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Latham Wins One for Orphan Drug

By Jenna Greene
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Who doesn't root for orphan drug makers? That is, when pharmaceutical companies dump money into developing medications to treat rare diseases that afflict only a handful of people. It's like pro bono for Big Pharma.

Or … not exactly. Because in return for these less-than-profitable endeavors, drugmakers can ask the Food & Drug Administration for seven years of market exclusivity as a reward.

But how far does this benefit stretch? What if the drug in question isn't new, but instead is an improvement on an existing treatment? Does that count too?

That was the question before U.S. District Judge Timothy Kelly in Washington, D.C. On Friday, he sided with Latham & Watkins client Eagle Pharmaceuticals, ruling that its drug Bendeka, which treats two rare lymphocytic cancers, is entitled to orphan drug exclusivity.

Bendeka has the same active ingredient as another orphan drug, Treanda, owned and marketed by a subsidiary of Teva Pharmaceuticals. (Oh, and Teva is now marketing Bendeka for Eagle.) But Eagle and its lawyers from Latham—Philip Perry, Andrew Prins and John Manthei—stress that Bendeka is formulated differently than the original drug.

Bendeka takes less time to administer; injecting it requires less fluid and sodium; it's more compatible with common medical devices, and it's got a longer shelf life. Eagle spent $30 million to develop and test it before bringing it to market.

Nonetheless, the FDA denied Eagle seven-year orphan drug exclusivity, noting that Bendeka has not in fact been proven to be clinically superior to Treanda.

"Eagle's drug, Bendeka, is the same as a previously approved drug that received its own exclusivity eight years

ago. That exclusivity has since expired," wrote Justice Department trial attorney Alexander V. Sverdlov in court papers. "FDA regulations logically give effect to the 'expiration' of exclusivity, by making exclusivity unavailable to a second-in-line drug—thus ensuring that exclusivity cannot be invoked in a way that would restrict approval of the same drug after the initial seven year period."

Sverdlov added, "[B]ecause Bendeka unquestionably has the same active moiety as Treanda, Eagle cannot obtain exclusivity unless it demonstrates that Bendeka is a clinically superior drug."

On June 8, Kelly sided with Eagle, and ordered the FDA to recognize orphan-drug exclusivity for Bendeka. His opinion is under seal until June 20, so we don't yet know his reasoning—but one thing is clear: This is a big win for Eagle and its team from Latham.

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