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Unique Issues Facing Brand-Compounder Patent Litigation

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Recent developments involving compounded GLP-1 tablet products have fostered questions about compounding pharmacies as new and substantial sources of prescription drugs, and whether intellectual property disputes may increase.

This article examines key differences between traditional brand generic Hatch-Waxman Act litigation and potential brand compounder litigation, including differences in timing, remedies and evidentiary development.

On Feb. 5, Hims & Hers Health Inc. announced plans to offer a compounded semaglutide tablet,[1] despite the lack of any U.S. Food and Drug Administration-declared shortage, or having an approved abbreviated new drug application.

Although it reversed course in the wake of FDA threat of enforcement action on Feb. 6,[2] indicating intent to restrict compounded drugs containing GLP-1 ingredients, Hims & Hers was sued by Novo Nordisk AS for patent infringement on Feb. 9.[3] These events raise broader questions about how compounders and brand companies would be positioned in patent litigation as compared to generic pharmaceutical companies.

As discussed below, patent litigation between brands and compounders would materially differ from traditional Hatch-Waxman Act litigation in ways that may require different litigation strategies and consideration on both sides.

Compounding Pharmacies: A Limited Exemption to NDA and ANDA Pathways

Typically, those seeking to market a drug product must seek FDA approval through the new drug application (NDA) or abbreviated new drug application (ANDA) pathways described in Section 505 of the Food, Drug and Cosmetic Act.

Under certain conditions, however, Section 503A exempts[4] drug products compounded by licensed pharmacists or licensed physicians from complying with Section 505's requirements for NDAs and ANDAs.[5]

One of those conditions is that compounded drug products may not be "essentially copies of commercially available drug products," according to FDA guidance on pharmacy compounding of human

drug products, released in 2016.[6]

Sponsors may "be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process," according to FDA guidance on compounded drug products that are essentially copies of commercially available drugs, released in 2018.[7]

The FDA states in this guidance that the "essentially" language is intended to prevent "relatively small changes to a compounded drug product" that is then offered "to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference."[8]

The FDA's guidance, however, permits compounding if "a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product."[9]

The condition has an exception. The FDA does not consider a drug product commercially available if it "appears on the FDA drug shortage list in effect."[10] Specifically, the drug must be currently in shortage status, and not resolved, in the FDA's drug shortage database.[11]

From 2022 to early 2025, this was the case for semaglutide injection products.[12] After the FDA declared certain shortages associated with GLP-1 injections, various compounding pharmacies and telehealth companies — including Hims & Hers — began offering compounded GLP-1 injections.

But in February 2025, the FDA announced that this shortage of semaglutide injection products was resolved.[13] The FDA has not announced any shortage for semaglutide tablets.

Differences in Private Patent Enforcement

Patent litigation involving branded pharmaceuticals companies and compounders, like the case against Hims & Hers, would differ from traditional Hatch-Waxman Act litigation in several important ways that are important for both brand companies and compounders to understand.

Focus on Actual Damages

Because Hatch-Waxman Act litigation typically resolves before the statutory 30-month stay on marketing the challenged generic drug expires, and ANDA applicants are often reticent to launch amid risk, litigation typically centers on issues of patent infringement and invalidity, but not damages.

By contrast, where a compounded product is already being sold, infringement — if proven — can involve actual, measurable sales during the infringement period. The patent infringement complaint against Hims & Hers, for example, alleges actual infringing sales and seeks a damages award.[14]

This distinction may shift the focus of litigation involving branded pharmaceuticals companies and compounders to damages, including lost profits, reasonable royalties and potential enhanced damages for willful infringement.

The availability of actual damages can materially alter what each side seeks to demonstrate through the evidence, as well as settlement dynamics, as monetary damages — and not only delayed or foreclosed

future entry — would be at play.

Different Factfinders

Hatch-Waxman Act trials are bench trials before a district court judge, whereas the Seventh Amendment jury right applies in ordinary patent infringement actions involving branded pharmaceuticals companies and compounders. The complaint against Hims & Hers, for example, includes a demand for a jury trial.[15]

Trying a complicated pharmaceutical case to a lay jury is a substantially different endeavor from trying such a case before a district court judge, and may vary from jurisdiction to jurisdiction based on the jury pool. This may affect the litigation approach of both brand companies and compounders.

Infringement Suits Could Be Delayed

To facilitate early resolution of patent disputes, the Hatch-Waxman Act framework requires ANDA applicants to file certifications regarding any patents listed in the Orange Book.[16]

If an ANDA applicant believes its proposed generic product would not infringe a listed patent and that a listed patent is invalid, it can include a Paragraph IV certification.[17]

Because the mere act of submitting an ANDA for a would-be infringing product itself constitutes infringement,[18] branded pharmaceuticals companies can immediately sue to resolve patent disputes — even if the ANDA applicant is years away from being prepared to launch its drug product.

In the case of compounding products, as compounders are not required to file an NDA or ANDA, the compounder would not have to make certifications for Orange Book patents, and Section 271(e)(2)'s artificial act of infringement would not apply.

