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Supreme Court Declines Opportunity to Clarify Scope of Hatch-Waxman Safe Harbor

The U.S. Supreme Court on Jan. 14, 2013, denied GlaxoSmithKline's petition for certiorari seeking review of the Federal Circuit's interpretation of the Hatch-Waxman safe-harbor provision at 35 USC 271(e)(1) in *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057 (Fed. Cir. 2011). GSK sought reversal of the Federal Circuit's holding that the scope of the safe harbor is limited to activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, and that 271(e)(1) "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained."

The Court's decision follows the Solicitor General's advice that the *Classen* case was not a good vehicle for review of the scope of the safe harbor, given its facts and in light of the Federal Circuit's subsequent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). The Solicitor General endorsed the Federal Circuit's narrow construction of *Classen* in the *Momenta* decision, as well as the court's observation in *Momenta* that the "plain language of [35 USC 271(e)(1)] is not restricted to pre-approval activities." In light of the Solicitor General's brief, the Supreme Court's decision to deny certiorari should not be taken as endorsement of the *Classen* court's argument that the safe harbor is limited to pre-approval activities.

The Solicitor General's arguments in its brief filed in the *Classen* case also suggest that further Supreme Court guidance may be needed regarding the scope of activities covered by the 271(e)(1) safe harbor for infringement "solely for uses reasonably related to the development and submission of information" to the FDA. The *Momenta* case squarely addressed this issue, and following the Federal Circuit's Nov. 20, 2012, decision denying rehearing en banc in *Momenta*, further development of this issue is likely in 2013.

Further discussion of the briefing in connection with the petition for certiorari in *Classen* is provided [here](#).

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Patent Litigation Department

| | | |
|--------------------|-------------------|--------------|
| BRIAN G. ARNOLD | BARNOLD@LOEB.COM | 310.282.2160 |
| LANA CARNEL | LCARNEL@LOEB.COM | 312.464.3191 |
| KATHLEEN M. GERSH | KGERSH@LOEB.COM | 212.407.4287 |
| JOHN M. GRIEM, JR. | JGRIEM@LOEB.COM | 212.407.4182 |
| JOSHUA H. HARRIS | JHARRIS@LOEB.COM | 212.407.4275 |
| ADAM G. KELLY | AKELLY@LOEB.COM | 312.464.3138 |
| WILLIAM J. KRAMER | WKRAMER@LOEB.COM | 312.464.3350 |
| EVELYN M. KWON | EKWON@LOEB.COM | 212.407.4038 |
| JULIE L. LANGDON | JLANGDON@LOEB.COM | 312.464.3196 |

| | | |
|-----------------------|----------------------|--------------|
| LEILY LASHKARI | LLASHKARI@LOEB.COM | 212.407.4962 |
| WARREN K. MACRAE | WMACRAE@LOEB.COM | 212.407.4098 |
| JORDAN A. SIGALE | JSIGALE@LOEB.COM | 312.464.3109 |
| JENNIFER B. STRONG | JSTRONG@LOEB.COM | 212.407.4111 |
| CHRIS M. SWICKHAMER | CSWICKHAMER@LOEB.COM | 312.464.3136 |
| WILLIAM J. VOLLER III | WVOLLER@LOEB.COM | 312.464.3143 |
| MARK E. WADDELL | MWADDELL@LOEB.COM | 212.407.4127 |
| LAURAA. WYTSMA | LWYTSMA@LOEB.COM | 310.282.2251 |
