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LEGAL ALERT

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"Safe Harbor" Provisions of Hatch-Waxman Offer Protection for Certain Post-Approval Activities

After finding that the Hatch-Waxman Act's "safe harbor" provision protects "post-approval studies that are 'reasonably related to the development and submission of information under a Federal law,'" a split panel of the U.S. Court of Appeals for the Federal Circuit vacated a preliminary injunction blocking the sale of a generic version of LOVENOX® (enoxaparin injection) by Amphastar Pharmaceuticals, Inc. and Watson Pharmaceuticals, Inc., because the generic drug makers' protected post-FDA approval activities did not infringe a Momenta Pharmaceuticals, Inc. patent (*Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, No. 2012-1062 (Fed. Cir. Aug. 3, 2012)).

Momenta is the assignee of U.S. Patent No. 7,575,886, which recites "methods for analyzing heterogeneous populations of sulfated polysaccharides," such as enoxaparin, the active ingredient in LOVENOX® used to prevent deep vein thrombosis. Momenta, collaborating with Sandoz, Inc., was the first company to bring a generic version of Sanofi-Aventis' developed LOVENOX® to market. Momenta filed suit to block Amphastar asserting that the competing generic drug maker used Momenta's patented method to analyze commercial batches of enoxaparin after obtaining FDA approval. The FDA, however, required Amphastar to conduct a laboratory determination of the identity and strength of the active ingredient for each batch of enoxaparin." Therefore, Amphastar's batch testing was necessary for the post-FDA approval sale of the generic drug.

While acknowledging that Amphastar used the patented method to develop information for possible submission to the FDA, the district court found that the safe harbor provision "does not permit a generic manufacturer to continue in otherwise infringing activity after obtaining approval" (slip op. at 9). Since Amphastar's post-approval activities likely infringed Momenta's patent, the district court granted a preliminary injunction, halting Amphastar's production of enoxaparin.

Amphastar challenged the district court's restrictive view of the "safe harbor" provision in the Federal Circuit. Judge Moore rejected the district court's interpretation of 35 U.S.C. § 271(e)(1), stating that "[a]s long as the allegedly infringing use is 'for uses reasonably related' to the development and submission of . . . information [under a Federal law] it is not an act of infringement, regardless of where that requirement resides in law" (slip op. at 14). This broad interpretation prevented Momenta from establishing a likelihood of success of proving infringement, because Amphastar's post-approval activities were "reasonably related" to the FDA's requirement that each batch of enoxaparin be tested. Accordingly, the Federal Circuit vacated the preliminary injunction.

This decision met a stiff challenge in Chief Judge Rader's dissent, in which he concluded, in part, that Judge Moore's opinion ignored the binding precedent of *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), an opinion written by Judge Newman, with Chief Judge Rader concurring. In *Classen*, the Federal Circuit held that the "safe harbor" provision "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained" (slip op. at 18). In view of this holding, Chief Judge Rader stated that the current decision "cannot be genuinely reconciled with *Classen*," and that an *en banc* panel of the Federal Circuit should resolve whether the "safe harbor" provision protects post-approval activity.

Instead of an *en banc* Federal Circuit, this issue may be resolved by the U.S. Supreme Court. A petition for *certiorari* in *Classen* is pending (*GlaxoSmithKline v. Classen Immunotherapies*, Supreme Court No. 11-1078), and the Court recently invited the Solicitor General to provide advice on the "safe harbor" provision. Meanwhile, the seemingly inconsistent holdings in *Classen* and *Amphastar* may increase the likelihood that the Supreme Court will grant the petition for *certiorari* in *Classen*.

Resolution of this issue is important to the pharmaceutical industry, because innovator brand companies and, as here, competing generic companies, must increasingly rely on these downstream manufacturing analytical patents for market protection in the face of expiring traditional active pharmaceutical ingredient, composition and method of use patents, and particularly for protecting against future biosimilar biologics competitors. Until the Supreme Court or the Federal Circuit sitting *en banc* settles the issue, it will be difficult for patentees and generic drug manufacturers to determine the scope of the "safe harbor" provision for post-approval activities.

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If you have any questions about this Legal Alert, please feel free to contact either of the attorneys listed below or the Sutherland attorney with whom you regularly work.

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