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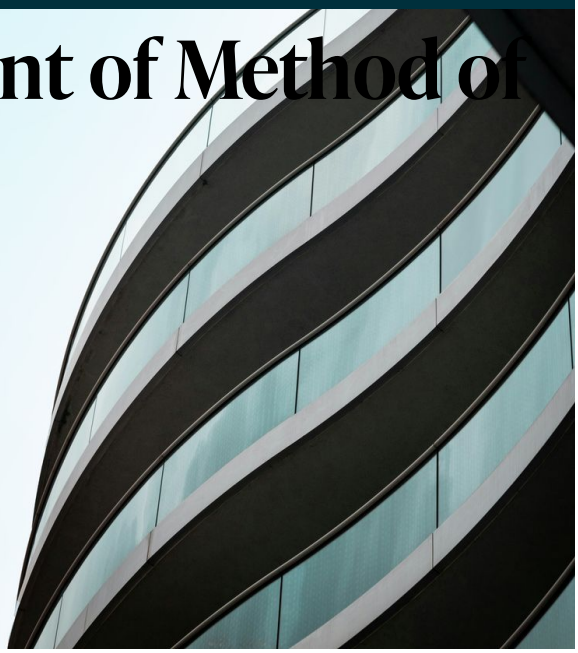
The Skinny on Infringement of Method of Treatment Claims



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By: Rebecca L. Clegg

In Hatch-Waxman litigation, method of treatment patents present unique infringement issues. Because generic drug manufacturers typically do not treat patients, patentees frequently allege induced or contributory infringement. The Federal Circuit's precedential opinion in *H. Lundbeck A/S v. Lupin Ltd.* narrows the grounds on which brand product manufacturers can allege infringement of method of treatment patents, particularly when the ANDA applicant seeks approval for "skinny" labeling.

The brand drug Trintellix (vortioxetine) is FDA approved for the treatment of major depressive disorder ("MDD") in adults. After receiving FDA approval, the plaintiffs obtained two new method of treatment patents – one for the treatment of MDD in patients who have previously taken an antidepressant and had to stop or reduce their use of it due to sexually related adverse events ("the '096 patent"), and one for treatment of cognitive impairment ("the '910 patent"). Plaintiffs alleged that defendants' ANDA applications seeking approval to market vortioxetine for the treatment of MDD in adults infringed these later patents directed to narrower or altogether different methods of treatment. Both Judge Stark (when he was still a district court judge) and the Federal Circuit disagreed.

The Federal Circuit affirmed Judge Stark's finding that defendants did not induce infringement of the '096 patent directed to a method of treating MDD in a particular population. Plaintiffs' only inducement evidence was the proposed labels for the ANDA products, which matched

the label that FDA required for Trintellix before the issuance of the new method of treatment patents. The defendants' carve out of the additional clinical study data relating to the '096 patent meant that there was no instruction that encouraged an infringing use. Thus, Judge Stark found that the label could not induce infringement of the '096 patent's narrow method of treatment claims. In addition to finding no error in Judge Stark's findings, the Federal Circuit further explained that a patentee cannot "bar the sale of a drug for a use covered only by patents that will have expired simply by securing a new patent for an additional, narrower use."

Turning to plaintiffs' contributory infringement claims, the Federal Circuit held that the "substantial noninfringing use in section 271(c) refers to the uses that do not infringe the [asserted] patent in question, not other patents." The Federal Circuit thus found no error in Judge Stark's conclusion that there was no contributory infringement of the new '096 and '910 patents because there were substantial noninfringing uses of vortioxetine that fell outside those narrow claims, including, for example, prescribing it to patients who had no prior treatment or who had no cognitive impairment.

Raised for the first time on appeal, the Federal Circuit also addressed plaintiffs' argument that merely filing an ANDA was sufficient to establish infringement of the new method of treatment patents under § 271(e)(2)(A) because the labels do not prohibit prescribing the drug for other patented uses. The Federal Circuit, citing *Warner-Lambert Co. v. Apotex Corp.* and its progeny, explained that "actions for infringement of method of use patents under section 271(e)(2)(A) are limited to patents that claim an indication of the drug for which indication the [ANDA] application is seeking approval." 316 F.3d 1348, 1361 (Fed. Cir. 2003). The Federal Circuit accordingly affirmed Judge Stark's finding that the defendants only sought approval to market the drug for the treatment of MDD – not the narrower methods of treatment claimed in the new patents – and thus plaintiffs had no independent basis for alleging infringement.

