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Recent Exclusivity Rulings Favor Generic Filers

Generic drugmakers would be wise to weigh recent FDA decisions upholding 180-day exclusivity when planning their patent challenge strategies, legal experts say.

In a Jan. 17 letter to Teva Parenteral Medicines, the agency agreed that Teva is entitled to 180 days of exclusivity for generic Kytril (granisetron HCl), even though it failed to begin marketing the product within 30 months of submitting its ANDA (*Generic Line*, Feb. 6). Similarly, in a Jan. 29 letter, the FDA decided that Cobalt Pharmaceuticals' Paragraph IV certification for Altace (ramipril) remains intact, despite the company's settlement with King Pharmaceuticals, which involved a delayed generic entry date.

These decisions show — despite what many thought after Congress passed the Medicare Modernization Act (MMA) in 2003 — that exclusivity parking is still possible, Chad Landmon of Axinn, Veltrop & Harkrider said last week at an FDAnews audioconference.

Before the MMA, brand companies would often settle with first filers, delaying market entry not only of the first generic but of subsequent generics as well, Landmon explained. To fix this parking of exclusivity, Congress passed the MMA, which contained provisions under which a first filer forfeits its exclusivity.

Under the MMA, the first applicant forfeits its 180-day exclusivity if it doesn't launch its product by certain deadlines. With respect to Teva's generic Kytril, the FDA decided that, even though the firm didn't begin selling its product within 30 months of filing its ANDA, Roche could still decide to sue Teva or delist its patent from the Orange Book, potentially creating a later launch deadline.

A first filer also forfeits its exclusivity if it withdraws its Paragraph IV certification or enters into a settlement that violates antitrust laws. But in the Altace example, the FDA decided that Cobalt and King's settlement does not force Cobalt to amend its Paragraph IV certification. Additionally, a court has not found the agreement in violation of antitrust laws.

These recent examples show that the MMA did not weaken the generic exclusivity period, Landmon said. He recommended that generic firms should challenge patents early and consider challenging just one patent, for exclusivity is linked to the product as a whole.

Companies also should seek first-to-file opportunities even where there is a blocking patent that expires later than 30 months after filing. "According to FDA, it is not the case that you'll lose your exclusivity in that situation," he said.

The decisions also indicate that generic filers should consider settlements with delayed entry dates. "I think there are opportunities to settle patent cases in a way that is easier, because there can be a way to do it past 30 months and keep exclusivity," Landmon said.

However, Michael Keeley, also of Axinn, Veltrop & Harkrider, noted that the FTC is on the lookout for settlement agreements that involve reverse payments.

Keeley said a settlement that involves both a reverse payment and parked exclusivity is likely to catch the FTC's attention, as evidenced by the agency's recent lawsuit against Cephalon. On the other hand, settlements involving only delayed entry are almost always found to be lawful.

It is likely that a court will eventually clarify the exclusivity forfeiture issues, and the Supreme Court may one day decide to address reverse payment agreements. Until then, Landmon and Keeley recommended that generic drugmakers plan their patent challenge strategies around these recent FDA exclusivity decisions and consider antitrust risks before entering agreeing to settlements.— Breda Lund