Federal Circuit Called on Once Again to Judge the 'Patent Dance'

Genentech is looking to block sales of Amgen's cancer biosimilar Mvasi because Amgen failed to provide 180 days notice when it shifted manufacturing plans from California to Rhode Island. Judge Kimberly Moore said Genentech proposing "an extraordinarily broad view" of the Biologics Price Competition and Innovation Act.

By **Scott Graham** (https://www.law.com/therecorder/author/profile/Scott-Graham/) | June 03, 2020 at 09:12 PM

Luke McCloud of Williams & Connolly/courtesy photo

A Federal Circuit panel seemed to resist Genentech Inc.'s efforts Wednesday to pull a generic Amgen Inc. cancer treatment off the shelves for six months.

Genentech told a Federal Circuit panel that Amgen failed to serve the 180-day notice of commercial marketing required by the Biologics Price Competition and Innovation Act when, in August 2018, it supplemented its Food and Drug Administration application for Mvasi, Amgen's biosimilar version of Genentech's $3 billion-a-year drug Avastin.

Roche-owned Genentech asked the Federal Circuit to enjoin Amgen from marketing Mvasi until it complies with the BPCIA, the 2009 law that established **"the patent dance" (https://pbs.twimg.com/media/CodjxejWYAATEgz.jpg)** for biosimilars.

Amgen gave notice when it first applied for FDA approval in 2017. U.S. District Judge Colm Connolly of the District of Delaware ruled last year that Amgen was not required to serve new notice when it supplemented that application. The

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supplement outlined plans to manufacture Mvasi at both Amgen's home base in Thousand Oaks, California, and at a Rhode Island facility. It also made revisions to the Mvasi label.

"As long as your supplement is a change to the existing license, and it is the same biological product, it would not trigger a new notice," MoloLamken partner Jeffrey Lamken argued on behalf of Amgen.

Williams & Connolly associate Luke McCloud argued that would let companies such as Amgen disclose "Potemkin versions" of their manufacturing process—"the version that implicates the fewest of the innovators' patents"—while keeping their real plans secret until close to launch. "Congress could not have intended to create a statutory scheme that could be so easily gamed," McCloud said.

McCloud gave a poised and polished argument in ***Genentech v. Immunex***, **(http://oralarguments.cafc.uscourts.gov/default.aspx?fl=19-2155.mp3)** which like all Federal Circuit arguments the last few months was conducted over the telephone. But Judge Kimberly Moore sounded wary from the outset.

"Suppose it was a very minor, minor, minor supplement, an ever-so-slight change in wording on the label that was really of no significance or consequence," she said. "You think that starts the 180-day clock over again, even if there were no change to the manufacturing facility, no change to the underlying product itself?"

McCloud argued that the clock would reset only on changes to the license that require FDA "pre-approval."

"What are we supposed to do?" asked Judge Kathleen O'Malley. "Make a determination as to what in each instance the FDA would decide needed approval?"

McCloud acknowledged that could occasionally pose challenges. But "that is an easy question to answer in this case," he said. "When they are making changes to the manufacturing facility and to the labeling that goes to the product, those are significant changes" that require FDA sign-off.

"To be clear, your view is an extraordinarily broad one," Moore told him.

Lamken and Amgen met some resistance too. O'Malley turned the argument around on him, asking, "Is it your position that there is no form of supplement that would ever trigger a new notice?"

Lamken said the court can defer to the FDA, which knows when changes to the product are so substantial as to require a new application.

"But isn't there possible mischief here," O'Malley asked him. The manufacturing process is often at the core of patent infringement allegations in biosimilar cases. "So doesn't this imply that there could be a bait-and-switch? You could say here that

e X process, and then turn around and use Y process at the last minute. Doesn't that create a potential problem?"

"I don't think so," Lamken replied, arguing that parties can typically learn that information via discovery. The BPCIA's notice provision "is a heads-up notice about launch. It's not an opportunity for further informational disclosures about the means of production."

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