UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OSSIFI-MAB LLC,	
Plaintiff	
v.	**Case No. 23-cv-10861-DJC**
AMGEN INC.,	**[PROVISIONALLY UNDER SEAL]**
Defendant.	

MEMORANDUM AND ORDER

CASPER, C.J. **February 24, 2026**

I. Introduction

Plaintiff OssiFi-Mab LLC ("OMAB") alleges that Defendant Amgen Inc. ("Amgen") has infringed certain claims of United States Patent Nos. 8,877,196 ("'196 patent"), 11,608,373 ("'373 patent") and 11,807,681 ("'681 patent") (collectively, the "Patents-in-Suit"). D. 73.[1] Amgen has moved for summary judgment, D. 167; D. 168; D. 169, and has moved to exclude certain opinions of two of OMAB's proffered expert witnesses, D. 181; D. 183. OMAB has moved for partial summary judgment, D. 171, and has moved to exclude certain testimony of three of Amgen's proffered expert witnesses, D. 175; D. 178; D. 185. For the reasons stated below, the Court ALLOWS Amgen's motions for summary judgment, D. 167; D. 168; D. 169. In light of these rulings, the Court DENIES OMAB's motion for partial summary judgment, D. 171, and the

[1] On January 31, 2025, the Court approved the parties' joint stipulation to dismiss all claims and counterclaims regarding United States Patent No. 8,178,099 ("'099 patent"). D. 159.

parties' respective motions regarding expert testimony, D. 175; D. 178; D. 181; D. 183; D. 185, as moot.

II. Standard of Review

The Court grants summary judgment where "there is no genuine dispute as to any material fact" and the undisputed facts demonstrate that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "A fact is material if it carries with it the potential to affect the outcome of the suit under the applicable law." Santiago-Ramos v. Centennial P.R. Wireless Corp., 217 F.3d 46, 52 (1st Cir. 2000) (citation and internal quotation marks omitted). Where the movant bears the burden of proof at trial, it must demonstrate every element of its case such that no reasonable factfinder could find for the nonmovant. Harley-Davidson Credit Corp. v. Galvin, 807 F.3d 407, 411 (1st Cir. 2015); see Celotex Corp. v. Catrett, 477 U.S. 317, 323-25 (1986). If the movant meets its burden, the nonmovant must show that there is a genuine issue for trial, Harley-Davidson Credit Corp., 807 F.3d at 411, and "cannot rely on 'conclusory allegations, improbable inferences, [or] unsupported speculation,'" To-Ricos, Ltd. v. Productos Avícolas del Sur, Inc., 118 F.4th 1, 10 (1st Cir. 2024) (quoting Ellis v. Fid. Mgmt. Tr. Co., 883 F.3d 1, 7 (1st Cir. 2018)). The Court "view[s] the record in the light most favorable to the nonmovant, drawing reasonable inferences in [its] favor." Noonan v. Staples, Inc., 556 F.3d 20, 25 (1st Cir. 2009).

III. Factual Background

This lawsuit involves three OMAB patents related to methods of treating bone disorders like osteoporosis with a combination of two classes of drugs: sclerostin antagonists, which help stimulate bone growth, and antiresorptive drugs, which slow the resorption of bone mass. D. 170-2; D. 170-3; D. 170-4. The '196 patent was filed on March 12, 2013, and issued on November 4, 2014. D. 170-2 at 3. The '373 patent was filed on September 19, 2016, and issued on March 21, 2023. D. 170-3 at 3. The '681 patent was filed on March 20, 2023, and issued on November 7,

2023. D. 170-4 at 3. The Court draws the following facts from the parties' statements of undisputed facts, responses to same and accompanying exhibits. D. 170; D. 173; D. 174; D. 189; D. 191; D. 193; D. 222; D. 223; D. 230; D. 232; D. 234; D. 235; D. 236; D. 257; D. 259; D. 260; D. 270; D. 271; D. 288-1.

A. Osteoporosis and Antibodies

The human body maintains a balance between building new bone and breaking down old or damaged bone. D. 189 ¶ 31; D. 230 ¶ 31. This homeostasis is disrupted if, for instance, the body forms too little new bone or resorbs too much existing bone. See D. 189 ¶ 32; D. 230 ¶ 32. One component of the body's natural bone formation and resorption processes is the protein sclerostin, which binds to certain cells involved in bone formation, thereby inhibiting the creation of new bone. D. 189 ¶ 37; D. 230 ¶ 37. Individuals with low bone mass may develop osteoporosis, a chronic condition for which there is no cure. D. 189 ¶¶ 32-34; D. 230 ¶¶ 32-34. As of December 29, 2006, the claimed priority date for the Patents-in-Suit, there were only two types of approved osteoporosis treatments: (1) teriparatide, a synthetic form of parathyroid hormone that works by increasing bone formation, and (2) antiresorptive drugs, which instead work by slowing down bone resorption. D. 189 ¶¶ 6, 35; D. 230 ¶¶ 6, 35.

Scientists had also been investigating and developing antibodies for potential use to treat osteoporosis by binding sclerostin. D. 189 ¶ 41; D. 230 ¶ 41. Antibodies are naturally created by the human immune system to bind antigens, such as viruses, on a location known as an epitope. D. 189 ¶ 23; D. 230 ¶ 23. An antibody is a protein, made up of amino acids. D. 189 ¶ 18; D. 230 ¶ 18. As relevant here, there are twenty different amino acids. See D. 189 ¶ 18; D. 230 ¶ 18. Each protein has a specific amino acid "sequence"—i.e., particular amino acids chained together in a particular order to form a polypeptide, which folds into a three-dimensional shape. D. 189 ¶¶ 18-19; D. 230 ¶¶ 18-19. An antibody is made up of four such polypeptides—two "light chains" and

two "heavy chains" formed into a Y shape—and the amino acid sequence and shape determine its ability to bind a target antigen. See D. 189 ¶¶ 20-21; D. 230 ¶¶ 20-21. An antibody's amino acid sequence can be altered to optimize the ability to bind to an intended target. D. 189 ¶ 29; D. 230 ¶ 29. Different classes of antibodies (as relevant here, IgG, IgA, IgM, IgD and IgE) perform differently. D. 189 ¶ 25; D. 230 ¶ 25.

