ENDPOINTS NEWS

Novo's threat to sue Hims over Wegovy pill faces legal hurdle

by **Shelby Livingston on February 5th, 2026**

Novo Nordisk's threatened legal action against Hims & Hers for selling a compounded version of the pharma giant's newly launched Wegovy pill may be far from a slam-dunk win.

Dae Lee, an attorney at Buchanan, and other legal experts in pharmacy compounding said what Hims is doing is likely permitted under the Food, Drug, and Cosmetic Act.

"What are they going to go after?" Lee said. "I don't think it's going to be a patent case," trademark infringement or marketing claims produce mixed results, and the FDA is unlikely to challenge compounders if a doctor has said a drug is needed for a patient.

Hims said Thursday it will start offering a compounded semaglutide pill at $99 a month, a steep discount from Novo's pill priced at $149, just a month after the FDA approved it. A Novo spokesperson called Hims' move "illegal mass compounding" and said the company would take "legal and regulatory action to protect patients, our intellectual property and the integrity of the US gold-standard drug approval framework."

Pharmacies generally are permitted to make compounded versions of branded drugs in two cases: when that drug is in shortage, or, if it's not in shortage, by tweaking the formulation so its strength is at least 10% different from the brand-name drug and getting a clinician to declare it medically necessary for the patient. The compounder might also include another component, like an ingredient to combat nausea, for example.

There's no limit on how many patients a pharmacy can make such a "personalized" compounded drug for, as long as a prescriber says it's medically necessary, said Martha Rumore, of counsel at the Health Law Alliance, which represents compounding pharmacies.

In Hims' case, the company said its compounded semaglutide pill "features a specialized formulation that is engineered to protect the active ingredient through digestion and support absorption." Hims' shares $HIMS reflected investors' optimism that it was opening a new market, rising about 9% on Thursday morning, and then reversed into a loss as they grappled with Novo's legal threats.

Hims has taken a similar approach of altering the formulation when compounding GLP-1 injections, and so far hasn't met much resistance. Novo has sued dozens of compounding pharmacies and

telehealth companies, but it hasn't sued Hims. It did, however, kill a partnership with the company just weeks after it was announced last year.

Rumore said that while Novo and Eli Lilly have been somewhat successful when suing pharmacies for trademark infringement, they haven't been able to convince the courts that compounders' products are inferior and thus violate the FDCA. They've also been unsuccessful when arguing that compounders are mass-producing GLP-1s under the guise of personalizing them for each individual, she said.

Patent fights raise patent risks

Edgar Asebey, a partner at Frier Levitt, said Novo and Lilly have shied away from accusing compounders of infringing on their patents, likely because it opens them up to the huge risk of having their patents invalidated. It's well known that when pharmaceutical companies allege patent infringement, the defendant requests a review from the US Patent and Trademark Office to evaluate the underlying patent, he said.

"It's sort of like putting the goose that lays the golden eggs on the chopping block," Asebey said. "You don't want to do that right, because one bad decision at the USPTO undermines your entire multibillion-dollar market, and no one infringer is worth that to the companies."

Meanwhile, Hims is treading into territory in which it may already have received guidance from the FDA. The agency sent Hims a warning letter in September objecting to claims the company made on its website about its compounded GLP-1 injection as false and misleading, but it didn't challenge Hims' ability to make the injections themselves.

According to Asebey, the careful wording and footnotes that Hims used in announcing its semaglutide pill suggest it negotiated the language with the FDA as part of its corrective action plan related to the warning letter.

It's unclear whether the FDA will further challenge Hims or other compounders, barring a public health catastrophe. The agency has limited resources, and the current administration has been critical of pharmaceutical companies and supportive of alternative sources of healthcare.

Another outcome is that state boards of pharmacy could challenge compounders' claims that they are providing personalized GLP-1 drugs. Already, boards of pharmacy have been taking much more action than the FDA, Asebey said.

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