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Federal Circuit Examines Written Description Requirements for U.S. Patent Application Publications Used as Prior Art Under Pre-AIA

On March 24, 2025, a Federal Circuit panel consisting of Judges Moore, Stoll, and Cunningham issued a precedential opinion, authored by Judge Stoll, in *In re Riggs*, No. 2022-1945 (Fed. Cir. Mar. 24, 2025). Appellants in *Riggs* are the named inventors listed on U.S. Patent Application No. 11/005,678 (the "678 Application"). *Riggs*, slip op. at 2. They appealed, among other rulings, the Patent Trial and Appeal Board's determination that a published patent application qualified as prior art under pre-AIA 35 U.S.C. § 102(e)(1). *Id.*[1] The Federal Circuit vacated and remanded, finding that the Board did an incomplete analysis in determining whether the published application did, in fact, qualify as prior art under § 102(e). *Id.*

During prosecution of the 678 Application, the examiner rejected certain claims under pre-AIA 35 U.S.C. § 102(e)(1) as anticipated by U.S. Patent Application Publication No. 2002/0049622 A1 ("Lettich"), which claims priority to U.S. Provisional Application No. 60/200,035 ("the Lettich Provisional"). *Id.* at 5. Lettich qualifies as prior art to the claims of the 678 Application only if it is entitled to the priority date of the Lettich Provisional. *See id.* at 10. The Board reasoned that because the Lettich Provisional provides adequate support for *claim 1* of Lettich, Lettich is prior art against the claims of the 678 Application. *Id.* at 11. The Board then sustained the examiner's anticipation and obviousness rejections. *Id.* at 2.

In finding that Lettich is entitled to priority of the Lettich Provisional, the examiner and the Board relied on *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015) and *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017). *Riggs*, slip op. at 11. In these cited cases, the Federal Circuit explained that, for a prior art published application to claim benefit of its provisional application's filing date, the provisional application must provide support for the "claims" of the prior art application. *Id.* at 12. The challengers in those cases failed to meet the threshold requirement of demonstrating that the provisional application provided adequate support for the claims of the prior art application. *Id.* at 13 (citing *Dynamic Drinkware*, 800 F.3d at 1381-82; *Amgen*, 872 F.3d at 1380)). However, the Federal Circuit in *Dynamic Drinkware* and *Amgen* did not address whether it is sufficient for patent challengers (or examiners) to demonstrate written description support for one claim in order to then rely on other portions of the specification for purposes of anticipation or obviousness. *Id.* ("As such, [the court] did not address the subsequent issue of whether the content of the prior art relied on in the rejection also required written description support in the provisional application.").

In *In re Riggs*, the Federal Circuit settled that question, holding that written support for one claim was insufficient: "Even if one demonstrates that a provisional application provides written

[1] The inventor-appellants raised three issues on appeal, one of which was an issue preclusion matter. *Riggs*, slip op. at 7-10. That issue is not discussed here.

description support for one claim of the non-provisional application or patent, the provisional application must also provide written description support for the specific portions of the patent specification identified and relied on in the prior art rejection." *Id.* at 12. So even though the Board had identified corresponding support in the Lettich Provisional for each limitation of claim 1 of Lettich, *id.* at 11, that was an insufficient basis for allowing the actual portion of the application relied on by the Board to enjoy the benefit of the earlier provisional date. The panel reasoned that "[i]t makes no sense to suggest that if a single claim is supported by the provisional application, then everything in the later filed application gets the benefit of the provisional date whether supported or not." *Id.* at 12.

The panel confirmed that "this ***additional*** requirement is both logical and consistent with [Federal Circuit] precedent." *Id.* at 12-13 (emphasis added). Finding the Board's analysis insufficient, the panel vacated and remanded for the Board to determine whether the Lettich Provisional provides written description support for the "specific disclosures" in Lettich that the examiner had identified and relied on in the prior art rejections. *Id.* at 14.

In sum, *In re Riggs* clarifies that, under pre-AIA 35 U.S.C. § 102(e)(1), for a challenger (or examiner) to rely on a specific portion of a published application with the benefit of the earlier provisional application date, the provisional application not only must support at least one claim in the published application but also must support the subject matter of the specific portion of the published application. It remains to be seen if and how *In re Riggs* will have an impact on post-AIA patents.

Federal Circuit Denies Preliminary Injunction in a Biologics Price Competition and Innovation Act Case

On March 14, 2025, a Federal Circuit panel consisting of Judges Moore, Lourie, and Stark issued a decision in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2024-2351 (Fed. Cir. Mar. 14, 2025). The panel affirmed the District Court for the Northern District of West Virginia's denial of Regeneron's motion for a preliminary injunction ("PI") against one of the defendants, Amgen, in the consolidated multi-district Biologics Price Competition and Innovation Act litigation, *In re Aflibercept Patent Litigation*, No. 1:24-md-3103. *Regeneron Pharms.*, slip op. at 2.