As of December 2006, there were no approved antibody treatments for osteoporosis. D. 189 ¶ 36; D. 230 ¶ 36. The active ingredient in Amgen's product, Evenity, is the anti-sclerostin antibody romosozumab. D. 189 ¶¶ 1-3; D. 230 ¶¶ 1-3. OMAB alleges that Amgen's sale and marketing of Evenity in the United States induces or contributes to infringement of the Patents-in-Suit. D. 189 ¶ 3; D. 230 ¶ 3.

B. Prior Art

In the 1970s, scientists developed a way to design proteins that would bind to a desired target, which involved immunizing mice with a target protein, then isolating the immune system cells that produced the resulting mouse ("murine") antibodies to that protein. D. 189 ¶ 27; D. 230 ¶ 27. By 2006, there was significant knowledge in the field regarding antibody structure. D. 230 ¶ P40; D. 271 ¶ P40. It was routine and predictable to use well-known techniques to generate antibodies, including immunization followed by hybridoma generation, phage display and transgenic mice having human antibody genes. D. 230 ¶¶ P50-P51; D. 271 ¶¶ P50-P51. The hybridoma technique had been established as useful to generate antibodies against a human protein. D. 230 ¶ P51; D. 271 ¶ P51. At this time, numerous assays and protocols to screen antibodies for desired functions were known in the field. D. 230 ¶ P50; D. 271 ¶ P50. There were also many routine methods to determine antibody affinity, meaning whether and how strongly an antibody binds to a particular target, and specificity, meaning an antibody's ability to preferentially bind a target antigen over other antigens. D. 189 ¶ 21; D. 230 ¶¶ 21, P53; D. 271 ¶ P53.

Before December 2006, scientists were developing anti-sclerostin antibodies. D. 189 ¶¶ 40, 57; D. 230 ¶¶ 40, 57. The parties dispute whether this class of antibodies is limited or well defined, D. 230 ¶ P23; D. 271 ¶ P23, whether it was well known, D. 230 ¶¶ P36, P41; D. 271 ¶¶ P36, P41, and whether methods for characterizing and identifying antibodies in this class were routine, D. 230 ¶¶ P52, P58; D. 271 ¶¶ P52, P58. Dr. Debra Ellies, the named inventor on the Patents-in-Suit, discovered with colleagues in Dr. Robb Krumlauf's laboratory at the Stowers Institute for Medical Research ("Stowers") that sclerostin acts by binding to two proteins, LRP5 and LRP6. D. 189 ¶¶ 38-39; D. 230 ¶¶ 38-39. This discovery was published in a 2006 scientific journal article ("Ellies 2006"), which also reported that Drs. Ellies and Krumlauf had successfully generated two monoclonal anti-sclerostin antibodies, "4G10" and "4A6." D. 189 ¶¶ 39-40; D. 230 ¶¶ 39-40, P43; D. 271 ¶ P43. Ellies 2006 did not disclose the amino acid sequences for these antibodies. D. 189 ¶¶ 47, 50; D. 230 ¶¶ 47, 50. 4G10 and 4A6 were generated in rats as antibodies to the sclerostin protein found in mice, and there are no data showing these antibodies bind to human sclerostin. D. 189 ¶¶ 52-53; D. 230 ¶¶ 52-53. The parties dispute whether Ellies 2006 included in vivo data regarding 4G10 and 4A6. D. 189 ¶ 51; D. 230 ¶ 51.[2] OMAB also disputes Amgen's assertion that 4G10 and 4A6 could not be used as a human therapeutic, see D. 189 ¶¶ 52-53, because OMAB contends that humanization was routine, D. 230 ¶¶ 52-53. Additionally, Ellies 2006 described use of an assay to evaluate an antibody's inhibition of sclerostin's function. D. 230 ¶ P73; D. 271 ¶ P73.

[2] An OMAB expert, Dr. Juan Carlos Almagro, testified that in vivo experiments occur in live animals, D. 170-12 at 18, and that Ellies 2006 lacks such data based on same, id. at 34. OMAB relies upon his statement, "But if she's calling this in vivo because she's using material from a rat, . . . well, I will go with that," id., to dispute that Ellies 2006 lacks in vivo data, see D. 230 ¶ 51.

Drs. Ellies and Krumlauf also filed several patent applications. D. 189 ¶ 55; D. 230 ¶ 55. One, United States Patent Publication No. 2007/0298038 (the "Krumlauf '038 application"), disclosed twenty-seven anti-sclerostin murine antibodies. D. 189 ¶¶ 55-56; D. 230 ¶¶ 55-56, P62; D. 271 ¶ P62. The Krumlauf '038 application also discussed the generation protocol that resulted in these antibodies, but it did not disclose any amino acid sequence information. D. 189 ¶ 55; D. 230 ¶¶ 55, P44; D. 271 ¶ P44. Other such patent applications included, for instance, experiments and data regarding the roles of sclerostin, LRP5 and LRP6 in bone growth regulation and in bone dynamics of the Wnt signaling pathway, D. 230 ¶¶ P45, P63; D. 271 ¶¶ P45, P63; disclosure of the use of anti-sclerostin antibodies to increase bone density, D. 230 ¶ P56; D. 271 ¶ P56; and discussion of Wnt signaling, the biological functions of sclerostin and LRP and methods for anti-sclerostin antibody generation, D. 173 ¶ 25; D. 223 ¶ 25.