Accordingly, a company seeking a declaratory judgment of direct or indirect infringement would instead have to wait for manufacture, sale, use or importation of the drug to be of sufficient immediacy and reality.[19]

Depending on the circumstances, that could delay a branded pharmaceuticals company's ability to file an infringement suit by months or years, which may even come after the compounded product has been established in the market. In this instance, the complaint against Hims & Hers alleged actual infringing sales had occurred.[20]

No Automatic Stay

In Hatch-Waxman Act litigation, final approval of the proposed generic product is automatically stayed, typically for 30 months, if the branded pharmaceuticals company sues within 45 days of receiving notice of the ANDA applicant's paragraph IV certification.[21]

This would not apply to actions involving compounders. Instead, a branded pharmaceuticals company would need to rely on a temporary restraining order or preliminary injunction and would need to demonstrate that the applicable legal criteria are met, i.e., (1) the branded company is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in its favor; and (4) that an injunction is in the public interest.[22]

Different Types of Infringement Evidence

Because FDA regulations require ANDA applicants to include data demonstrating that the proposed generic has the same active ingredient and is bioequivalent to the branded pharmaceuticals company's approved drug,[23] defendants in Hatch-Waxman Act litigation must often concede a high degree of similarity between the branded product and the generic product accused of infringement.

ANDA applicants also are required to copy all or a portion of the branded product label that provides prescribing instructions and warnings for the generic product.[24]

These regulatory requirements simplify infringement proofs for branded pharmaceuticals companies, which can rely upon (1) clinical trial results using the branded product as evidence regarding how the proposed generic product would perform in patients and (2) the proposed label as evidence of both the ANDA applicant's inducing acts, e.g., instructing how to engage in an infringing use, and its specific intent to induce infringement.[25]

Because, outside of the Hatch-Waxman Act context, there is no FDA finding of bioequivalence or requirements for label similarity, infringement-related evidence likely would need to be developed from other sources in litigation involving branded pharmaceuticals companies and compounders.

This can become more complex in the context of compounded drugs where, absent an FDA-declared shortage, the compounded drug may not be essentially a copy of a commercially available product.

For instance, in the context of Hims & Hers, when announcing the availability of a compounded semaglutide pill, the company specifically stated that it "uses a different formulation and delivery system than FDA-approved oral semaglutide" and did not reference a label for the compounded semaglutide pill.[26]

Conclusion

The recent events are a pressing reminder that patent litigation involving branded pharmaceuticals companies and compounders may require different litigation strategies and considerations than traditional brand-generic Hatch-Waxman Act litigation.

Compounders should be mindful not only of the regulatory requirements governing compounded drugs, but also patent coverage relating to their intended drug and what marketing practices they plan to use.

Depending on the state of a branded patent portfolio, carefully selecting an active pharmaceutical ingredient or a novel formulation may materially change the merits of a potential patent litigation, if not avoid that litigation entirely.

Although the FDA threatened enforcement action here — given the Hims & Hers' high-profile GLP-1 practices — the FDA is likely to be selective in its enforcement targets, and will not investigate or take action against every alleged compounding violation.

Therefore, branded pharmaceuticals companies must be prepared to protect their intellectual property and commercial investments outside the traditional Hatch-Waxman Act context with which they may be more familiar and experienced.

In much the way that compounded companies can strategically select their products, branded pharmaceuticals companies can ensure they are not disadvantaged in potential litigation through strategic, proactive patent prosecution. For example, a company might seek claims covering alternative product formulations or delivery methods.

Branded pharmaceuticals companies and compounders should also be mindful what other causes of action could be potentially asserted. In the past, litigation involving branded pharmaceuticals companies and compounders have included Lanham Act, antitrust and state unfair competition claims, including from consumers.[27]

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[1] Hims & Hers Expands Personalized Weight Loss Portfolio with Access to Compounded Semaglutide Pills Starting at $49/Month* (Feb. 5 2026).

[2] FDA Statement, FDA Intends to Take Action Against Non-FDA-Approved GLP-1 Drugs (Feb. 6, 2026).

[3] https://www.law360.com/lifesciences/articles/2439477?nl_pk=c2fd739b-627d-4c52-84f3-87e0f11e2994&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences&utm_content=2026-02-10&read_main=1&nlsidx=0&; (Feb. 9, 2026).

[4] This article focuses on 503A compounded products. The Federal Food, Drug, and Cosmetic Act also has a separate section, Section 503B, that is applicable to outsourcing facilities.

[5] See, e.g., FDA Guidance, Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act, Revision 2 at 2 (June 2016).

[6] Id. at 4.

[7] FDA Guidance, Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act, at 4 (January 2018).

[8] Id. at 6.

[9] Id.

[10] Id. at 5.

[11] Id.

[12] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[13] Id.

[14] Case No. 1:26-cv-00143, Dkt. 1, ¶¶ 41-51, 71-72.

[15] Case No. 1:26-cv-00143, Dkt. 1, ¶¶ 41-51, 71-72.

[16] Caraco Pharm. Labs., Ltd. Et al v. Novo Nordisk A/S, 566 U.S. 399, 404-08 (2012).

[17] Id. at 407-08.

[18] 35 U.S.C. 271(e)(2)

[20] Case No. 1:26-cv-00143, Dkt. 1, ¶¶ 41-51.

[21] 21 U.S.C. §§ 355(j)(B)(iii), 355(j)(5)(C); 355(q)(1)(G).

[22] Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7 (2008).

[23] FDA Guidance, Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act, at 4 (January 2018).

[24] See 21 U.S.C. § 355(j)(2)(A)(v) ("[T]he labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . .").

[25] See, e.g., Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1128-33 (Fed. Cir. 2018).

[27] See https://www.law360.com/lifesciences/articles/2444753?nl_pk=c2fd739b-627d-4c52-84f3-87e0f11e2994&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences&utm_content=2026-02-24&read_main=1&nlsidx=0&nlaidx=6.