IP LAW360

Portfolio Media, Inc. | 648 Broadway, Suite 200 | New York, NY 10012 | www.law360.com
Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Exclusivity Parking Still Possible Under Teva Ruling

By **Sara Stefanini** , sara.stefanini@portfoliomedia.com

Tuesday, Apr 29, 2008 --- The U.S. Food and Drug Administration's finding this year that Teva Parenteral Medicines Inc. would not have to renounce its exclusivity window for its generic granisetron cast light on certain holes in the Medicare Modernization Act of 2003 that could allow generic-drug makers to continue “parking” their exclusivity past the forfeiture deadline the legislation attempted to set.

By stating that Teva had not forfeited its exclusivity period for the generic version of Hoffmann-La Roche Inc.'s Kytril, which treats nausea from chemotherapy, the FDA letter ruling in January sparked off a debate among attorneys.

While some argue that the regulator read the MMA language almost too literally, others note that Congress failed to consider all potential situations that could arise when generics makers submit abbreviated new drug applications.

“I think it's a sensible interpretation of the language of the statute,” said Aaron Barkoff, a partner at McDonnell Boehnen Hulbert & Berghoff LLP who counsels pharmaceutical and biotechnology companies on patent matters. “The statute is not very clear; I don't think Congress anticipated this situation when it wrote the statute.”

But the ruling effectively countered the goal that Congress made explicit when it passed the MMA: to stop generic-drug makers from parking their 180-day exclusivity period by setting provisions that would require the companies to give up that edge on rival generics, some attorneys countered.

Despite the fact that Teva missed the 30-month deadline for putting its generic granisetron on the market and holding on to its exclusivity rights, the FDA determined that the company would not have to forfeit the 180-day period because the second of the two forfeiture provisions in the MMA had not yet taken place.

Since Roche had not taken legal action for patent infringement, a court had not yet ruled on the matter, but the possibility that it eventually would was still there, the FDA found.

“The FDA took a very literal reading of the statute and said, 'The court decision still hasn't occurred, so there hasn't been a forfeiture,'” said Chad Landmon, a partner at Axinn Veltrop & Harkrider LLP who focuses on

intellectual property litigation and food and drug law. “What it did was say that there will almost never be a forfeiture for failing to go to market within 30 months. That's generally understood to not be the way Congress intended the statute to be interpreted.”

Since Congress passed the Hatch-Waxman Act in 1984, the first generics maker to lodge an ANDA asserting that either its drug does not infringe the patent protecting the brand-name medication or that the patent is invalid and unenforceable, gets a six-month exclusivity period during which other generics makers are barred from competing.

Under the law, the generics company's exclusivity clock begins ticking as soon as its product reaches store shelves or as soon as a court rules in the company's favor, whichever of the two events comes first.

This, however, presented at catch-22 for generic-drug makers, Landmon said. The company could launch its generic medication at the risk that an appellate court would later reverse a lower court decision, or wait for the appeals court to rule at the risk of losing its exclusivity window.

As a result, first-filer generic-drug makers would often strike a pact with the brand-name company, agreeing to delay sales of the competing product while holding on to, or parking, their six-month exclusivity and blocking other generics from coming in.

To thwart this bottleneck, lawmakers passed the MMA in 2003, which amended the trigger for the generic exclusivity period and set provisions that would force a generics maker to renounce its exclusive rights if it hadn't put its product on the market within 30 months.

According to the new law, the generic would have to forfeit its exclusivity either following an appeals court ruling on a patent dispute or 30 months after the generics maker submitted its ANDA, whichever happened later.

“Most of the MMA changes were in favor of generics,” Landmon said. “The biggest pitfall had to do with these forfeiture provisions.”

The granisetron case, however, cast light on circumstances that the MMA failed to account for — when a generics maker's ANDA asserts both Paragraph IV and Paragraph III certifications.

Teva's ANDA, filed in May 2004, asserted a Paragraph IV certification regarding U.S. Patent Number 6,294,548 and a Paragraph III certification to U.S. Patent Number 4,886,808, claiming that the company would not be challenging the patent and would wait for it to expire on Dec. 29, 2007.

In a letter to the FDA in September, Teva argued that because Hoffmann-La Roche had not yet commenced a patent infringement suit against the generics maker, and because Teva had to wait until the '548 patent expire, it had a right to hold on to the exclusivity period even though 30 months had

passed.

“That is so because the statute provides that a first applicant's exclusivity is forfeited only upon 'the later of' two potential events (or 'forfeiture triggers'),” Teva said in its letter. “While one of those events has occurred in this case (30 months have passed since Teva submitted the first Paragraph IV ANDA for generic granisetron), there is an ongoing possibility that a 'later' forfeiture event could be triggered.”

Since the FDA has not issued a rule under the MMA, it based its letter ruling on the statute's language and sided with Teva.

“The 'failure to market' provision results in forfeiture when there are two dates on the basis of which FDA may identify the 'later' event as described in Section 505,” the FDA said. “This is not a situation in which it would be impossible for a later event to occur.”

Teva's case, and the fact that its ANDA asserted both Paragraph III and Paragraph IV certifications, is not entirely unusual or unique, attorneys said. As long as the FDA letter ruling remains standing, it is likely to set a precedent for future cases, they added.

“I think the interpretation that FDA has provided, until it is challenged, is what we have to go by,” said Amanda Kessel, a patent litigator at Woodcock Washburn LLP. “The way the statute was written, forfeiture is triggered by the occurrence of the later of two events. Here, the first event had already occurred, but the possibility existed that the second event, which could be a final court decision or a settlement order, could still happen in the future.”

While it is clear that Teva did not intend to park its exclusivity — as the FDA noted, the company initiated commercial marketing as soon as it obtained final approval — the ruling does leave room for exclusivity parking, despite the efforts in Congress to abolish it, attorneys noted.

A generics company seeking to hold on to its 180-day exclusivity period while keeping rivals away could theoretically file a Paragraph III certification for a patent that is not set to expire for several years and avoid being hit with a patent infringement suit for its Paragraph IV certification.

“Just the possibility that an infringement suit or a declaratory judgment action could be filed in the future would be enough under the writing of the current statute to allow first-filers to maintain their exclusivity rights,” said Dianne Elderkin, a partner and patent litigator at Woodcock Washburn. “It appears that there is still the potential for abuse.”

If the FDA continues to follow the precedent set in its letter ruling to Teva, most attorneys expect the decision to eventually be appealed in court. Meanwhile, the decision eases the race to get to market in time to keep a six-month exclusivity period for generic-drug makers, but it may force brand-name-drug makers to rethink their litigation strategy, attorneys said.

"For generics, it alleviates a concern, because they can file their ANDA with a Paragraph III certification on one patent and Paragraph IV certification on another, even if there are more than 30 months before the Paragraph III patent would expire," Barkoff said. "If the decision had come out the other way, a generic drug would have to wait until they are within 30 months of Paragraph III patent expiration before they can file an ANDA."