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The Skinny Labeling Saga Continues

WRITTEN BY

Alan B. Clement | Jeremy Murphy

Generic and branded drug manufacturers may soon have long-awaited answers from the Supreme Court regarding skinny labeling practices. On January 16, the Supreme Court granted a generic company certiorari in *Amarin Inc. v. Hikma Pharm. USA, Inc.* following the U.S. solicitor general's submission of its brief on skinny labeling.

Skinny labeling — the practice of carving out patented indications in an attempt to avoid inducing infringement — is a core issue in the case. Since last fall, industry players have been waiting with bated breath for the case to potentially provide clarification regarding the impact of advertising and other marketing activities on a generic manufacturer's use of a skinny label to avoid induced infringement of method-of-treatment patents.

The Solicitor General's Brief

The solicitor general's brief emphasized the balance Congress struck in enacting the Hatch-Waxman Act: promoting access to affordable generic drugs, while ensuring that patent rights are protected. Consistent with the carve-out prescribed in 21 U.S.C. 355(j)(2)(A)(viii) (skinny labeling or section viii carveout), the solicitor general stressed that generic manufacturers should be able to market products for nonpatented indications without the threat of patent infringement liability.

The solicitor general urged the Supreme Court to grant certiorari and reverse the Federal Circuit's decision denying the generic manufacturer's motion to dismiss, arguing the complaint failed to identify specific, affirmative steps that a generic manufacturer took to induce health care providers to use the generic drug for the patented cardiovascular indication. The solicitor general argued the complaint was deficient because: (1) the label content is consistent with a lawful section viii carve-out, (2) advertising statements regarding bioequivalence and AB-rating statements informed health care providers of substitutability for approved indications, and (3) other marketing-type statements were in the context of press releases directed primarily at investors, not health care providers. According to the solicitor general, these statements alone do not satisfy the pleading standard for inducement.

In its response brief, the branded manufacturer maintained that it met the applicable pleading standard at the motion to dismiss stage and contended that the Federal Circuit's decision poses no threat to section viii carve-outs. The brand manufacturer framed the issue as a factual question of intent based on marketing and advertising that went beyond the skinny labeling, arguing that there is no legal question warranting Supreme Court review and that its allegations must be accepted as true at the motion to dismiss stage.

Conclusion

Now that the Supreme Court has granted certiorari, we may get clarification on the effect of a generic manufacturer's use of the skinny labeling procedure and how other marketing and advertising impact the inducement analysis.

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