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Judge Invites a Patent ‘Sea Change’ With Plea to Upend Precedent

By Christopher Yasiejko

Deep Dive
Documents

Alnylam Pharms. Inc. v. Pfizer Inc. (D. Del., 22-cv-336)

- Upending case law on preambles could send lawyers scrambling
- Judge’s ruling dared appeals court to ‘jettison’ case law

A federal judge’s impassioned plea to substitute “common sense” for years of precedent governing how patents are interpreted in litigation would throw innumerable patents into limbo, attorneys say.

Judge Colm F. Connolly’s entreaty, in a Delaware district court decision regarding Covid-19 vaccines, focused on a line of cases at the US Court of Appeals for the Federal Circuit establishing that preambles in patent claims generally aren’t “limiting”—that they aren’t an essential part of the invention being claimed.

In patent litigation, the meaning of a single term can determine the fate of billions of dollars, and lawyers craft patent applications with that precedent in mind: Language setting the table for what's claimed is merely prelude. A claim's preamble usually won't bind the invention it purports to cover.

Connolly called for the Federal Circuit "to jettison its rulings that treat language in the preamble of a patent claim as not limiting the scope of the claim." If the appeals court heeds the request, attorneys said, it would cast doubt on exactly what is covered by patents issued under the existing framework.

"That changes everything," said Daniel L. Shores, a partner at Rothwell Figg who specializes in biotech and intellectual property law. "What we're talking about is a rabbit hole in patent law that we go down."

Connolly also leaned on "Alice in Wonderland" imagery in his Aug. 9 opinion that found "vaccine" is a limitation of two claims in US Patent No. 11,590,229—one of six patents Alnylam Pharmaceuticals Inc. alleges Pfizer Inc. and BioNTech SE's Comirnaty shots infringe. The word appears only in the preamble of each claim.

"The real culprit here," according to Connolly's ruling, "is a long line of binding Federal Circuit case law that has endorsed the Mad Hatter logic" of the premise of Alnylam's argument—"that a patent does not necessarily claim what it claims if what it claims is set forth in the claim's introductory words (i.e., the claim's preamble)."

"All the words of a patent claim should matter," the judge wrote.

Connolly's approach may find at least one amenable judge at the Federal Circuit, should this decision or another considering the preamble issue be appealed—his opinion quoted a 2010 dissent from Circuit Judge Timothy B. Dyk raising the issue.

"Neither the Supreme Court nor our court sitting *en banc* has ever addressed the preamble limitation issue," Dyk wrote more than a decade ago. "I think the time may have come for us to eliminate this vague and confusing rule."

'Downstream Consequences'

"It's quite unusual for a district judge to do something like this," said Mark Lemley, a Stanford University law professor.

Connolly's opinion quoted a passage from Lemley's 2020 Boston University Law Review article titled "Without Preamble" in which Lemley called the Federal Circuit's rules for interpreting preambles "an incoherent mess."

"It's also very important for a respected patent judge like Connolly to signal to the appellate court that they need to fix this mess," Lemley said.

The potential fallout if the Federal Circuit were to reconsider its precedent has some lawyers watching with caution.

Currently, if a patent claim's preamble merely describes the invention's purpose or intended use, it doesn't typically affect the patent's scope. And the narrower a patent's scope, the harder it is to prove infringement.

If that rule is cast aside, Shores said, "then certain issued patents with borderline preamble language could be in jeopardy of being more limited than the applicant intended when it was relying on the old standard."

Connolly "is confronting what he feels is an ambiguous area of the law, and he's confronting it with common sense," Shores said. Though it's "unlikely" the Federal Circuit follows Connolly's tack, doing so would create "unintended downstream consequences."

That could prompt lawyers to reassess clients' patent portfolios to identify which ones might suddenly be interpreted as much narrower than before.

It "would be a sea change in patent-prosecution practice," Shores said.

"If I knew that every word mattered, I would be more careful in word choice," said Nicole Morris, a professor at Emory School of Law. "How do I want to define this invention, and am I defining it broadly enough that it adequately protects what my client has invented, but, more importantly, gives me claim scope that I can enforce against competitors?"

Attorneys and their clients would be forced to decide whether to stand pat or try to reinforce potentially vulnerable preambles by applying for reissued patents, which would expose all the issued patent's claims to fresh validity assessments and restart the clock on the available pool of damages.

That potential fallout, and Connolly's clear exasperation, could lead to an expedited appeal of the Aug. 9 opinion.

"The Court's frustration with the existing case law is palpable," said Alan Fisch of Fisch Sigler. The Delaware district court regularly denies motions for interlocutory appeals, he said, but "this opinion could be read to be inviting one."

Attentive attorneys, though, might not be caught off-guard if the Federal Circuit ultimately sets its rule aside, Morris said. "Because practitioners know the line is somewhat fluid, you are mindful of what you put in the preamble."

She said there has never been a "straightforward, fairly transparent" rule on the matter.

"Most of patent law jurisprudence is, 'Well, you know, it depends,'" she said. "This would be an easy win for people, if we know, OK, all the words in a claim matter, period."

Covid ‘Vaccine’

Alnylam’s lawsuit is one in a swath of battles over billions of dollars in royalties for technology used to deliver the payloads of vaccines including Comirnaty and Moderna Inc.'s SpikeVax.

It isn’t clear why each side of the Comirnaty dispute considers it so important to determine whether “vaccine” is limiting, lawyers said. Alnylam spent 33 pages of its 96-page claim-construction brief arguing, unsuccessfully, that it isn’t.

To establish infringement, according to Connolly’s ruling, Alnylam must prove Pfizer’s Covid-19 shots are indeed vaccines. He wrote that if he hadn’t found “vaccine” to be limiting on the claims, “rational jurors would find it confusing, question my competency, and perhaps even laugh out loud” because he’d be telling them the two patent claims “do not claim what they explicitly claim.”

“The fact that the defendant wanted ‘vaccine’ to be a requirement would usually indicate that they think they don’t infringe because they don’t make a vaccine,” Lemley said.

But Pfizer doesn’t seem to be arguing Comirnaty isn’t actually a vaccine. And proving that it is for the purposes of infringement “may not be a big hurdle to clear” even under Connolly’s ruling, Shores said.

It’s possible that, like Connolly’s opinion, the true target of Alnylam’s argument lies beyond this specific lawsuit, Lemley said. He floated the possibility that the plaintiff might also be “targeting other formulations of the chemical for other uses.”

Morris, once the managing patent counsel at Coca-Cola Co. in Atlanta, said she thinks if the Federal Circuit weighs in, it would affirm Connolly’s decision.

She said she hopes the appeals court “will take up Connolly poking at them and clarify: When is a preamble limiting and when is a preamble not limiting?”

The case is Alnylam Pharms. Inc. v. Pfizer Inc., D. Del., No. 22-cv-336.

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