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FEDERAL CIRCUIT CLARIFIES CONFLICTING TRANSITIONAL TERMS AND APPLICATION OF PROSECUTION HISTORY ESTOPPEL

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In *Amgen v. Amneal*,[1] the Federal Circuit resolved apparently conflicting transitional terms in U.S. Patent No. 9,375,405 ("the '405 patent"), remanded infringement allegations for one defendant, affirmed infringement for another defendant, and affirmed noninfringement for a third defendant. This comment will focus on the claim construction issue and how the court applied prosecution history estoppel to one of the patentee's arguments against an alleged infringer.

Amgen owns the '405 patent, which is directed to a rapid dissolution formula of cinacalcet hydrochloride.[2] Amgen's product, Sensipar, is used to treat secondary hyperparathyroidism in adults receiving dialysis for chronic kidney disease and to treat hypercalcemia in patients with parathyroid cancer and primary and secondary hyperparathyroidism.[3] Claim 1 was representative and recited, in part:

> A pharmaceutical composition *comprising*:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg; …
>
> (c) from about 1% to about 5% by weight of *at least one* binder selected from the group *consisting of* povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
>
> (d) from about 1% to 10% by weight of *at least one* disintegrant selected from the group *consisting of* crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof…[4]

Amgen initially filed the '405 patent as U.S. Patent Application No. 12/942,646 ("the '646 application"). Following a

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[1] Amgen, Inc. v. Amneal Pharmaceuticals, LLC, 945 F.3d 1368 (Fed. Cir. 2020).
[2] U.S. Patent No. 9,375,405 at abstract.
[3] *Amgen*, 945 F.3d at 1371.
[4] U.S. Patent No. 9,375,405 at col. 13 ll. 18–39 (emphasis added).

Preliminary Amendment, claim 2, which would later issue as claim 1, recited, in part:

> A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl; …
>
> (c) from about 1% to about 5% by weight of at least one binder; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant.[5]

Amgen next amended element (a), specifying the amount of cinacalcet HCl, in order to avoid rejection under 35 U.S.C. §103 over references that included U.S. Patent No. 6,316,460 ("Creekmore") and U.S. Patent Application No. 2005/0147670 ("Hsu").[6] Amgen's counsel then participated in a telephone interview with the Examiner, during which the Examiner proposed and Amgen accepted an Examiner's Amendment that converted elements (c) and (d) to their current Markush group format.[7] The Examiner issued a Notice of Allowance, indicating that the "combination of components … in the amounts … set forth in claim 2" was not disclosed or made obvious by the prior art.[8] After filing several Requests for Continued Examination, Amgen submitted a Preliminary Amendment eight months later, asserting that the changes in the Examiner's Amendment "have not been made in response to a prior art rejection but rather to place the claims in proper format and to better define the claimed subject matter, including equivalents."[9]

Amgen sued twelve sets of defendants, each of which had filed an Abbreviated New Drug Application (ANDA) for generic cinacalcet, for infringement of the '405 patent in the District of Delaware. The three defendants relevant to the appeal – Amneal, Piramal, and Zydus – each allegedly infringed different claims with their specific formulations, but the parties stipulated that infringement findings for claim 1 would apply to other claims.[10] In a proposed

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[5] *Amgen*, 945 F.3d at 1372.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.* at 1372–73.
[10] *Id.* at 1371.

pretrial order but not during claim construction, Amgen sought for the binder and disintegrant Markush groups in elements (c) and (d) to be open, but the district court denied it.[11] At claim construction, the court further found that Amgen had not overcome the presumption that the Markush groups in elements (c) and (d) were closed.[12]

After bifurcating the infringement and invalidity issues, the district court held a bench trial on infringement. The court found that Amneal's binder Opadry – which contains hydroxypropyl methylcellulose, a binder within claim 1's Markush group in element (c) – did not infringe because claim 1 did not specify Opadry itself.[13] Piramal's product contains pregelatinized starch, the cold-water soluble fraction of which Amgen argued is equivalent to one of its listed binders in element (c), povidone. The district court found that Amgen's argument under the doctrine of equivalents was barred by prosecution history estoppel related to the prior Examiner's Amendment, so Piramal's product did not infringe.[14] However, Zydus used a diluent specified in element (d) and infringed.[15] Amgen appealed the decision as it related to Amneal and Piramal, and Zydus cross-appealed.[16]

Judge Lourie authored the panel's opinion, vacating and remanding the finding of noninfringement for Amneal and affirming the findings of noninfringement and infringement, respectively, for Piramal and Zydus.[17] For the first step of infringement analysis, the Federal Circuit reviews claim constructions as a question of law that may involve underlying questions of fact.[18] Because the district court's claim constructions were based exclusively on intrinsic evidence, the court reviewed the constructions *de novo*.[19] As the second step, the

