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Axinn FDA Update: A Difficult Analysis Is Not Necessarily a Deferential Analysis

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ATTORNEYS

Landmon, Chad

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Intellectual Property

Chad A. Landmon
Axinn Update

The District Court for the District of Columbia in *Genus Lifesciences, Inc. v. Azar* recently held that new chemical entity ("NCE") exclusivity only blocks others from *submitting* an application, but it does not prevent FDA from *approving* an application during that period of exclusivity. Although this may be a "loophole," as the court acknowledged, the court found that the statutory language makes clear that any application may be approved so long as the application is submitted before NCE exclusivity begins.

Typically, this conclusion would be the main headline, but we're more excited to discuss *how* the court reached this conclusion. Having followed the continuing debate surrounding agency deference over the past years, we anticipated that the Supreme Court's decision in *Kisor v. Wilkie* would put lower courts on notice to employ every tool of statutory interpretation before granting deference. We've written on several case developments since *Kisor* was issued, but no case demonstrates this better than *Genus Lifesciences*.

Genus submitted a 505(b)(2) "paper" NDA for Goprelto in 2016, and FDA approved the application in December 2017. Just days before that approval, however, Lannett submitted its own paper NDA for a product with the same active ingredient. In January 2020, FDA approved Lannett's application. Genus argued that this approval was prohibited because its 5-year NCE exclusivity was still in effect. Upholding FDA's decision, the court disagreed with Genus's argument. Instead of deferring to FDA's interpretation, however, the court analyzed the statutory language so closely that you might think you're back in English class.

The statutory provision at issue is comprised of two sentences containing more than two hundred sixty words. Although the court admitted that making sense of this provision would be difficult, difficulty "does not necessarily equate to ambiguity." The court systematically identified the conditional clause, the main clause, and the exception clause and then

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deciphered the meaning of the terms as they relate to other statutory language. Although FDA's interpretation did not take such a systematic approach to deciphering the statute, FDA argued that it is not prohibited from *approving* an application during the 5-year exclusivity period but instead applications are prohibited from being *submitted* to FDA during the exclusivity period.

Although the court agreed with FDA's ultimate decision—Lannett had already submitted its application when Genus obtained exclusivity, and FDA was not prohibited from approving Lannett's application—the court disagreed with FDA's interpretation of the statutory language. Even when the ultimate outcome is the same, the directives of *Kisor* are clear: *all tools of construction* are to be implemented before proceeding to deference. If courts continue down this path, it will certainly be interesting to see how FDA and other federal agencies deal with increased court scrutiny of their statutory interpretations.

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