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‘That’s A Much Broader Statement’: Hikma Grilled In Amarin Vascepa Skinny-Label Appeal

Hikma Faces Stern Words As Amarin Looks To Revive Induced Infringement Dismissal

by Dean Rudge

Hikma may have succeeded in dismissing Amarin’s induced infringement claim against the firm over Hikma’s skinny label generic Vascepa in the US, but a panel of judges for the US Court of Appeals for the Federal Circuit challenged that the generics manufacturer’s public disclosures “sound like an actual statement, encouraging use for the broad sweep of things: that this generic can be used instead of the brand, without any narrowing.”

Hikma faced down a barrage of questions and criticisms as oral argument began in Amarin’s bid to breathe new life into its claim for induced infringement against the London-listed firm regarding Hikma’s ‘skinny label’ generic version of Amarin’s Vascepa (icosapent ethyl), with a key patent-protected indication carved from the label.

In a 30-minute oral argument, counsel for both firms faced questions from three judges, including chief judge of the Federal Circuit Kimberly Moore. Each side was given 15 minutes to argue their points, but it was Hikma’s counsel who faced the sternest test from the panel of judges.

Amarin is appealing to the US Court of Appeals for the Federal Circuit after Delaware district court judge Richard Andrews earlier came down on Hikma’s side in a closely watched case for industry.

Andrews more than two years ago granted Hikma's motion to dismiss Amarin's allegations, after finding that Amarin had failed to plead induced infringement based on Hikma's generic icosapent ethyl label or the firm's public statements, including certain press releases. (Also see "*Hikma Triumphs As Vascepa Induced-Infringement Case Dismissed*" - Generics Bulletin, 10 Jan, 2022.)

Only a relatively small proportion of Vascepa sales are linked to the severe hypertriglyceridemia indication for which Hikma's generic is approved. The patent-protected indication, to reduce cardiovascular risk, is said to generate more than 75% of the brand's revenues, according to the Federal Circuit.

"Plaintiffs," Andrews noted, "must plead that 'Hikma took affirmative steps to induce, not affirmative steps to make sure others avoid infringement'."

Meanwhile, finding that Hikma's press releases "do not support actual inducement," Andrews explicitly stated that "Hikma's advertising of icosapent ethyl as the 'generic equivalent' of Vascepa does not expose Hikma to liability."

Ahead of oral argument, Amarin had insisted to the Federal Circuit that Andrews improperly considered Amarin's allegations in isolation instead of weighing them together. (Also see "*Vascepa Infringement Dismissal 'Resulted In Multiple Errors,' Amarin Argues*" - Generics Bulletin, 27 Mar, 2023.)

The US-based originator also argued that the lower court had made "improper, implicit factual determinations while bypassing the key factual dispute regarding what Hikma communicated to prescribing physicians; and it incorrectly analogized the case law."

Concerned With Your Press Releases

Hikma's counsel in the case, Charles Klein of Winston & Strawn, argued the firm's case before Federal Circuit judge Alan Lourie and district court judge for the Western District of Texas, Alan Albright, who together sat alongside Moore.

"Amarin argues that physicians may infer inducing conduct from vague statements. That's not the law. The Patent Act does not impose liability for inferred inducement. The statute expressly requires actively induced infringement," Klein said in his opening salvo.

"Active inducement requires affirmative steps in this context to tell healthcare providers that they *should* perform – not even *may* perform, *should* perform – each and every element of an asserted patent claim."

Mere knowledge of direct infringement or off-label use cannot be used to establish induced

infringement, Klein concluded.

Challenged that a "reasonable fact finder" could find that Hikma's use of language in its press release could find that a broader use of its product was "expressed," Klein responded: "That type of evidence could go to knowledge, but it doesn't go to the conduct element of induced infringement."

"This court in *GSK* agreed generics could not be held liable for merely marketing and selling under a skinny label omitting all patented indications," he said, referencing – not for the last time – GlaxoSmithKline's jury decision triumph over Teva over the Israeli firm's skinny label generic Coreg (carvedilol). (*Editor's note: The GSK case was decided by a jury, as opposed to the current case, a bench trial involving a Rule 12(b)(6) motion to dismiss. For a full history, see the sidebar article*).

Industry Impact Weighed As US Supreme Court Refuses Skinny-Label Review

By David Wallace

18 May 2023
Teva has been denied in its attempt to convince the US Supreme Court to re-examine long-running litigation with GSK over skinny-label carve-outs of generic indications. However, the generics firm has vowed to fight on as the case is returned to the district court level, while the wider off-patent industry weighs the impact of the latest decision.