Dr. Ellies filed the application to which the Patents-in-Suit claim priority approximately six months after she left Stowers, and during the time between leaving Stowers and filing the application, Dr. Ellies did not conduct any experiments, enter a laboratory or supervise anyone conducting an experiment in connection with the inventions claimed in the Patents-in-Suit. See D. 189 ¶ 63; D. 230 ¶ 63. During that time, Dr. Ellies conducted market research and analyzed literature. D. 191 ¶ 20; D. 232 ¶ 20. Dr. Ellies, a Ph.D. scientist, is not a licensed medical doctor and has never treated a human patient. D. 191 ¶ 18; D. 232 ¶ 18.

Amgen scientists were also developing and testing anti-sclerostin antibodies. D. 189 ¶ 57; D. 230 ¶ 57. In a patent application, PCT Publication No. 2006/119107 ("Paszty"), published November 9, 2006, Amgen disclosed twenty-eight such antibodies, including sequence data for all twenty-eight, in vitro data for ten and in vivo data in cynomolgus monkeys for three. D. 189 ¶ 58; D. 230 ¶ 58. Paszty disclosed no fewer than sixteen "representative" anti-sclerostin antibodies, at

least nine of which are humanized. D. 230 ¶ P46; D. 271 ¶ P46. Paszty includes experimental data characterizing each antibody's functional properties, its binding affinity for sclerostin, its epitope within sclerostin and antagonism of sclerostin's function in both cell-based and in vivo assays. D. 230 ¶ P46; D. 271 ¶ P46. Paszty discloses that these antibodies can be used in pharmaceutical compositions and methods to increase, for example, bone formation or density. D. 230 ¶ P46; D. 271 ¶ P46. Amgen presented regarding same at annual meetings of the American Society for Bone and Mineral Research between 2004 and 2006 and publicly presented data demonstrating that several of its antibodies were effective for increasing bone density in rats and cynomolgus monkeys. D. 230 ¶¶ P47, P56; D. 271 ¶¶ P47, P56. Amgen also publicly collaborated with Celltech to develop anti-sclerostin antibodies. D. 230 ¶ P48; D. 271 ¶ P48.

C. Person of Ordinary Skill in the Art ("POSA")

The parties agree that a POSA would have been knowledgeable about prior art teachings regarding anti-sclerostin antibodies. D. 230 ¶ P34; D. 271 ¶ P34. A POSA would have had knowledge and experience regarding prior art techniques for generating, characterizing and humanizing antibodies, including those referenced in the specification of the Patents-in-Suit. D. 230 ¶ P35; D. 271 ¶ P35. It would have been routine for a POSA to generate antibodies via immunization and hybridoma technology. D. 230 ¶ P51; D. 271 ¶ P51.

A POSA would have had at least some knowledge about drug development, including use of humanized antibodies in therapeutics; formulation, administration and determination of an effective dose of a biologic drug; and prior art regarding bone formation or bone growth dynamics. D. 230 ¶ P38; D. 271 ¶ P38. A POSA would have education and experience regarding osteoporosis treatment. D. 230 ¶ P39; D. 271 ¶ P39. A POSA would have known how to use antiresorptive drugs, which were well known, as a routine part of osteoporosis treatment. D. 232 ¶ P7; D. 288-1 ¶ P7. OMAB's position is that a POSA would have believed that anti-sclerostin antibodies could

be used as a long-term treatment for osteoporosis and would not have been motivated to combine same with serial administration of antiresorptive drugs. See D. 232 ¶¶ 30-31.

The parties dispute whether generating, humanizing, identifying and characterizing sclerostin-inhibiting antibodies were routine techniques familiar to a POSA. D. 230 ¶ P37; D. 271 ¶ P37. Additionally, the parties dispute whether a POSA could have easily determined if a human subject was being treated with a sclerostin-recognizing antibody. D. 230 ¶¶ P57-P59; D. 271 ¶¶ P57-P59. Although the parties proposed slightly different definitions of a POSA, see D. 235-1 ¶¶ 24, 27; D. 235-2 ¶¶ 30-31, neither contends that any difference in same is material to the Court's analysis.

D. Patents-in-Suit

The Patents-in-Suit and the '099 patent are part of the same patent family, share a common specification and claim the same priority date. D. 189 ¶¶ 5-6; D. 230 ¶¶ 5-6. At this stage of the case, OMAB asserts sixteen claims against Amgen: dependent claims 8 and 10 from the '196 patent; independent claim 15 and dependent claims 16, 17, 18, 19, 21 and 22 from the '373 patent; and independent claims 27 and 29 and dependent claims 7, 9, 12, 28 and 30 from the '681 patent. D. 189 ¶ 3; D. 230 ¶ 3; D. 170-6 at 2; see D. 170-2; D. 170-3; D. 170-4.