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[11] *Id.* at 1373.
[12] *Id.*
[13] *Amgen*, 945 F.3d at 1373.
[14] *Id.*
[15] *Id.* at 1374.
[16] Because Zydus' invalidity defense and counterclaim of invalidity had not been heard, the judgment against it was not yet final. On appeal, it cured the jurisdictional defect by waiving its defense and counterclaim.
[17] *Amgen*, 945 F.3d at 1384.
[18] *See* Teva Pharm. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 332 (2015).
[19] *Amgen*, 945 F.3d at 1375; *see also* HTC Corp. v. Cellular Commc'ns Equip., LLC, 877 F.3d 1361, 1367 (Fed. Cir. 2017).

court reviews for clear error the district court's determination of whether each product met each limitation of the claim as construed.[20]

For claim construction, Amgen argued that the first "comprising" term rendered the claim open-ended, even though elements (c) and (d) had restrictive "consisting of" language.[21] Accordingly, a product meeting the limitations of all four elements in claim 1 but also containing an additional component that does not meet those limitations – even though it serves a similar purpose – would fall within the scope of the claim. The defendants argued that precedent in *Multilayer*,[22] which had similar "comprising" followed by "consisting of" language for each element, required that any additional components serving a similar purpose be within the appropriate element's limitations in order for the product to fall within the ambit of the claim.[23] Siding with Amgen, the court clarified that *Multilayer* only stood for the narrow proposition that terms of a claim limitation that used "consisting of" Markush group language were restricted to members of that Markush group.[24]

The court then answered the underlying question of "whether all binders or disintegrants in the claimed formulation are subject to the specific binder or disintegrant limitations" in the negative.[25] Absent any evidence to the contrary, the use of the open "comprising" transition meant that at least one compound satisfying each element's requirements must be present, but additional binders or disintegrants could be present that did not comply with their respective requirements. Accordingly, the court vacated and remanded the analysis for whether Amneal met the disintegrant limitation, as well as to reconsider its analysis of Opadry's infringement.[26]

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[20] *See* Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1443 (Fed. Cir. 1997).
[21] *Amgen*, 945 F.3d at 1375–76.
[22] Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350 (Fed. Cir. 2016); *see also* Shire Dev., LLC v. Watson Pharm., Inc., 848 F.3d 981, 984 (Fed. Cir. 2017).
[23] *Amgen*, 945 F.3d at 1376.
[24] *Id.* at 1376–78.
[25] *Id.* at 1378.
[26] *Id.* at 1380.

The court next found that Amgen failed to demonstrate that the Examiner's Amendment it accepted during prosecution "had a purpose unrelated to patentability" in order to avoid prosecution history estoppel.[27] Amgen's earlier amendment narrowing element (a) did not lead to acceptance of the claims; only after Amgen accepted the Examiner's Amendment did allowance occur. The court reasoned that the Examiner's Amendment must have served some purpose in overcoming the obviousness rejection and was not made for a trivial reason.[28] Indeed, Piramal argued that the Examiner's Amendment narrowed the scope of binder-disintegrant combinations disclosed in Creekmore and Hsu from 152 and 120, respectively, to 12, having a substantial effect on patentability.[29] The court also dismissed Amgen's comment in its Preliminary Amendment eight months after allowance as a "conventional boilerplate statement" that provided, at best, unclear insight into the rationale of the Examiner's Amendment.[30] Because Amgen failed to carry its burden of showing that the Examiner's Amendment was unrelated to patentability, it surrendered the equivalent but unclaimed binders and disintegrants.[31] Accordingly, the court affirmed the district court's judgment that Piramal's product did not infringe under the doctrine of equivalents.[32]

Despite the court's findings on the prosecution history estoppel issue, practitioners may still have some space in which to maneuver in similar cases. The court's emphasis on the eight-month gap between Amgen's acceptance of the Examiner's Amendment and their providing the boilerplate language in question suggests at least two ways of differentiating future instances of potential prosecution history estoppel. First, closer temporal proximity between the amendment and any clarifying language might suggest that the clarification is less an afterthought and more directly related to the meaning of the amendment. Second, more specific language about the allowance could help distinguish meaningful arguments from mere recitation of generic language.

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[27] *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40–41 (1997).
[28] *Amgen*, 945 F.3d at 1381.
[29] *Id.* at 1381–82.
[30] *Id.* at 1382.
[31] On unrelated grounds, the court found no clear error in the district court's determination that Zydus infringed.
[32] *Amgen*, 945 F.3d at 1382.

One additional factor that may have harmed Amgen was the lack of detail in the Examiner-Initiated Interview Summary prepared by the Examiner.[33] The only comment about the substance of the interview is that the applicant's attorney "authorized for the Examiner's Amendment," with no detail as to either party's understanding of what that Amendment meant for patentability. It seems implausible that the specifically mentioned authorization was the only substantive matter discussed on the call, and that not even the content of the Amendment itself was discussed. But because "[t]he action of the Patent and Trademark Office [is] based exclusively on the written record in the Office,"[34] that written Summary provided the only relevant description of what happened on the call.

[33] *See* Examiner-Initiated Interview Summary, U.S. Patent Application No. 12/942,646 (March 12, 2015). Retrieved from https://portal.uspto.gov/pair/PublicPair
[34] 37 C.F.R. § 1.2 (2018).