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GSK Redo Doesn't Cure Generics' 'Skinny Label' Uncertainty

By **Dani Kass**

Law360 (August 9, 2021, 10:05 PM EDT) -- While the Federal Circuit may have walked back part of an induced infringement ruling that left the generic-drug industry warning a fundamental law had been gutted, attorneys say the court's revised opinion last week still leaves generics makers steeped in uncertainty.

When the Federal Circuit **revived** GlaxoSmithKline's $235 million infringement verdict against Teva in October, the generics industry said the court had created a situation where companies could no longer sell generic versions of drugs with labels that carve out uses that are still patent protected.

Following the uproar, the panel vacated its ruling, **reheard** the case and on Thursday **issued an opinion** the panel majority said was more case specific while still favoring GSK. However, attorneys, a dissenting judge and representatives for the generic-drug industry say the revision still leaves the Hatch-Waxman Act's allowance of these so-called skinny labels in unclear territory.

"The majority said this is a unique case and very fact specific, and that we're not doing away with skinny labeling, but I think a lot of generics feel otherwise," said Axinn Veltrop & Harkrider LLP partner Aziz Burgy. "They're going to really have to take a deeper and harder look at any of their skinny labels than they've done in the past."

The original opinion from Judges Pauline Newman and Kimberly A. Moore had left the industry concerned that simply declaring that a drug had an AB rating — meaning it is interchangeable with the branded product — was enough to induce doctors to prescribe the generic for patent-protected uses. Their revised opinion pinned the inducement to additional comparisons Teva made in things like marketing materials.

"I think the consequences of the reissued opinion are less draconian than the original," said Columbia Law School professor Chris Morten. "The original was deeply problematic. The majority really broke from decades of case law."

Attorneys who work with the generics industry agree, but said the new ruling isn't good enough.

"In the first opinion, it wasn't clear where the floor was," said Schiff Hardin LLP partner Imron Aly. "What's clear now is how low that floor is. Any amount of evidence can be pieced together to say there is inducement."

The key difference between the majority and the dissent is how one proves induced infringement. Benesch Friedlander Coplan & Aronoff LLP partner Charan Brahma said the majority thinks actions taken by the alleged inducer that could lead to direct infringement are enough to prove inducement, while Judge Sharon Prost's dissent wants proof that the infringement occurred because of a party's inducement.

"I think the majority views it as its sufficient for inducement if acts of inducement are taken by the accused infringer with the knowledge of the patent and then the direct infringement occurs, without a particular tie saying that the direct infringer actually relied on those acts of inducement and that's what caused them to perform the infringing acts," Brahma said. "Whereas I think the dissent wants to attach a more direct caution element to it."

Morten — who has represented Teva but not in this case — said it didn't appear that GSK had sufficiently proven that doctors followed Teva's label to then prescribe the drug in an infringing manner. In this specific case, the infringement was prescribing a generic of GSK's Coreg for congestive heart failure.

"The majority pulls together some evidence, but I don't find it very convincing," Morten said. "Judge Prost writes more convincingly. In future cases, patent plaintiffs are going to be able to win on claims of induced infringement based on very little information."

Attorneys said it was hard to see what else Teva could have done to comply with the law, and that uncertainty could scare generic-drug makers from bothering with skinny labels. Teva only sold about $74 million of the drug it now owes $235 million for infringing.

"The [U.S. Food and Drug Administration] basically gave them the nod to go ahead [with the skinny label]," Burgy of Axinn Veltrop said. "I think generics may feel that the rug was pulled out from under them. They don't see why this decision went the way that it did in light of the facts that were at play here."

Jeff Francer, the general counsel for generic-drug industry group the Association for Accessible Medicines, said the Federal Circuit has thrown a "typical" practice into question.

"The two judges in the panel really dug their feet in, and the new decision has not decreased the amount of uncertainty," Francer said. "We're seeing copycat filers by some of the branded companies that are using the same tactic as GSK and trying to stop or even take away approvals that have already been provided."

Attorneys across the board said they expect an en banc or U.S. Supreme Court petition, and that legislation addressing the issue may pop up as well given the drug pricing concerns at hand.

"I suspect billions and billions of dollars in U.S. drug spending are saved by generic suppliers that launch using skinny labels," Columbia's Morten said. "We've come to rely on that in our health care system. Generics may be afraid to use the skinny label pathway to approval because they're afraid they're going to end up like Teva."

Brahma of Benesch Friedlander, who represents branded drugmakers, said Teva may have been able to avoid this outcome by making it explicit on its label that the contested indication is patent protected. He also suggested that these suits may start involving pharmacists and pharmacy benefit managers, since they're usually the ones interpreting a doctor's prescription for a brand-name drug and filling it with a generic equivalent.

During the case, GSK had maintained that Teva's label wasn't even a true skinny label, which Burgy said branded-drug makers may use to show this case isn't a big change to skinny label law.

The part of Teva's label that the court found induced infringement was in material about clinical studies, rather than the indications, Morten said. He noted that "brands have a lot of power" because they write the reference label, and he theorized that could be manipulated.

"It's really hard for the generic to cut language out of sections like the clinical studies section," Morten said. "I wonder if brands will use this fact strategically — if they'll be encouraged to say, 'What if we strategically mix up a lot of language in various sections of our label about different methods of use, different patented methods, such that it's harder for the generic to cleanly carve out?'"

The Federal Circuit's ruling will generally be limited to the pharmaceutical space, attorneys said, but there are rare instances where it could be extended.

For example, Brahma said the question of causation for inducement could apply to other industries, while Morten pointed to companies in the do-it-yourself or repair spaces.

Morten noted that during particularly rough times in the pandemic, open source hardware groups were able to release instructions for things like 3D printing replacement parts for ventilators. That

fear was somewhat quelled by the latest GSK ruling, he said.

"Under GSK, you could imagine a scenario where someone is making a replacement part and saying it's an equivalent of Siemens," Morten said. "Under the original GSK decision, if the original manufacturer had a patent on using the part in some way, that alone may make the copycat product a problem. The notion that a mere statement of equivalence could induce infringement was really scary for the DIY, open source hardware world. The majority is now much more of the opinion that a statement of equivalence alone is not in and of itself enough to create inducement liability."

--Editing by Jill Coffey.