1. Shared Specification

The specification references certain prior art, such as Ellies 2006 and the Krumlauf '038 application, and purports to incorporate all cited publications and patent applications by reference. D. 173 ¶¶ 12, 14-15; D. 223 ¶¶ 12, 14-15. The specification describes methods for humanizing anti-sclerostin antibodies and for making human anti-sclerostin antibodies. D. 230 ¶ P68; D. 271 ¶ P68. It discusses protocols for immunizing mice to generate such antibodies and to produce hybridomas secreting same, and it describes how DNA of these hybridomas can be isolated, such

as for humanization. See D. 230 ¶¶ P69-P70; D. 271 ¶¶ P69-P70.[3] Further, it describes methods to purify recombinant antibodies and details additional techniques, like the phage method, that can be used to produce a mixture of peptides that can be tested as agonists or antagonists, and describes how to assess antagonist candidates. D. 230 ¶¶ P71, P73; D. 271 ¶¶ P71, P73. The parties dispute whether the specification teaches a POSA how to characterize and identify suitable antibodies, D. 230 ¶¶ P72, P74; D. 271 ¶¶ P72, P74, and the extent to which the specification discloses dosing and administration of same, D. 230 ¶¶ P77-P78; D. 271 ¶¶ P77-P78.

The specification includes formulations and compositions of anti-sclerostin antibodies usable in the claimed methods and routes of administration for same. D. 230 ¶ P76; D. 271 ¶ P76. As to specific suitable antibodies, the specification discloses the following: "Suitable humanized monoclonal antibodies have been created by Amgen, for example. Stowers Institute also provides suitable blocking antibodies designated 4G10, 4B9 and 6E6. Another suitable blocking antibody is 1A12 commercially available from Abcam." D. 170-3 at 16. Ellies 2006 references 4G10, D. 189 ¶ 49; D. 230 ¶ 49, as noted above. The amino acid sequences of 4B9 and 6E6 are not disclosed in the Patents-in-Suit or prior art. D. 189 ¶¶ 47, 54; D. 230 ¶¶ 47, 54. 1A12 is not an anti-sclerostin antibody. D. 189 ¶ 46; D. 230 ¶ 46. OMAB contends that the specification's reference to Amgen "would have drawn the person of skill in the art's attention to [certain] Amgen prior-art disclosures," including Paszty, D. 230 ¶¶ 45, P66, while Amgen maintains that the specification discloses no antibodies beyond those listed and disputes OMAB's assertion regarding the reference's effect on a POSA, D. 189 ¶ 45; D. 271 ¶ P66. The specification does not otherwise disclose the amino acid sequence of any suitable antibody. D. 189 ¶ 59; D. 230 ¶ 59. The specification discloses no new anti-sclerostin antibodies or new techniques for generating such

[3] Amgen disputes the level of detail regarding mouse immunization. D. 271 ¶ P69.

antibodies or assessing their ability to increase bone density, D. 189 ¶ 61; D. 230 ¶ 61,[4] but does disclose the range of binding affinities expected for a suitable anti-sclerostin antibody and established methods to assess affinity, D. 230 ¶ P75; D. 271 ¶ P75. The specification does not itself include experimental data, D. 189 ¶ 60, but OMAB contends that it incorporates certain prior art containing such data, D. 230 ¶ 60.

The parties dispute whether members of the class of anti-sclerostin antibodies referenced in the Patents-in-Suit share structural features that would allow a POSA to recognize them. D. 189 ¶ 67; D. 230 ¶ 67. Amgen contends that they do not, D. 189 ¶ 67, whereas OMAB asserts that anti-sclerostin antibodies "have the common structural feature of being structurally complementary to sclerostin, particularly including portions of sclerostin involved in binding LRP5 and LRP6," D. 230 ¶ 67. To the extent antibodies are needed to practice the asserted claims, a POSA would need to "make and screen" any such antibodies not disclosed in the patents or prior art. D. 189 ¶ 68; D. 230 ¶ 68. The parties dispute whether a POSA would even know which of the five human immunoglobin classes could be used. D. 189 ¶ 69; D. 230 ¶ 69.

The specification also identifies antiresorptive drugs. See D. 191 ¶ 10; D. 232 ¶ 10. This disclosure (apparently erroneously) includes "PTH [and] analog (i.e., Forteo)," which are anabolic drugs. D. 191 ¶¶ 11-13; D. 232 ¶¶ 11-13. It also includes vitamin D. D. 193 ¶ 9; D. 234 ¶ 9. No new antiresorptive drugs are disclosed. D. 189 ¶ 62; D. 230 ¶ 62. As of the priority date, supplemental vitamin D was a standard part of osteoporosis treatment in post-menopausal women, including administration before, during and after treatment with an anabolic drug. D. 193 ¶¶ 15-

[4] Here and elsewhere, OMAB disputes certain quotes as "taken out of context," but OMAB does not appear to dispute the accuracy of this assertion. See D. 230 ¶ 61.

16; D. 234 ¶¶ 15-16. Vitamin D deficiency can hinder the efficacy of osteoporosis treatments. D. 193 ¶ 20; D. 234 ¶ 20.

While Amgen contends that only two passages in the specification describe "the claimed invention of serially or sequentially using anti-sclerostin antibodies and antiresorptive drugs to increase bone density or promote bone growth," D. 191 ¶ 15, OMAB's position is that for a POSA, "the specification as a whole explains how an antisclerostin antagonist can be combined with antiresorptive drugs," D. 232 ¶ 15 (emphasis in original). Among other aspects of the claimed methods, the parties dispute the testing and experimentation required for a POSA to "figure out whether the claimed methods work and how to perform them." D. 191 ¶ 29; D. 232 ¶ 29.

