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Federal Circuit Affirms Noninfringement in BPCIA Case

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In *Amgen Inc. et al. v. Sandoz Inc. et al.*, the U.S. Court of Appeals for the Federal Circuit issued a precedential opinion affirming a district court's finding of noninfringement in an action brought under the Biologics Price Competition and Innovation Act (BPCIA).[1] The *Amgen* court affirmed the district court's summary judgment that Sandoz's biosimilar products—filgrastim and pegfilgrastim—do not infringe claim 7 of U.S. Patent No. 8,940,878 (the '878 patent).[2] The *Amgen* court also held that the district court correctly denied a motion for continuance and correctly construed the claims of U.S. Patent No. 6,162,427 (the '427 patent).[3]

Background

In 2014, Sandoz submitted to the U.S. Food and Drug Administration (FDA) an Abbreviated Biologics License Application (aBLA) seeking license to market a biosimilar filgrastim drug product—Zarxio—referencing Amgen's Neupogen product.[4] Sandoz subsequently received FDA approval and launched its Zarxio product in 2015.[5] Also in 2015, Sandoz submitted an aBLA seeking license to market a biosimilar pegfilgrastim drug product, which is not yet approved by FDA, referencing Amgen's Neulasta product.[6] Amgen brought actions against Sandoz alleging infringement of the '878 patent by both of Sandoz's biosimilar products.

On appeal, Amgen argued that the district court erred in construing claim 7 as requiring two separate steps that, in turn, require the addition of two distinct solutions to the matrix at different times.

The '878 patent is directed to methods of protein purification using adsorbent chromatography—"a well-known method that involves separating the components of a solution ('the mobile phase') based upon their chemical attraction to the molecules or ions that comprise a stationary separation matrix ('the stationary phase')."[7] More specifically, claim 7 of the '878 patent recites a "method of purifying protein expressed in a non-native limited solubility form in a non-mammalian expression system" comprising seven steps (identified as (a) through (g) in the patent).[8]

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During the claim construction phase, the district court construed steps (f) (washing) and (g) (eluting), of claim 7, as separate and distinct steps using different solutions that must occur in the order recited in the claim.[9] Because it was undisputed that Sandoz's process for preparing its biosimilar products did not include separate washing and eluting steps, the district court granted summary judgment of noninfringement of claim 7 of the '878 patent.[10]

The Appeal

On appeal, Amgen argued that the district court erred in construing claim 7 as requiring two separate steps that, in turn, require the addition of two distinct solutions to the matrix at different times.[11] Amgen further argued that "the claims cover any number of solutions or steps as long as the functions of washing and eluting happen in sequence."[12] Amgen pointed to Sandoz's process and argued that "washing precedes elution at any given point in the separation matrix; that is, washing may occur toward the bottom of the matrix at the same time that elution occurs toward the top."[13]

The Federal Circuit Decision

The Federal Circuit rejected Amgen's arguments. The Federal Circuit stated that "the claim language logically requires that the process steps, lettered (a) through (g), be performed in sequence" and that "washing and eluting are consistently described in the specification as separate steps performed by difference solutions."[14] Thus, the district court did not err in construing "the washing and eluting limitations as separate process steps performed by adding discrete solutions to the separation matrix in sequence" and finding that Sandoz did not literally infringe claim 7.[15]

With respect to Amgen's doctrine-of-equivalents argument, the Federal Circuit stated that claim 7 is not so broad as to encompass "any method of using a salt concentration gradient in an adsorbent matrix to separate a protein of interest from other solutes."[16] The Federal Circuit agreed with the district court's holding that "Sandoz's one-step, one-solution process does not function in the same way as the claimed process."[17] Because Sandoz's "one-step, one-solution purification process works in a substantially different way from the claimed three-step, three-solution process," the district court did not err in granting summary judgment in favor of Sandoz.[18]

In holding no infringement under the doctrine of equivalents, the Federal Circuit also originally stated that the "doctrine of equivalents applies only in exceptional cases and is not 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.'"[19]

However, as a result of a Petition for Panel Rehearing, the Federal Circuit granted the petition to remove the "applies only in exceptional cases and" portion of the above quote, but denied the petition in all other respects.[20]

Amgen also argued that the district court abused its discretion when it denied Amgen's motion for a continuance under Rule 56(d).[21] Amgen argued that "judgment cannot be rendered on a technical act of infringement of a process patent under 35 U.S.C. § 271(e)(2) if a biosimilar applicant plans to submit a modification of a relevant process to the FDA but has not yet done so."[22] Sandoz countered that (1) Amgen was provided with ample notice of the proposed modifications to use a different resin in Sandoz's separation matrix; (2) Amgen failed to diligently pursue discovery and should be barred from invoking Rule 56(d) to avoid summary judgment; and (3) the information sought by Amgen was "immaterial to infringement because it will continue to use the one-step, one-solution process that has already been held noninfringing."[23] The Federal Circuit sided with Sandoz, holding that the district court did not abuse its discretion in denying Amgen's motion for a continuance and that the district court "was not obligated to postpone summary judgment until Sandoz submitted its amended pegfilgrastim aBLA."[24]

The Federal Circuit further noted that Amgen would not be without a remedy for possible future infringement if the facts were to change. Amgen could assert a future patent infringement action based on changes to the two Sandoz products, subject to the principles of *res judicata* and collateral estoppel.[25]

The number of cases arising under the BPCIA still remains lower than expected, but is expected to increase in the near future.

Regarding the '427 patent, because Amgen had consented that under the district court's construction there was no infringement, the only issue on

appeal was claim construction concerning the term "disease treating-effective amount."[26] The Federal Circuit held that the district court correctly construed the claim term as relating to the treatment of the underlying disease as opposed to only stem cell mobilization based on the claim preamble and support in the patent specification.[27]

Conclusion

The number of cases arising under the BPCIA still remains lower than expected, but is expected to increase in the near future. Precedential Federal Circuit opinions have been few and far between—when issued, they should be studied closely. The *Amgen* decision presents interesting holdings regarding claim construction and doctrine of equivalents in the context of biosimilars.

Notes

1. *Amgen Inc. v. Sandoz Inc.,* 923 F.3d 1023 (Fed. Cir. 2019).
2. *Id.* at 1025.
3. *Id.* at 1029-31.
4. *Id.* at 1025.
5. *Id.*
6. *Id.* at 1025-26.
7. *Id.* at 1026.
8. *Id.*
9. *Id.* at 1027.
10. *Id.*
11. *Id.* at 1028.
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.* at 1029.
16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.* (citations omitted).
20. *Amgen Inc. v. Sandoz Inc.*, No. 2018-1551 (Fed. Cir. Sept. 3, 2019).
21. *Amgen,* 923 F.3d at 1029-30.
22. *Id.* at 1030.
23. *Id.*
24. *Id.*
25. *Id.* at 1031.
26. *Id.*
27. *Id.*