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Skinny drug labels and induced infringement: court decision creates divergence between U.S. and Canadian law

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Key Takeaways

- The U.S. Supreme Court has just clarified that patents on medical uses of pharmaceuticals should not disturb *bona fide* unpatented activities in the U.S.
- Current Canadian law diverges from U.S. law on what is required to ground an allegation of induced infringement of a patented dosing regimen.
- For companies and practitioners operating within both Canada and the U.S., the *Hikma* decision underscores the critical importance of jurisdiction-specific strategies.

The constant tension between patent protection for pharmaceutical innovations and affordable access to medicines is a challenge faced globally by policymakers, including in Canada and the United States (U.S.). The U.S. Supreme Court has just clarified that patents on medical uses of pharmaceuticals should not disturb *bona fide* unpatented activities in the U.S.

Generic product availability is a well-established and proven strategy for reducing overall prescription drug costs. However, in some circumstances, some brand manufacturers seek to delay or prevent the entry of generics and biosimilars to the market by securing multiple patents beyond the patent to the original drug compound or use, which extend protection to components beyond the original patent and beyond the drug's active ingredient. These follow-on patents often extend to new or more specific uses, such as treatment for different diseases, dosing regimens or for new patient demographics, beyond those covered by the original patents. These use patents can effectively postpone access to more affordable generic and biosimilar alternatives for significant periods of time, therefore sustaining higher drug prices for a corresponding period.

A legal mechanism known as "skinny labelling" is intended to enable generics to obtain regulatory approval to market and sell a generic or biosimilar, exclusively for unpatented uses of a drug. To comply with skinny labelling, generic manufacturers must "carve out" any indications — such as specific diseases or patient populations — that are still under the protection of use patents. This selective approval process is designed to facilitate earlier market entry for generics in areas not covered by existing patents, which typically are the original use for which patent protection has expired.

On June 4, 2026, the U.S. Supreme Court unanimously decided *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.,* No. 24-889 [PDF], reversing the Federal Circuit judgment [PDF]. This judgment solidifies U.S. case law on skinny labelling and creates a divide between U.S. and Canadian law on this important issue.

The U.S. Supreme Court's decision in *Hikma v. Amarin*

Justice Jackson, writing for the Court, held that a generic manufacturer's use of a "skinny label", combined with ordinary or routine industry communications such as marketing documents and statutory compliance, does not form the basis of an inducement claim absent clear, affirmative steps to encourage infringement. The decision draws a sharp line between affirmative encouragement of infringement and the mere possibility that physicians could use a drug for a patented purpose.

Case background

Amarin developed Vascepa (icosapent ethyl), which was approved by the U.S. Food and Drug Administration (FDA) in 2012 for severe hypertriglyceridemia (SH) and in 2019 for reducing cardiovascular risk (CV Indication). After Amarin's SH patents were invalidated, Hikma filed an abbreviated new drug application for a generic icosapent ethyl product seeking approval of a skinny label that included only the SH indication, carving out the CV Indication. In 2020, the FDA approved Hikma's generic with the skinny label and assigned the drug an "AB" rating, indicating therapeutic equivalence to Vascepa when used according to its labelling.

Shortly thereafter, Amarin filed suit in the District of Delaware, alleging that Hikma had actively induced others to infringe Amarin's CV Indication patents, based on the "totality" of Hikma's statements: its skinny label, patient leaflet, website, and press releases.

The District Court granted Hikma's motion to dismiss for failure to state a claim, the Federal Circuit reversed the District Court's decision, and the Supreme Court reversed the Federal Circuit, holding that Amarin failed to state a claim for actively inducing infringement of its brand-name drug's patented uses, so its complaint cannot withstand Hikma's motion to dismiss.

The Court's ruling

The Supreme Court found that the central question was whether Amarin plausibly alleged that Hikma actively encouraged infringing use, not merely whether doctors could plausibly read the alleged statements as instructions to infringe. In analyzing Hikma's communications, the Supreme Court found each category insufficient to support a claim of inducement and that, while implicit inducement is possible, such inducement must be clear and affirmative, not constructed through speculations about how third parties might interpret neutral statements.