2. '196 Patent

OMAB asserts that Amgen infringes claims 8 and 10 of the '196 patent, D. 173 ¶ 5; D. 223 ¶ 5, and the parties have treated claim 8 as representative, see D. 188 at 10; D. 227 at 10. Claim 8 is a dependent claim from claims 1 through 3, and those claims recite:

> 1. A method of increasing bone density in a mammalian patient in need thereof, comprising the steps of:
>
> systemically administering to a said mammalian patient a [composition] comprising an effective amount of a Sclerostin antagonist sequentially with an antiresorptive drug, said Sclerostin antagonist comprising an antibody or FAB fragment specifically binding a peptide selected from the group consisting of SEQ ID NOS:2-13, 22 and 23, wherein
>
> the antibody interferes with [Sclerostin's] ability to bind to LRP, thereby systemically increasing bone density.
>
> 2. The method according to claim 1, wherein said patient is a human.
>
> 3. The method according to claim 2, wherein said patient has low bone density.
>
> 8. The method according to claim 3, wherein said Sclerostin antagonist is administered to said patient prior to administering said antiresorptive [drug].

D. 170-2 at 18, 22. The Court construed "administering . . . sequentially with" to mean "administering such that administration of one drug follows completion of the course of treatment with the other drug as part of a larger treatment regimen with a common therapeutic objective." D. 99 at 10, 13.

3. '373 Patent

OMAB asserts that Amgen infringes claims 15 through 19, 21 and 22 of the '373 patent, D. 173 ¶ 7; D. 223 ¶ 7, and the parties have treated claim 15 as representative, see D. 188 at 10; D. 227 at 10. Claim 15 recites:

> A method for increasing bone density in a human subject with low bone mass being treated with a sclerostin-recognizing antibody, comprising serially administering an antiresorptive drug to the subject.

D. 170-3 at 25. The Court construed "being treated with a sclerostin-recognizing antibody" to mean "during sclerostin-recognizing antibody treatment" and construed "serially administering" to mean "administer[ing] such that administration of one drug follows completion of the course of treatment with the other drug as part of a larger treatment regimen with a common therapeutic objective." D. 99 at 10-11, 13.

4. '681 Patent

OMAB asserts that Amgen infringes claims 7, 9, 12 and 27 through 30 of the '681 patent, D. 173 ¶ 9; D. 223 ¶ 9, and the parties have treated claim 29 as representative, see D. 188 at 10-11; D. 227 at 10. Claim 29 recites:

> A method for increasing bone mineral density in a human subject with low bone mass being treated with a sclerostin-recognizing antibody, comprising serially administering an antiresorptive drug to the human subject.

D. 170-4 at 21. The constructions relevant to claim 15 of the '373 patent also apply here. D. 99 at 10-11, 13.

IV. Procedural History

OMAB initiated this action on April 21, 2023, D. 1, and amended the complaint on January 4, 2024, D. 73. Amgen has asserted counterclaims against OMAB, seeking a declaration of non-infringement and invalidity as to the Patents-in-Suit. D. 76. On June 21, 2024, after conducting a Markman hearing, the Court issued an opinion construing certain disputed terms in the Patents-in-Suit. D. 99. Amgen now has filed three motions for summary judgment, D. 167; D. 168; D. 169, and moved to exclude certain expert testimony, D. 181; D. 183. OMAB has moved for partial summary judgment, D. 171, and to exclude certain expert testimony, D. 175; D. 178; D. 185. The Court heard the parties on the pending motions for which they requested oral argument, D. 291, and took these matters under advisement, D. 293.

V. Discussion

Amgen seeks summary judgment[5] as to invalidity of the Patents-in-Suit based on three, alleged failures to satisfy the requirements of 35 U.S.C. § 112.[6] Amgen first argues that the

[5] OMAB seeks summary judgment that certain documents cited in the specification are incorporated by reference therein. D. 171. Amgen assumes in its motions for summary judgment that the documents subject to OMAB's motion are effectively incorporated by reference. See D. 265 at 5 n.1; D. 271 ¶ P43. Accordingly, the Court adopts this assumption for purposes of resolving Amgen's motions for summary judgment, and it denies OMAB's motion regarding such incorporation, D. 171, as moot.

[6] As Amgen recognizes, because the priority date for the Patents-in-Suit is December 29, 2006, see D. 188 at 5, the pre-AIA Patent Act is applicable here. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(e), 125 Stat. 284, 296-97 (2011); 35 U.S.C. § 111 (note); see, e.g., In re Taylor, No. 2021-1613, 2022 WL 1792564, at *3 n.3 (Fed. Cir. June 2, 2022). Section 112 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

Patents-in-Suit fail for lack of enablement or written description as to the genus of antibodies suitable for use in the claimed methods. D. 167. Second, Amgen contends that the Patents-in-Suit fail for lack of written description as to the claimed methods. D. 168. Third, Amgen argues that certain claims should be invalidated as obvious or, alternatively, for lack of written description. D. 169. As relevant to the motions, a "patent [is] presumed valid," 35 U.S.C. § 282(a), and "an invalidity defense [must] be proved by clear and convincing evidence," Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011). "Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." Eli Lilly & Co. v. Barr Lab'ys, Inc., 251 F.3d 955, 962 (Fed. Cir. 2001).

A. Failure to Enable or Describe the Genus of Antibodies for Use in the Claimed Methods

1. Written Description

A patent's written "description must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (alteration in original) (quoting Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). "A specification adequately describes an invention when it 'reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quoting Ariad, 598 F.3d at 1351). If a patent claims more than what the inventor invented and described, the patent is void. Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008). "What is required to meet the written description requirement 'varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.'" Juno, 10 F.4th at 1335 (quoting Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005)).