The district court denied Regeneron's PI motion on the grounds that Regeneron failed to establish a likelihood of success in showing that Amgen infringed U.S. Patent 11,084,865 (the "865 Patent"). *Id.* at 3. The 865 Patent relates to Regeneron's biologic product EYLEA®, an ophthalmic drug product, whose active ingredient is aflibercept, used for treating uncontrolled blood vessel growth in the retina. *Id.* The asserted claims at issue are directed to an ophthalmic formulation that comprises, among other things, "a vascular endothelial growth factor (VEGF) antagonist" and a "buffer." *Id.* at 4-5. The EYLEA® formulation, for example, contains 40 mg/ml aflibercept (the VEGF antagonist) and 10 mM sodium phosphate.[2] *Id.* at 3.

Amgen filed an abbreviated Biologics License Application (aBLA) seeking to market its biosimilar drug product of EYLEA®. *Id.* Unlike EYLEA®, Amgen's formulation does not

[2] According to the 865 Patent, sodium phosphate can function as a buffer.

contain a separate buffer component because Amgen had discovered that the VEGF antagonist, aflibercept, itself provides sufficient buffering capacity to stabilize the formulation. *Id.* at 4. When Amgen filed its aBLA, Regeneron moved for a PI against Amgen, alleging that Amgen's aflibercept drug product infringes the 865 Patent. *Id.* The key dispute before the district court was whether the 865 Patent claims require the VEGF antagonist and the buffer limitations to be "separate and distinct" components of the claimed formulation. *Id.* at 5.

Regeneron argued that aflibercept satisfies not only the VEGF antagonist limitation but also the buffer limitation. *Id.* Regeneron relied on extrinsic evidence, including expert testimony, to show that using aflibercept as a buffer was so well known in the art such that no description in the specification was necessary for a skilled artisan to understand that aflibercept can also serve as the claimed buffer. *Id.* at 5-6. But the district court disagreed, instead determining that the claims require the VEGF antagonist and buffer limitations to be separate components. *Id.* at 8. The court therefore found that Regeneron had not demonstrated a likelihood of success on the merits of its infringement action. *Id.* Regeneron appealed, and the panel affirmed.

The panel focused on *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010), where the Federal Circuit held that "where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention." *Regeneron Pharms.*, slip op. at 8-9. Relying on *Becton*, the panel first confirmed that because the plain language of the claim establishes a "clear implication" that the VEGF antagonist and buffer components are distinct components, the district court committed no error. *Id.* at 11.

The panel then considered whether the evidence overcomes the implication of separateness under *Becton*, such that Amgen's formulation comprising a self-buffering VEGF antagonist may infringe the claims even in the absence of a separate buffer component. *Id.* at 11-12. Starting with intrinsic evidence, the panel found no error in the district court's determination that the evidence failed to overcome the implication of separateness. *Id.* at 12-13. Specifically, the panel noted that the dependent claims of the 865 Patent required the VEGF antagonist and buffer limitations to have *different* concentrations and *different* units of measurement; *i.e.*, the VEGF antagonist is 40 mg/ml and the buffer is 5-25 mM. *Id.* at 13.

The panel also credited the district court's finding that "[t]he specification does not suggest that the VEGF antagonist can be a buffer or vice versa," and that "Regeneron has not identified any such disclosure." *Id.* at 14 (quoting *In re Aflibercept Pat. Litig.*, No. 1:24-md-3103, 2024 WL 4958308, at *14 (N.D. W. Va. Oct. 1, 2024)). Citing specific passages of the specification—notably eight formulations and twenty-two embodiments—the panel found that "the specification describes a formulation containing a VEGF antagonist plus a distinct buffer component," and the specification nowhere gives an example of a "single component performing both functions (*e.g.*, a self-buffering protein)." *Id.* at 14-16.

Finally, the panel considered but rejected Regeneron's arguments based on extrinsic evidence. Regeneron argued that proteins containing histidine, such as aflibercept, had been known for decades to be buffers, and that the district court erred in disregarding a reference that predated the 865 Patent which described that proteins could be formulated in self-buffering compositions.

Id. at 17-18. The panel disagreed and found no error in the district court's finding that, given the proximity of the reference and the 865 Patent's filing date, "self-buffering proteins were not well known." *Id.* at 19.

In sum, the Federal Circuit held that Regeneron did not establish a likelihood of success on the merits of its infringement allegations because Amgen's aflibercept product does not contain a separate buffer. *Id.*
