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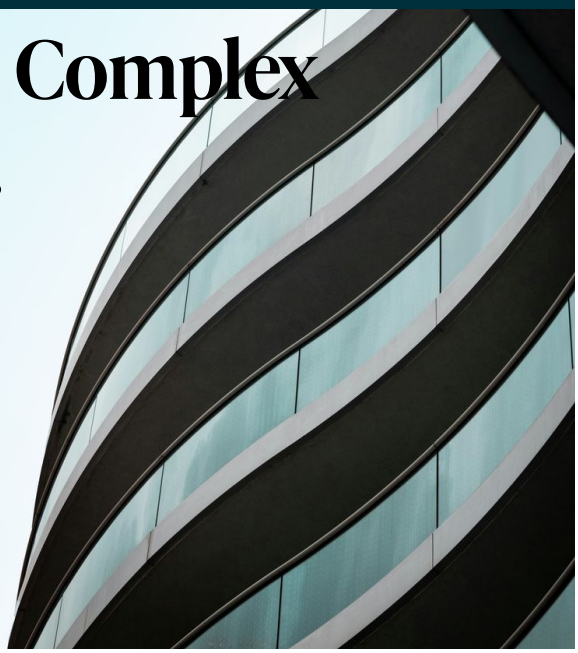
The Pleading Standard for Complex Technology? It's Complex.



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April 15, 2024, 9:43 AM
By: Ted Mathias

Can a patentee really just take a pass on alleging that an accused product meets a limitation in an asserted claim, even where the case involves complex technology? That's the upshot of the court's decision in *Lindis Biotech, GMBH v. Amgen, Inc.*, C.A. No. 22-35-GBW, 2024 WL 1299930 (D. Del. Mar. 27, 2024).

The independent claim at issue "requires administration of a trifunctional, bispecific immunostimulating antibody." This is plainly not a case with "simple technology," where the Federal Circuit has held that a patentee can provide less detail, such as identifying the accused products and "provid[ing] information 'akin to including photos' of the products," along with allegations that the products meet each limitation of an asserted claim. Here, the court explained that the patentee needed to do more – to allege facts plausibly indicating that an accused product meets each limitation of an asserted claim. What Lindis neglected to do, however, was allege that the accused product is "trifunctional." Sounds pretty grim for Lindis, right?

The court nevertheless adopted a more lenient standard. It pointed out that Amgen had "concede[d] that Lindis is not required to establish every element of Claim 1 to survive dismissal." But Amgen didn't "concede" that Lindis could get a pass on providing facts that could plausibly support an infringement finding on the "trifunctional" requirement. In the passage cited by the court, Amgen merely stated black-letter pleading law that a patentee

need not "establish that each element of an asserted claim is met." In other words, Lindis didn't need to "prove" its case in the complaint. But for the court, it was enough that "the Complaint connects elements from the [asserted patent] to elements of Amgen's accused product [and] puts Amgen on notice as to what activity is being accused and how that activity infringes [the asserted patent]."

The court's decision leaves substantial uncertainty in the pleading standard. How many limitations in an asserted claim can a patentee choose to address with conclusory allegations rather than actual facts? Is it enough to have the accused infringer dead to rights on all other limitations? I suspect that this case is going to be cited and argued over frequently in District of Delaware patent cases for some time.

> **While Lindis does not allege that Blincyto® is trifunctional, Amgen concedes that Lindis is not required to establish every element of Claim 1 to survive dismissal. Further, as noted above, the Complaint connects elements from the '421 Patent to elements of Amgen's accused product. The Court finds that, by doing so, the Complaint puts Amgen on notice as to what activity is being accused and how that activity infringes the '421 Patent.**
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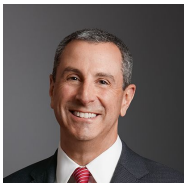

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