"An applicant may show possession of the claimed invention by describing it with all of its limitations using 'such descriptive means as words, structures, figures, diagrams, formulas, etc.'" Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333, 1342 (Fed. Cir. 2021) (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)). Further, a "'patentee may rely on information that is well-known in the art' to the extent it informs how a relevant artisan would reasonably understand what is actually described in the specification." BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Organisation, 28 F.4th 1247, 1264 (Fed. Cir. 2022) (quoting Ajinomoto Co. v. Int'l Trade Comm'n, 932 F.3d 1342, 1359 (Fed. Cir. 2019)); see In re Xencor, Inc., 130 F.4th 1350, 1362 (Fed. Cir. 2025) (noting that for written description inquiry, factfinder may consider extrinsic evidence "to understand what a person of ordinary skill in the art would have known as of the pertinent date"). Elements of a patent claim are treated as a whole, and written description "is not met when . . . the specification provides at best disparate disclosures that an artisan might have been able to combine in order to make the claimed invention." Flash-Control, LLC v. Intel Corp., No. 2020-2141, 2021 WL 2944592, at *4 (Fed. Cir. July 14, 2021). The adequacy of a written description "is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." BASF, 28 F.4th at 1264 (quoting Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1063 (Fed. Cir. 2020)).

a) '196 Patent

Claim 8 of the '196 patent, which depends from claims 1 through 3, recites a method of treatment using, in the first step, a genus of antibodies defined by the function of binding sclerostin and increasing bone density. D. 170-2 at 18. Claim 1 requires the administration of a "Sclerostin antagonist comprising an antibody or FAB fragment specifically binding a peptide selected from the group consisting of SEQ ID NOS:2-13, 22 and 23, wherein the antibody interferes with Sclerostin's ability to bind to LRP, thereby systemically increasing bone density." Id. The

specification explains that an "antibody" includes "naturally occurring antibodies as well as non-naturally occurring antibodies, including, for example, single chain antibodies, chimeric, bifunctional and humanized antibodies, as well as antigen-binding fragments thereof," and "both polyclonal and monoclonal antibodies." Id. at 8. The written description requirement applies "[r]egardless [of] whether a compound is claimed *per se* or a method is claimed that entails the use of the compound." Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004) (analyzing method requiring administration of a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product"); see, e.g., In re Alonso, 545 F.3d 1015, 1018-22 (Fed. Cir. 2008) (discussing method requiring use of genus of monoclonal antibodies specific to neurofibrosarcoma cells). Where a patent claims a genus, sufficient description "requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." Ariad, 598 F.3d at 1350 (quoting Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997)). Where a field is "unpredictable," it is appropriate for the Court to "recognize the variability in the science." See Capon, 418 F.3d at 1358. Amgen argues that the specification discloses neither representative species of anti-sclerostin antibodies nor features common to the members of the genus. D. 188 at 20. While OMAB faults Amgen for relying upon "cases involving a novel class of antibodies, rather than—as here—a class of antibodies already well known in the prior art," see D. 227 at 23 (emphasis in original), the "test for written description is the same whether the claim is to a novel compound or a novel combination of known elements," Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353,

1365 (Fed. Cir. 2011); accord Juno, 10 F.4th at 1341.[7]

Here, the specification discloses, at most, thirty-one anti-sclerostin antibodies.[8] Dr. Almagro opined that "a POSA reading the specification would have understood the exemplary antibodies disclosed there, including the examples in Ellies 2006, to be representative of the class of [suitable] antibodies as a whole." D. 235-2 ¶ 254; see id. ¶¶ 266, 275.[9] The antibodies disclosed

[7] Moreover, it is unclear what standard OMAB believes applies. OMAB first implies the representative species or common structural feature framework is inapplicable, see D. 227 at 23-24 (citing Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co., 276 F. Supp. 3d 629 (E.D. Tex. 2017), aff'd, 739 F. App'x 643 (Fed. Cir. 2018)); then states that it "need only show possession of the innovative method of treatment, not the underlying class of antibodies," id. at 25 (citing one case in which representative species or structural characteristics were required and one in which they were not); then argues that the specification "teaches representative anti-sclerostin antibodies" and that "a POSA would have recognized the class of anti-sclerostin antibodies as well-known in the prior art and been equipped to visualize the class," id.; and finally suggests that only a "threshold showing" that the class of antibodies "was well-known in the prior art" is required, after which point the specification need only describe the method of treatment, id.

[8] OMAB stops short of arguing that Paszty's twenty-eight antibodies are disclosed in the specification's statement that "[s]uitable humanized monoclonal antibodies have been created by Amgen," see D. 227 at 8; D. 170-2 at 9, although it does contend as a factual matter that this "would have drawn the person of skill in the art's attention to the Amgen prior-art disclosures," D. 271 ¶ 45; see, e.g., D. 235-2 ¶ 294; D. 235-3 ¶¶ 593, 610. Dr. Almagro testified that without Paszty, the antibody class could be described as "known" but not necessarily "well[] known." See D. 170-12 at 47.

[9] Relying upon Dr. Almagro, OMAB disputes that the members of the relevant genus lack a common structural feature differentiating them from non-members. See D. 271 ¶ 67 (citing D. 235-2). But Dr. Almagro's description of the "common structural features" of anti-sclerostin antibodies mirrors his description of the features of all antibodies. Compare D. 235-2 ¶ 219 (opining that "all antibodies have a common and conserved Y-shaped, 3D structure"), and id. ¶ 47 (opining that Fab regions of IgG contain two variable and two constant regions), and id. ¶ 49 (opining that "specific binding of each antibody for a given target is governed by the precise arrangement of CDRs and [more conserved regions]"), with id. ¶ 298 (opining that sclerostin-recognizing antibodies have "common structural elements like a common Y-shaped architecture, the arrangement of constant and variable regions within that architecture, structural domains such as a Fab domain with constant and variable regions, and the formation binding sites from a set of [CDRs] that specifically recognize and bind sclerostin"), and id. (opining that "sclerostin-recognizing antibodies have common CDRs that are arranged within the antibody and structured to form . . . binding sites that are structurally complementary with sclerostin"). This does not create a genuine dispute, particularly given Dr. Almagro's testimony that he "didn't take the structure[/]function [approach]" and that he only opined on such features "[i]n general." See D. 170-12 at 53; see, e.g., AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d

