a 0.3% adapalene product under the name Differin XP. The issue before the PMPRB and later the Federal Court was whether Galderma was required to provide pricing information on its 0.1% adapalene product, Differin, when the last patent covering that particular product expired in December 2009.

Before that patent expired, Galderma had provided pricing information to the PMPRB as required by law, but – after the patent expired – Galderma stopped providing this information. In 2016, the PMPRB ordered Galderma to produce pricing information about Differin for 2010-2016, but Galderma refused, on the basis that the PMPRB only regulates patented medicines, not unpatented ones.

On the question of jurisdiction, the *Patent Act* provides that the PMPRB has jurisdiction over a "rights holder for an invention *pertaining to* a medicine […]." And section 79(2) of the *Patent Act* provides some additional clarity: "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." Nevertheless, the precise scope of this jurisdiction would be litigated for nearly a decade.

Procedural History and Background

In 2016, the PMPRB assumed jurisdiction on the basis that Galderma held an unexpired patent for Differin XP – covering the use of a higher concentration of the same active ingredient – was sufficient to pertain to Differin and ground the PMPRB's

jurisdiction to request pricing information.

In 2017, Galderma sought judicial review and Justice Phelan of the Federal Court quashed the PMPRB's order. The Federal Court identified several issues with the PMPRB's analysis. Most notably, the PMPRB failed to properly examine what the invention in the patent covering Differin XP actually was – instead, short-circuiting this analysis to focusing almost entirely on the commonality of the active ingredient. In that respect, the Federal Court also took issue with the PMPRB's unsupported assumption that Differin XP could simply be diluted to create Differin.

In 2019, on further appeal, the Federal Court of Appeal noted that the PMPRB "referred to other facts which, if they had been considered, may have influenced its decision", including clinical similarities between the products (*e.g.*, "evidence before the Board included a product monograph which applies to both Differin and Differin XP which does not appear to suggest any clinical differences between the two") and studies in the relevant patent comparing the efficacy of Differin and Differin XP. The Federal Court of Appeal found that, on administrative law principles, the degree of clinical similarity that could support a finding that a patent "pertains to" a medicine was a question that fell within the PMPRB's expertise to determine, and remitted the matter back for reconsideration, with directions as to the actual invention in the patent covering Differin XP.

In 2020, on remand – and unsurprisingly, having already previously found jurisdiction – the PMPRB issued a new decision maintaining jurisdiction. To that end, the PMPRB found significant clinical similarities between Differin XP and Differin (e.g., both medicines used the same active ingredient (adapalene), treated the same dermatological conditions, and worked in the same way, though with different concentrations). The PMPRB's finding was supported by evidence including a shared product monograph and expert testimony about the medicines' comparable clinical effects and side effects.

Shortly thereafter, Galderma once again sought judicial review. After unsuccessfully seeking to introduce new evidence in 2022, Justice Fothergill of the Federal Court ultimately dismissed Galderma's application for judicial review in 2024. The Federal Court emphasized that while the relationship between a patented invention and an off-patent medicine may be tenuous, the key question under section 79(2) of the *Patent Act* is whether the invention is "intended or capable of being used for" the medicine, which is focused on the clinical similarities between the medicines – a party need not prove actual market effects.

In 2024, Galderma appealed, and the Federal Court of Appeal ruled that the PMPRB exceeded its constitutional and statutory authority. In so doing, it provided guidance on the limits of the PMPRB's jurisdiction when dealing with unpatented medicines.

The Federal Court of Appeal's Most Recent Decision in *Galderma FCA*

The Court's reasoning in *Galderma FCA* emphasized the fundamental constitutional boundaries at play. While the federal government has exclusive jurisdiction over patents pursuant to section 91(22) of the *Constitution Act*, the regulation of unpatented medicine prices falls within provincial jurisdiction over property and civil rights (section 92(9) of the *Constitution Act*).

The Federal Court of Appeal took issue with the PMPRB's approach. The PMPRB, created by federal legislation and deriving its authority solely from federal patent jurisdiction, tried to regulate Differin based on similarities to a patented medicine (Differin XP). The Court recognized the precedent this would set: if similarities alone were enough, the PMPRB could indefinitely regulate any unpatented medicine that shared characteristics with patented products. This would both exceed the PMPRB's authority under the *Patent Act* and inappropriately encroach on provincial jurisdiction. Instead, the Court provided guidance: the PMPRB can only regulate medicines that have a direct and clear connection to a valid patent.

It therefore follows, on the facts of *Galderma FCA*, that the PMPRB could not extend its reach to regulate Differin, which had lost patent protection years earlier. Put differently, the 'use patent' covering Differin XP specifically claimed a 0.3% concentration of adapalene, which could not be stretched to encompass a different product (Differin) with a different concentration (0.1% adapalene), even if both medicines contained the same active ingredient (adapalene).

Practical Takeaways

For innovative pharmaceutical companies, the *Galderma FCA* decision brings welcome clarity after nearly a decade of litigation. Companies can now be more confident that the PMPRB's oversight will end when a medicine's last patent expires, even if they hold patents on related products.

1) The PMPRB's Constitutional Boundaries Are Strict. The PMPRB cannot regulate medicine prices simply because they share characteristics with patented medicines. Their jurisdiction comes exclusively from federal legislation – the *Patent Act* – and must maintain a clear connection to actual patent rights. When a patent expires, so does the PMPRB's authority to regulate that medicine's price.

2) Consumer Protection Cannot Override Constitutional Limits. While the Courts have acknowledged the PMPRB has a consumer protection mandate, such a mandate cannot expand its jurisdiction beyond medicines that are under patent protection.

3) Patent Claims Matter. The Court emphasized that the scope of patent claims is crucial – the PMPRB cannot stretch a patent beyond its clear technical limits to establish jurisdiction. Here, the patent over Differin XP (0.3% adapalene) could not be expanded to cover Differin (0.1% formulation).