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Ozempic Gains Popularity, Its Maker Loses First Legal Fight

Minding Your Business on **November 15, 2023**

With Hollywood celebrities speaking out both in favor of and against the use of drugs like Ozempic and Wegovy for weight loss, it was only a matter of time before demand outpaced supply. Although most might believe that increased demand is a good problem to have, a recent case involving Ozempic shows that pharmaceutical companies with popular drugs might face increased competition, without the ability to obtain legal remedies against their competitors.

On July 6, 2023, Novo Nordisk Inc., a pharmaceutical company, sued Brooksville Pharmaceutical Inc., an independent pharmacy in Florida, over its sale of semaglutide products in the Middle District of Florida. Novo Nordisk had previously received exclusive approval from the Food and Drug Administration to develop and sell three drugs—Ozempic (2017), Rybelsus (2019) and Wegovy (2021)—containing semaglutide as their key ingredient to treat diabetes and obesity. According to the complaint, Novo Nordisk was the "only pharmaceutical company with express FDA approval to create, manufacture, and sell drugs containing semaglutide." Even though it had been approved for over five years, Ozempic has recently become the standout, as it is prescribed more and more for its off-label use, weight loss. Its rising popularity as a weight loss drug earned it the title of "blockbuster drug", meaning a drug that earns its maker at least $1 billion dollars in sales per year.

But with a growing patient population for Ozempic and Wegovy, Novo Nordisk struggled to meet demand. In response, and despite Novo Nordisk having exclusive approval to sell Ozempic, Rybelsus and Wegovy, Brooksville Pharmaceutical began selling its own drugs containing semaglutide. Novo Nordisk's lawsuit soon followed.

According to Novo Nordisk, Brooksville's sale of semaglutide was not FDA-approved and therefore violated the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). In addition to violating the FDUTPA, Novo alleged that Brooksville's use of the key ingredient resulted in unfair competition and was a public safety concern.

On August 14, 2023, Brooksville Pharmaceutical moved to dismiss the complaint arguing that Novo: (1) lacked standing; (2) its claims were preempted by the Food, Drug, and Cosmetic Act ("FDCA"); and (3) that it failed to satisfy the elements of the FDUTPA.

On November 8, 2023, Brooksville Pharmaceutical won the first battle when United States District Judge William F. Young granted Brooksville's motion to dismiss. Despite determining that Novo Nordisk had standing to bring the suit, Judge Young agreed with Brooksville finding that Novo Nordisk's claim was preempted by the FDCA and that Novo Nordisk did not state a claim upon which relief could be granted under the FDUTPA.

On preemption, Judge Young held that the claims were preempted under the FDCA because the only party that can enforce the statute is the United States, not a private party like Novo Nordisk. Novo Nordisk's sole option was to argue that Brooksville's conduct violated a duty owed to Novo Nordisk independent of the FDCA. Because the economic loss suffered by Novo Nordisk was a direct result of Brooksville's alleged violation of the FDCA, and not some other state law, said injury would not exist absent the FDCA. Therefore, Novo Nordisk's FDCA claim was dismissed as preempted.

As to the FDUTPA claim, Judge Young noted that the FDCA allows for the sale of a drug when "there is a shortage of the FDA-approved medication." Therefore, the sale of an unapproved drug by Brooksville, alone, was insufficient to state a case upon which relief could be granted. Novo Nordisk would have to do more to show that Brooksville's sale of the semaglutide-containing drugs in fact violated the FDCA.

Although a blow to Novo Nordisk, this saga is not over. Novo Nordisk made clear it would be filing an amended complaint, which makes sense in light of the large number of other entities selling their own drugs containing semaglutide. Indeed, Novo Nordisk has filed suit against several other pharmacies for engaging in the same conduct. These cases are still pending, notwithstanding the Judge Young's decision.

What happens next depends on several things. First, the strength of Novo Nordisk's claims once it amends its complaint, and whether it is able to overcome the deficiencies that led to its first complaint's dismissal. Second, and more broadly, the FDA could choose to intervene – by either pulling the non-approved drugs from the market or allowing them to be sold, due to the rising demand and Novo Nordisk's struggle to meet it. The FDA has yet to get involved. While it is unclear what position it will take, if any, one thing is certain: Novo Nordisk is not alone in the crackdown of copycat drugs – states are sharing in the concerns and "threatening to take legal action against pharmacies that make or dispense unauthorized versions of the weight-loss medications Ozempic and Wegovy."

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