# Fed. Circ. In September: The Printed Matter Doctrine Expands

By **Jeremiah Helm and Sean Murray** (October 30, 2025)

*This article is part of a monthly column that highlights an important patent appeal from the previous month. In this installment, we examine the Federal Circuit's ruling in Bayer Pharma Aktiengesellschaft v. Mylan Pharmaceuticals Inc.*

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On Sept. 23, the U.S. Court of Appeals for the Federal Circuit decided Bayer Pharma Aktiengesellschaft v. Mylan Pharmaceuticals Inc., which involved an issue that often arises in patents directed to pharmaceutical products.

To obtain U.S. Food and Drug Administration approval for a new drug product, an applicant must provide clinical testing to demonstrate the safety and efficacy of the drug product. The results of such testing are submitted to the FDA in support of the drug's approval. Often, pharmaceutical companies seek patents based on those clinical testing results, including claims drawn to the clinical effects, or side effects, observed in the clinical trials.

Bayer involved one such patent directed to findings made during a clinical trial. The patent in Bayer was based on the results of a Phase III clinical trial that evaluated the safety and efficacy of administering a drug, rivaroxaban, either with or without aspirin, for the prevention of major adverse cardiac events.

The claims at issue were directed to a method of reducing the risk of myocardial infarction, stroke or cardiovascular death by administering the two drugs "in amounts that are clinically proven effective in reducing" those risks. The claims also recited a specific amount of rivaroxaban and a specific range of amounts of aspirin.

The amounts of rivaroxaban and aspirin were known, at least because the clinical trial protocols were published long before the patent application was filed. Mylan, and others, challenged Bayer's patent in an inter partes review proceeding at the U.S. Patent and Trademark Office's Patent Trial and Appeal Board.

Bayer defended against the patentability challenge by arguing the "clinically proven effective" requirement distinguished the prior publications of the clinical trial protocols because the protocols, unlike the patent, did not include the ultimate result demonstrating clinical efficacy. The board rejected that argument, and so did the Federal Circuit on appeal.

The Federal Circuit, however, did not adopt the board's reasoning and instead reached its conclusion by extending a line of prior cases related to instructions and written words. That line of cases involves what is sometimes referred to as the printed matter doctrine. Under that doctrine, simply adding new words to an existing product or method will not support patentability unless there is a functional relationship between the new words and the underlying substance of the claim.

In King Pharmaceuticals Inc. v. Eon Labs Inc., a 2010 Federal Circuit decision that the Bayer panel discussed, the court found unpatentable claims directed to a known method of

treatment that also added a step of informing the patient about a property of the drug. The court in King analogized those "informing" claims to similar issues raised by the printed matter doctrine. Even though the claims in King did not specifically involve printed matter, such as written instructions, the court applied the same printed matter doctrine analysis: whether the added instructional limitation has a "new and unobvious functional relationship" with the known method of administration.

The claims in Bayer, in contrast, did not merely inform the patient of effectiveness. Nevertheless, the Federal Circuit recognized that allowing the words "clinically proven effective" to determine patentability would have resulted in a pernicious situation where "one could claw back from the public domain an anticipated method of treatment merely by adding a limitation that the method subsequently performed well in a clinical trial."

In Bayer, the court reasoned, the limitation did not impose a functional restriction on the composition; instead, the limitation merely indicated that the composition had been proven to have clinical efficacy, i.e., it performed well in clinical trials. Under the court's reasoning, like King, the added limitation merely provided information about the underlying drug.

Bayer represents an extension of the printed matter doctrine beyond King's holding. Unlike King, which expressly involved informing the patient of the information, the relevant claim language in Bayer was "administering" the drugs "in amounts that are clinically proven effective in reducing the risk" of various conditions. That limitation would appear to be somewhat functionally related to the underlying method of administering the two drugs to achieve a clinical effect, and thus beyond the mere instruction to patients addressed in King.

Nevertheless, the Federal Circuit held the "clinically proven effective" limitation in Bayer "cannot breathe patentability into the challenged claims as a functionally unrelated limitation."

Many pharmaceutical patents include a limitation requiring the method of treatment or administration to be effective, and the Federal Circuit distinguished one of those in its Bayer analysis: Allergan Sales LLC v. Sandoz Inc. In that 2019 decision, the Federal Circuit considered a claim that required a method of treatment using two drugs, twice a day, be as effective as the administration of one drug three times a day, and also required the claimed method reduce the incidence of at least one adverse event.

Facially, the claims in Allergan seem very similar to those in Bayer because both are related to the safety and efficacy of a method that recites administering a drug. The patent in Allergan, like Bayer, also involved the results of a clinical trial. The Federal Circuit, however, distinguished Allergan because in Allergan the effectiveness limitation was found in a "wherein" clause.

The court explained that the wherein clause served to directly link the method of administration to meeting the safety and efficacy benchmarks. Accordingly, the efficacy requirement excluded methods that did not meet those benchmarks. That was enough to create a functional relationship between the result and the method and thus distinguish Allergan and Bayer.

The line between Bayer (no functional relationship) and Allergan (sufficient functional relationship) is unclear. In the short term, patent challengers, particularly in the abbreviated new drug application context, should consider raising arguments asserting that a claimed result of a clinical trial does not actually limit the underlying method, and therefore does not have the required functional relationship to breathe patentability into the

claim.

Patent holders should be mindful of establishing that the claimed results do provide a meaningful limitation on the claim's scope and be prepared to articulate that limitation as early as claim construction.

Moving forward, it will be interesting to see whether the Federal Circuit continues to apply the "functionally related" analysis, derived from the printed matter doctrine, in new contexts. For now, however, litigants should be aware that the functional relationship analysis extends beyond its traditional scope.

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