The Supreme Court found that several of Hikma's statements had obvious alternative explanations rooted in compliance with law or standard industry practice. For example, Hikma's label retained information about a clinical study, as required by federal statute (duty of sameness), and Hikma's product was described as a "generic equivalent" to the brand-name comparator, as was normal industry practice. These statements were found to be insufficient to ground allegations of active inducement.

The Supreme Court also found that Amarin may not rely on mere omissions, inactions, or nonfeasance to allege active inducement. The Court should look to affirmative statements or actions to avoid trenching on regular commerce. Otherwise, ordinary merchants could become liable for any misuse of their goods and services, no matter how attenuated their

relationship with the wrongdoer.

Additionally, vague statements combined with speculation about how medical providers may act were found to be insufficient to ground Amarin's active inducement allegations. Hikma's patient information leaflet's warning about side effects for people with cardiovascular disease, the website's therapeutic category description, the AB rating, and press release sales figures were all found to be implausibly roundabout ways to induce medical providers to infringe. Vague statements requiring a possible but not plausible chain of events for a medical provider to draw encouragement to infringe, are not sufficient to find active inducement.

Moreover, the Supreme Court was explicit regarding the policy stakes, stating that it would not put generic manufacturers between a rock and a hard place by turning adherence to the law and industry standards into building blocks for illegal conduct.

Divergence between Canada and the U.S.

The *Hikma* decision highlights a divergence between Canada and the U.S. on the test for induced infringement of dosing regimen patents.

While the U.S. requires clear and affirmative active steps for a finding of induced infringement, Canada's Federal Court of Appeal (FCA) has not required such clear and affirmative active steps to ground an allegation of induced infringement. For example, in Canada, carving out a patented dosing regimen may not suffice if the remaining product monograph content, such as retaining clinical study information, could direct physicians to the patented dosing regimen. This means that certain dosing regimen patents may not be avoidable, despite a generic or biosimilar manufacturer's intent to do so, while complying with legal and regulatory requirements.

There is some Canadian jurisprudence indicating that information in a product monograph for safety purposes may not induce infringement, but recent cases have not given effect to this principle, instead finding infringement in the very types of circumstances that the U.S. Supreme Court considered inadequate to constitute affirmative encouragement. Although the FCA sets out a stringent test for establishing induced infringement that could be read as accommodating the U.S. Supreme Court's approach, recent cases have set a lower bar when considering medical use patents. The FCA's approach risks preventing market entry of generic drugs altogether, even for unpatented uses.

While the Supreme Court of Canada (SCC) has refused to review cases addressing infringement of induced infringement of dosage regimen patents in the context of skinny labelling, the SCC is expected to soon release a decision on the issue of whether a dosage regimen itself is unpatentable on the basis that it is a method of medical treatment that interferes with the exercise of skill and judgement by a physician.

If the SCC holds that such dosage regimens are unpatentable methods of medical treatment, then the issue of induced infringement of follow-on medical use patents may have less impact on generic and/or biosimilar entry to the market, as many dosing regimen patents, which are often at issue in induced infringement cases, may not be valid. However, if the SCC holds that such dosage regimens are potentially patentable, then the question of what steps, if any, a generic and/or biosimilar manufacturer could take to avoid inducing infringement of the follow-on dosing regimen patents, where there are non-patented uses, will remain critically important for determining the timing and scope of generic market access.

Conclusion

For companies and practitioners operating within both Canada and the U.S., the *Hikma* decision underscores the critical importance of jurisdiction-specific strategies. Strategies that are effective in one jurisdiction may fail in the other. A skinny label strategy, which protects against induced infringement in the U.S., may require additional measures to be taken to avoid liability in Canada. Intellectual property strategies should be tailored to each jurisdiction's enforcement landscape, and rigorous pre-launch review of product monographs and other marketing materials remains essential.

As the SCC prepares to rule on Canada's method of medical treatment doctrine, this area of law will remain dynamic and consequential for drug access and innovation alike.