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Novo Nordisk v. Mylan: Method of Treatment Claims Must Be Aligned with Label

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Method-of-treatment ("MoT") claims can be powerful tools for pharmaceutical companies seeking to extend market exclusivity for their products after the original composition-of-matter patents expire. However, the District of Delaware's recent decision in ***Novo Nordisk v. Mylan*** is another reminder that the scope of method of treatment claims must be aligned with an FDA approved drug label.

Patent prosecution often involves trade-offs. To overcome prior art rejections, applicants may introduce narrowing limitations. But these limitations can later become liabilities if they don't align with a drug's approved use and description in the FDA-approved label. In litigation, every word added during prosecution is fair game for scrutiny. Even if it's highly likely that some physicians will practice the claimed MoT, that alone may not be enough.

Novo Nordisk, Inc. and Novo Nordisk A/S ("Novo") manufacture Wegovy®, one of the blockbuster GLP-1 receptor agonist approved for weight management. Mylan Pharmaceuticals Inc. ("Mylan") filed an Abbreviated New Drug Application ("ANDA") seeking approval for a generic version of Wegovy. Novo responded with a lawsuit asserting five patents, including U.S. Patent No. 9,764,003 ("the '003 patent"), which claims a method of reducing body weight by administering semaglutide "without another therapeutic agent."

This "without another therapeutic agent" limitation was added during prosecution to overcome a § 103(a) obviousness rejection. But it became the focal point of the Mylan's recent Motion to Dismiss regarding the '003 patent.

As a method of treatment patent Novo relied on induced infringement under 35 U.S.C. § 271(b), which requires showing that the defendant actively and knowingly encouraged others to perform the patented method.

In ANDA cases, the proposed generic label is the primary evidence of intent. Since the generic product isn't yet on the market, marketing materials and real-world usage aren't available. The key question becomes: Does the label instruct users to perform the patented method?

Novo argued that Mylan's label discouraged coadministration with other drugs and that this implied an intent to induce infringement. The label included:

- Warnings against combining semaglutide with other GLP-1 agonists or semaglutide-containing products
- Cautions about coadministration with other weight-loss drugs.
- And advised to "consider reducing" the dose of concomitantly administered insulin to mitigate hypoglycemia risk.

Novo claimed these warnings amounted to suggesting use of semaglutide without another therapeutic agent, satisfying the claim limitation.

But the court disagreed, finding that Mylan's label did not instruct physicians to avoid all other therapeutic agents. Instead, the label acknowledged and anticipated coadministration with other drugs, including insulin and antihypertensives. The court emphasized:

"The label does not state, imply, or suggest in any way that Mylan's semaglutide product should be administered without any other therapeutic agent."

Novo's argument that physicians would "inevitably" prescribe semaglutide alone was deemed irrelevant. The court reiterated that inducement requires active encouragement, not mere foreseeability.

This case provides the following reminders and takeaways:

1. Align claims with the label: If a MoT claim includes limitations not reflected in the label, proving inducement becomes significantly more challenging.
2. Be cautious during prosecution: Narrowing amendments may help secure a patent but can later limit enforceability.
3. Understand the evidentiary burden: In ANDA cases, the label is often the only available evidence of intent. It must clearly support the claimed method.

Patent prosecution often involves trade-offs and during litigation every word added (or removed) during prosecution is fair game for scrutiny. Even if it’s highly likely that some physicians will practice the claimed MoT, that alone may not be enough to maintain an infringement claim.

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