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A Tale of Two Standards: Why Hikma May Have Had a Different Fate in Canada

On June 4, 2026, the US Supreme Court issued its decision in *Hikma Pharmaceuticals USA Inc v Amarin Pharma Inc*, a motion to dismiss against the backdrop of a claim for inducement of patent infringement in the pharmaceutical context. The Court held that the patentee, Amarin, had not pleaded more than a "sheer possibility" that Hikma actively induced infringement under the applicable US plausibility standard. Would a Canadian court have reached the same conclusion on identical facts? Possible, but not "plausible."

Inducement & Skinny Labels

Amarin's underlying claim alleged that Hikma induced patent infringement in relation to the drug Vascepa. Both US and Canadian courts recognize inducement claims, under which a party may be liable for patent infringement despite not directly infringing the patent itself. This issue often arises in pharmaceutical cases, where the patient or prescribing physician – not the generic manufacturer – is the ultimate user of the patented invention and therefore the direct infringer.

The tripartite tests for inducement in the US and Canada are broadly similar:

	US Inducement
1	• Direct infringement by a third party
2	• Knowledge that the induced acts constitute patent infringement
3	• Active steps to encourage direct infringement

In Canada, inducement allegations against a generic drug manufacturer are often advanced by reference to statements in

the generic's Product Monograph (PM). As the Federal Court of Appeal (FCA) noted in *Teva Canada Limited v Janssen Inc*, inclusion in the PM of the alleged infringing use as a recommended use, among others, may be sufficient to satisfy the second prong of the inducement test. Importantly, the FCA in *Apotex Inc v Janssen Inc* rejected the proposition that the absence of explicit instructions, or of an intention that direct infringement should result, necessarily defeats the required influence. While explicit instruction and intention may be relevant to the issue of influence, neither is invariably required. Nor is direct contact between the alleged inducer and the direct infringer necessary.

In *Hikma*, the generic defendant employed a so-called "skinny label" strategy, under which a generic manufacturer intentionally narrows the scope of its regulatory approval relative to the brand-name comparator to avoid infringement. Canadian courts have also considered several skinny-label cases. In *Genpharm Inc v AB Hassle*, the generic defendant limited its approval to a non-patented use, though its PM still referred to studies relating to the patented use. The FCA held that this was a "blatant attempt" to leave the reader with the impression that Genpharm's product could also be used for the patented indication.

"Plausibility" vs "Plain and Obvious"

Would *Hikma* have unfolded differently in Canada? Quite possibly, given the material differences between the two countries' thresholds for striking pleadings.

The US Plausibility Standard

As described in *Hikma*, a plaintiff in the US must plead a claim that is "plausible" on its face to proceed to discovery.

- The standard requires more than a "sheer possibility" that the defendant acted unlawfully.
- If the pleaded facts are merely consistent with liability, the claim falls short of plausibility.
- To cross the line from conceivable to plausible, the plaintiff must plead facts that permit the court to draw a reasonable inference of liability, including by addressing obvious alternative explanations for the defendant's conduct.
- The court undertakes a limited but real assessment of whether the pleaded facts plausibly support the claim: a "merits-lite" review.

The Canadian "Plain and Obvious" Standard

By contrast, the threshold for striking a pleading in Canada is exacting. A claim will be struck only where it is “plain and obvious” that the pleading discloses no reasonable cause of action, or where it is frivolous, vexatious, or an abuse of process.

More commonly, a Canadian court will grant leave to amend or strike discrete allegations rather than dismiss the claim in its entirety. Unlike a US court applying a plausibility threshold, a Canadian court does not weigh competing inferences or assess the credibility of the pleaded facts, provided the material facts necessary to support the recognized cause of action have been alleged.

Applying the Distinction to Hikma

In *Hikma*, the focus of the Court’s analysis was the third element of US inducement: whether Hikma took active steps to encourage direct infringement. Amarin relied on statements in Hikma’s label, patient information leaflet, website, and press releases. The Court concluded that these allegations did not adequately establish affirmative encouragement of infringement, particularly because several of the cited statements had obvious alternative explanations or were too vague or speculative to support a plausible inference of active inducement. On the pleaded facts, inducement was therefore possible, but not plausibly alleged.

On the same pleaded facts, a Canadian court may have been less inclined to strike. Because a motion to strike in Canada does not invite the court to weigh credibility or assess alternative explanations, allegations that might fail the US plausibility screen may nonetheless survive if they adequately plead the recognized elements of inducement. That does not mean the claim would succeed on the merits; it means only that, at the pleadings stage, the bar to proceed is materially lower. As a practical matter, that procedural difference may make it easier for patentees in Canada to reach discovery and develop a fuller evidentiary record.

Key Takeaways

The practical significance is clear: even where inducement allegations arising from a skinny-label strategy may struggle to satisfy the US plausibility standard, similar claims in Canada may still survive a preliminary challenge. For generic manufacturers, that increases the litigation risk associated with regulatory and marketing materials; for patentees, it preserves a meaningful opportunity to test inducement theories on a developed factual record.