Read the full article here

"That's what we [Hikma] have. Or for merely noting, without mentioning any infringing use – the press release, the website don't mention any infringing use – that the FDA had rated a product as therapeutically equivalent to a brand name drug. That's directly on point."

Chief judge Moore interrupted, stating: "I'm not concerned with your website, but I am concerned with your press releases."

"It's different to say something is AB-rated, because I understand to industry that means equivalent for the uses on Hikma's label. But that's not what you say on the press releases: you say it's a generic version of Amarin's drug. So that's different. That's a much broader statement."

Have To Accept As True

When Klein countered that Hikma's generic label, unlike Teva's generic label in *GSK*, did not actively induce infringement, Moore observed: "The difference between their press release and your press release is that when they said it was a generic equivalent, they also said for AB-rated purposes. Your press release doesn't do that. It doesn't have that limitation in it."

Klen argued that in *GSK*, the press releases referred to the generic as a cardiovascular agent,

"which gets pretty close to the patent claims." Hikma did not do that. "All it says is that it's a generic version, which this court in *GSK* said is not enough."

"Your problem is this is a 12(b)(6); that was following a jury trial. So we're here at the 12(b)(6) standard stage [asking], could somebody think that this is *plausibly* enough? Not it *is* enough, but *plausibly*?" Moore replied.

"That's Amarin's allegation, whether correct or not or provable at trial or not. But I have to accept as true that by calling it a generic version in this press release, it would cause healthcare providers and patients to believe that this should be prescribed for all of the equivalent uses," she concluded.

The Broad Sweep Of Things

Klein fired back that in order to "infer" induced infringement in this case, "the reader would have to go to a document outside the press release – the Vascepa label – and make the assumption that, 'Well, now I can use Hikma's product for any indication in the Vascepa label.' That's not what the press release is."

Again, Moore challenged this point, underlining: "I don't think it is inferential." Hikma had included in its press release that Vascepa achieved annual sales of $919m, "75% of which are in fact the non-severe HTG sales.

Maybe the point about the sales figures is inferential, she acknowledged. "But the earlier statement that Hikma's product can be sold as a generic version of [Vascepa] doesn't seem inferential to me."

"It seems," Moore commented, "like an actual statement, encouraging use for the broad sweep of things: that this generic can be used instead of the brand, without any narrowing."

In perhaps the most telling statement that the Federal Circuit may well look to grant Amarin's request to revive the case, Moore concluded: "I'm really struggling with how I'm supposed to say at the 12(b)(6) stage that this isn't enough."

Albright then chipped in, wondering whether it "should be a jury that hears evidence from both sides that decides whether you're [Hikma] right in your position or not."

Two Words. How Hard Is That?

Klein once again insisted that in the current case, "there's no plausible allegation that Hikma is actively encouraging a healthcare provider to actually perform every step of the patented method."

“The patented methods are very specific. There’s not a description of the patented methods in the press release,” he argued.

Then Hikma’s counsel looked to put the case in the broader context of the longstanding practice of generics manufacturers carving out patented indications from the generic label – via a section viii statement – in order to compete on unprotected indications.

Ahead of the final decision in *GSK*, the US solicitor general had argued that an unfavorable decision for Teva would “subvert the balance struck by Congress, create significant uncertainty for FDA and generic manufacturers, and invite gamesmanship by brand-name manufacturers.”

“The elephant in the room, is that this is not just a typical 12(b)(6) case,” Klein insisted. “The entire industry is watching this case. It’s a test case. It goes back to the entire controversy with *GSK*. And if merely calling a generic product a ‘generic version’ is sufficient to get past the pleading stage, section viii is dead.”

“This is not a section viii case anymore,” Moore replied. Klein countered: “The point is, we weren't sued under 271(e) because of the section viii. And what’s going to happen is brands are going to –.”

But Moore interrupted. “This isn’t going to unravel section viii. How is it going to unravel section viii? This is not a section viii case.”

“It will absolutely unravel section viii,” Klein rejoined. “Brands will lie in wait when there’s a section viii carve-out and not sue under 271(e), and instead wait until the launch and then sue under 271(b) for damages based on statements like, ‘Oh, you called it a generic version’.”

“Then all you will have to do if you want to avoid future litigation,” Moore said, “is in your press release: be more specific. ‘We have a generic version which can be used to treat severe HTG in the same fashion as the branded version, Vascepa,’ and then you're off the hook,” she suggested.

“It doesn’t unravel section viii. It doesn’t make it so generics can’t sell. It just makes it so generics, when they’re claiming they’re generic, have to explain what they’re generic *for*. How hard is that?” she asked. “It doesn’t feel like a hard burden. It feels like you add two words to your press release. Two words.”