This case is a reminder to patent litigants that a proper "skinny" ANDA label can avoid induced and contributory infringement of some method of treatment claims. Although brand drug manufacturers may supplement their patent portfolio by obtaining new method of treatment patents after getting FDA approval, the listing of those patents in the Orange Book alone is insufficient to establish liability. Instead, a more exacting analysis that considers the scope of the new method of treatment claims in relation to both the approved indications and the proposed generic product's label is required, particularly where the ANDA applicants have carved out a patented use via a section viii statement.

> **A patentee may not use Hatch-Waxman to "maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA."**
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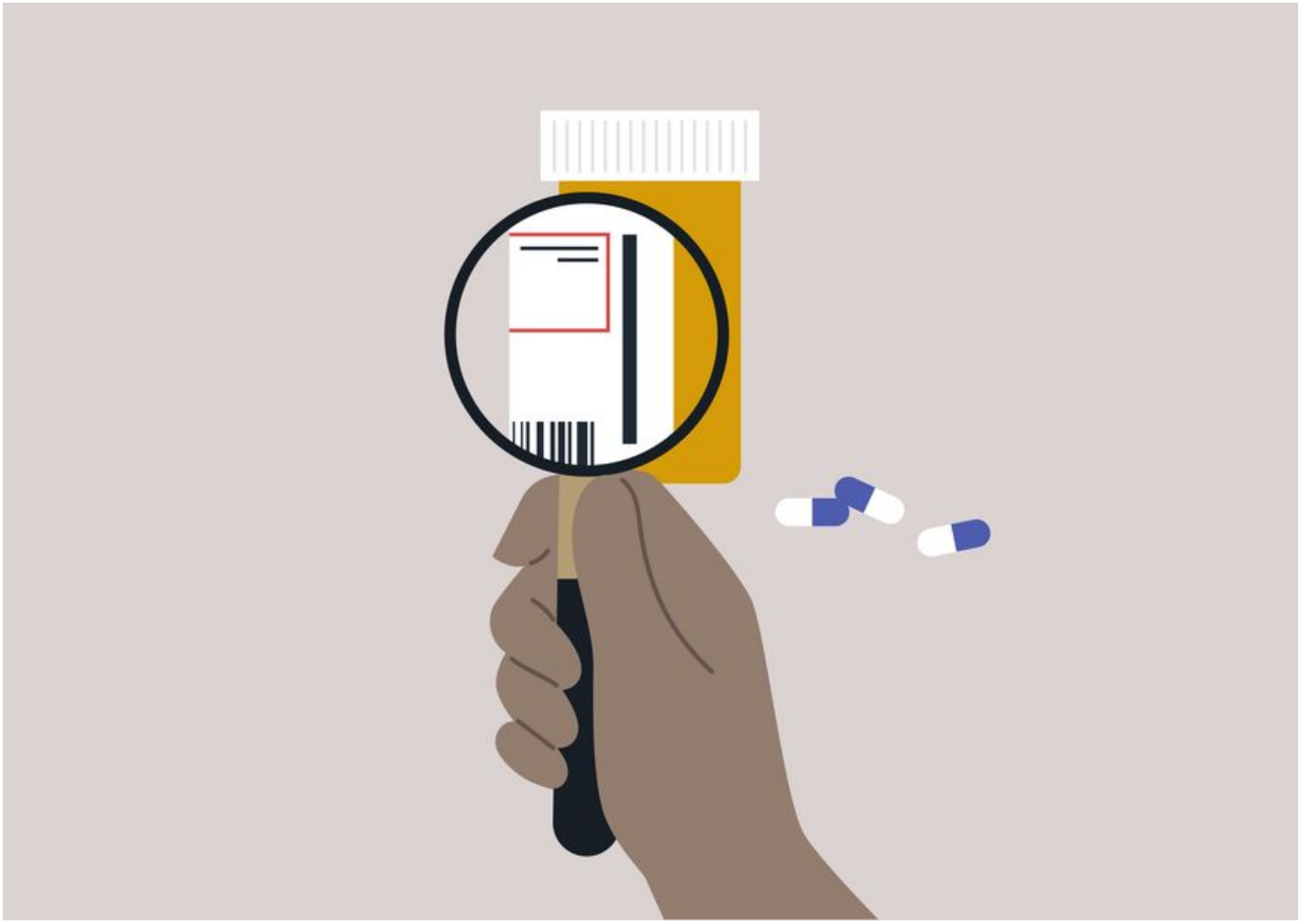

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