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Supreme Court Denies Review in Hatch-Waxman Case

- Supreme Court declines to take up Amphastar's invitation to review contours of safe harbor provision
- Patent litigators say high court's declination of review may affect biosimilar makers

By Dana A. Elfin

Oct. 3 -- Patent lawyers won't be getting additional clarity from the U.S. Supreme Court any time soon on the boundaries of the Hatch-Waxman Act's "safe harbor" provision (*Amphastar Pharms., Inc. v. Momenta Pharms., Inc.*, U.S., No. 15-1402, petition denied 10/3/16).

In an Oct. 3 order, the high court denied review of a petition filed by Amphastar Pharmaceuticals Inc. that asked whether the Federal Circuit properly interpreted the scope of the safe harbor in a case involving a process patent for testing the anticoagulant drug Lovenox.

The Supreme Court's rejection of the petition means that a fuzzy area of the law governing generic pharmaceuticals will remain unclear, and it also means potential obstacles for makers of biosimilars.

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an already-approved biological product, known as a reference product. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product.

"The potential impact for makers of biosimilars is that branded companies could use similar process patents [to the one in the Lovenox case] as a way of stifling biosimilar development," patent attorney Shashank Upadhye told Bloomberg BNA Oct. 3. Upadhye is with Amin Talati Upadhye, LLP's Chicago office.

Safe Harbor Still Fuzzy.

The Hatch-Waxman Act's safe harbor is important to companies on both sides of pharmaceutical patent litigation because it can exempt from infringement liability any activity that's "reasonably related to the development and submission of information" to the Food and Drug Administration. The harbor is typically used by generic companies that perform certain activities prior to the market launch of their products.

In the ruling that the Amphastar petitioners wanted the high court to review, the U.S. Court of Appeals for the Federal Circuit held that the safe harbor didn't apply to information that may be

“routinely reported” to the FDA after marketing approval . This meant that the safe harbor's protection from infringement liability didn't extend to Amphastar's ongoing bioequivalence testing for its generic version of Lovenox. In this case, the patent in question was Momenta Pharmaceuticals Inc.'s patent on a process to ensure that generic anticoagulant enoxaparin met quality standards.

Amphastar argued that it was important that the high court clarify the scope of the safe harbor provision because of the growing number of Hatch-Waxman cases involving biosimilar generics that have similar testing requirements to enoxaparin.

Amphastar also argued that the word “routine” is nowhere in the statutory text and conflicts with the intent of the Hatch-Waxman Act.

“The Federal Circuit has created the categories of 'routine' and 'non-routine' to narrow the scope of the wide berth of the safe harbor,” Upadhye said.

Blocking Competition.

The Federal Circuit's ruling in the *Momenta* case, Upadhye said, “breathed some life into the notion that certain process patents may be used to patent standards the FDA may require or want” applicants to use.

Now that the ruling won't be disturbed, it could be used by owners of patent portfolios covering tests, assays and diagnostics to block competition, he said.

“The Federal Circuit,” he said, “seems to have embroiled itself in adding value to certain patents by concocting rules to protect them.”

Future Issues.

And while the safe harbor's application to pre-marketing activities appears pretty settled, “what the courts are wrestling with is post-marketing activity,” Andrew M. Alul, a patent litigator with Taft Stettinius & Hollister LLP in Chicago, told Bloomberg BNA in an Oct. 3 e-mail.

“[T]he critical issue becomes whether the post-marketing activity was really related to obtaining FDA approval for something, or was simply routine testing related to the commercial production process,” he said.

In the *Momenta* case, Alul said, the Federal Circuit “felt that the patented Quality Control testing carried out post-marketing was more in line with the latter and therefore did not qualify for safe harbor protection.”

But Alul said not to read too much into the Supreme Court's refusal to review the petition in the *Momenta* case. “It may just be that the Supremes felt this issue didn’t affect that many litigants and therefore didn’t rise to the threshold level of importance,” he said.

Eye on *Classen* Case.

Nevertheless, Alul said practitioners should keep an eye on the *Classen Immunotherapies* case.

In that case, the U.S. District Court for the District of Maryland, on remand from the Federal Circuit, ruled Sept. 27 that Elan's provision of information on the safety and efficacy of Skelaxin to the FDA fell within the safe harbor provision.

The information submission related to a revision to Skelaxin's product label and proposed changes to the approval requirements for generic versions of the drug.

“[T]here’s most likely going to be an appeal here,” Alul said.