in the specification include three "suitable blocking antibodies designated 4G10, 4B9 and 6E6" provided by Stowers. D. 170-2 at 9. It is undisputed that these antibodies' amino acid sequences are not set forth in the specification or any prior art. D. 271 ¶ 47. Amgen's expert Dr. Geoffrey Hale opined that it is unknown whether 4B9 and 6E6 are polyclonal or monoclonal antibodies, D. 170-13 ¶ 238, which Dr. Almagro does not appear to dispute, see D. 235-2 ¶ 296. Ellies 2006 disclosed 4G10 and a fourth antibody, "4A6," D. 271 ¶¶ 49-50, which are both monoclonal, D. 170-15 at 4, but did not provide sequence information for either antibody, id. at 4, 8; D. 271 ¶¶ 47, 50.[10] Moreover, although OMAB contends that generation and humanization of antibodies were routine, it does not dispute that 4G10 and 4A6 are rat antibodies to mouse sclerostin and could not themselves be used in a human therapeutic. See D. 271 ¶ 52. The Krumlauf '038 application discusses the generation of twenty-seven monoclonal murine antibodies but does not include any sequence information. See D. 271 ¶¶ 55-56, 60. Moreover, it appears unknown whether the disclosed antibodies inhibit sclerostin's function. See D. 235-2 ¶¶ 250-54 (opinion of Dr. Almagro, identifying only 4B9, 6E6, 4G10, 4A6 and Paszty antibodies as examples of sclerostin antagonists).[11] At most, then, the only potentially representative antibodies disclosed in

1285, 1292 (Fed. Cir. 2014) (noting that patent "define[d] the claimed antibodies by their function, i.e., IL-12 binding and neutralizing characteristics, rather than by structure" (emphasis in original)); GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., 744 F.3d 725, 731 (Fed. Cir. 2014) (noting, as examples of "shared performance propert[ies]," "a compound's ability to inhibit the action of a particular protein" and "an antibody's ability to bind to a particular antigen"); see also Duke Univ. v. Sandoz Inc., 160 F.4th 1305, 1312-13 (Fed. Cir. 2025) (rejecting reliance upon generic structural feature of claimed subgenus that did not distinguish same from described genus).

[10] Dr. Almagro agreed at his deposition that a POSA would find no evidence in the patent that 4B9 or 6E6 "ever existed," see D. 170-12 at 31, and that Ellies 2006 lacks "data to show that 4G10 or 4A6 would have activity against human sclerostin," id. at 32. He testified that to practice the method of the '196 patent with 4G10, a POSA could "[c]all Dr. Ellies and ask for" the antibody. Id. at 47. Dr. Ellies testified that the sclerostin antibodies identified in Ellies 2006 were generated by "call[ing] somebody who does that stuff and pay[ing] for it." See D. 170-14 at 51.

[11] Dr. Almagro and another OMAB expert, Dr. Kurt Hankenson, agreed that a sclerostin-binding antibody does not necessarily antagonize sclerostin's function. D. 170-12 at 45; D. 235-

the specification appear to be 4B9, 6E6, 4G10 and 4A6. D. 170-2 at 9; D. 170-15 at 4, 8. The specification, however, "contains no details about these . . . species beyond the alphanumeric designations . . . for a skilled artisan to determine how or whether they are representative of the entire claimed genus." Juno, 10 F.4th at 1336.

Moreover, relevant to whether a patent describes representative species to support a genus "is how large a genus is involved and what species of the genus are described in the patent." AbbVie, 759 F.3d at 1299. 4G10 and 4A6 are monoclonal, and claim 8 is not limited to such antibodies. See D. 170-2 at 18. The asserted claims include bispecific and humanized antibodies, id. at 8, and no such antibodies are disclosed. Dr. Hale opined that he was unaware of any "examples in the prior art of anti-sclerostin antibodies, much less antagonists," that are, *inter alia*, "naturally occurring, single chain, chimeric, bifunctional, [or] fragments." D. 170-13 ¶ 242; see AbbVie, 759 F.3d at 1300 (concluding written description was lacking where "the number of the described species appear[ed] high quantitatively, [but] the described species [were] all of the similar type and [did] not qualitatively represent other types of antibodies encompassed by the genus"). Dr. Almagro opined that as of the priority date, there were three bispecific antibodies in clinical trials, and that because "[b]ispecifics do not exist in nature," their "construction and testing . . . required a deep knowledge of antibody engineering methods in 2006 to achieve the desired results." D. 235-2 ¶ 110. To the extent OMAB suggests that there is written description support because the specification and background knowledge would allow a POSA to generate antibodies usable in the claim, this is insufficient. See Alonso, 545 F.3d at 1022 (noting, in affirming Patent Trial and Appeal Board ("PTAB") precursor's decision of inadequate written

5 ¶ 144. Dr. Hankenson opined that as of the priority date, "a POSA would have known that a variety of assays were available to probe an antibody's antagonism of sclerostin." D. 235-5 ¶ 143.

description, that the "sparse description of antibody structure in the claim [stood] in stark contrast to the detailed method of making the antibodies found in the specification" (emphasis in original)).

The antibodies disclosed in Paszty do not alter this conclusion. Although prior art is relevant to a POSA's understanding of what was actually disclosed in the specification, BASF, 28 F.4th at 1264, even the additional sclerostin antagonists disclosed in Paszty would not render the species disclosed in the specification representative. See Ajinomoto, 932 F.3d at 1359 (explaining that in light of background knowledge, it was permissible to find representative number of species disclosed in patent specification); Juno, 10 F.4th at 1338 n.2 (explaining that although specification need not redescribe prior art, claims covered numerous species relatively unknown in prior art and failed to describe same); PureCircle USA Inc. v. SweeGen, Inc., No. 2022-1946, 2024 WL 20567, at *4 (Fed. Cir. Jan. 2, 2024) (affirming summary judgment of inadequate written description where species disclosed was not shown to be representative of claimed genus).

Taken together, these facts demonstrate that no reasonable jury could find the written description requirement satisfied here. While the '196 patent seeks certain exclusive rights to use any anti-sclerostin antagonist antibody, it includes "only a research plan" for same. AbbVie, 759 F.3d at 1300. Accordingly, Amgen is entitled to summary judgment as to the asserted claims of the '196 patent.

b) '373 and '681 Patents

Unlike the '196 patent, the representative claims of the '373 patent (Claim 15) and '681 patent (Claim 29) do not recite administration of a sclerostin-antagonizing antibody as a step. D. 170-3 at 25; D. 170-4 at 20-21. Rather, the representative claims recite "serially administering" an antiresorptive drug to a human subject with low bone mass during treatment with "a sclerostin-recognizing antibody." D. 170-3 at 25; D. 170-4 at 21; see D. 99. OMAB contends that because antibody treatment is a patient population descriptor rather than a claimed method step, the written

description requirement is inapplicable. D. 227 at 19-20. The Court, however, agrees with Amgen that the requirement applies to the limiting preambles here. See D. 264 at 6.

The parties agreed (and the Court adopted) that the preambular phrase "being treated with a sclerostin-recognizing antibody" is limiting. D. 69-1 at 4-5; D. 99 at 1 n.1; see Eli Lilly & Co. v. Teva Pharms. Int'l GmbH, 8 F.4th 1331, 1341 (Fed. Cir. 2021) (recognizing that "claim construction analysis of statements of intended purpose in methods of using . . . compositions has tended to result in a conclusion that such preamble language is limiting"). Although OMAB is correct that the '373 and '681 patents "do not include administering antibodies as a step in their claimed methods," see D. 227 at 13, it does not follow that the statutory requirements only apply to such steps rather than to all claim limitations.[12] The Federal Circuit has reached the opposite conclusion. In Xencor, the court affirmed a decision of the PTAB Appeals Review Panel ("ARP") rejecting certain patent application claims for lack of written description. Xencor, 130 F.4th at 1353-54. The claims at issue were a "Jepson claim" to an improvement over "a method of treating a patient by administering an anti-C5 antibody with an Fc domain" and a claim to a "method of treating a patient by administering an anti-C5 antibody." Id. at 1354-55 (emphases deleted).[13]

[12] The cases upon which OMAB relies, see D. 227 at 14-15, also do not compel such a conclusion. In Janssen Pharmaceuticals, Inc. v. Mylan Laboratories Ltd., No. 20-cv-13103, 2023 WL 3605733 (D.N.J. May 23, 2023), aff'd, No. 23-2042, 2025 WL 946390 (Fed. Cir. Mar. 28, 2025), the court analyzed whether having "been last administered a PP3M injection 4 to 9 months ago" was a "step" in a method claim to determine whether proposed labels would induce direct infringement, which "depend[ed] on whether any claimed dosing regimen steps [would] be performed by a second actor." Id. at *12-14. In Summit 6, LLC v. Samsung Electronics Co., 802 F.3d 1283 (Fed. Cir. 2015), the court construed use of the phrase "being provided to" as merely "a reference back to the previously claimed 'pre-processing parameters'" that "characteri[zed]" the parameters, rather than a step. Id. at 1291. It then explained that this characteristic "must be proved, just like any other limitation" but rejected the argument that the language required "the provision of pre-processing parameters only during the operation of the method." Id.

[13] In a claim in Jepson format, "a patentee uses the preamble to recite 'elements or steps of the claimed [combination] which are conventional or known.'" Xencor, 130 F.4th at 1357 (quoting

OMAB misreads Xencor as applying the written description requirement only to the Jepson claim, see D. 227 at 19, but with respect to the method claim, the court affirmed that "treating a patient" was limiting and that the application failed to satisfy the written description requirement for that limitation.[14] Xencor, 130 F.4th at 1359. As to the Jepson claim, whose preamble was undisputedly limiting, the court held that a Jepson claim preamble requires written description because the preamble defines the claim's scope, and "the Jepson claim invention is the totality of what is set out in the claim, just as it is for a non-Jepson claim." Id. at 1360-61 & n.9. Finally, the court concluded there was substantial evidence supporting the finding that the applicant "had not established that the limitation in the Jepson preamble, the anti-C5 antibodies, was well-known in the art," and it affirmed that the application failed to satisfy the written description requirement as to the Jepson claim. Id. at 1362-63. OMAB's reliance upon United Therapeutics Corp. v. Liquidia Technologies, Inc., 74 F.4th 1360 (Fed. Cir. 2023), is misplaced. See D. 227 at 19-20. The relevant phrase in that case was "[a] method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose" of a compound. United Therapeutics, 74 F.4th at 1364. The Court is not persuaded that the Federal Circuit's omission by ellipses of "by inhalation to a human suffering from pulmonary hypertension" in its written description analysis, see id. at 1371, has the legal significance OMAB advocates here, D. 227 at 19-20. Moreover, the patient characteristics "suffering from pulmonary hypertension" and "being treated with a sclerostin-recognizing

37 C.F.R. § 1.75(e) (1996)); see Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (noting Jepson claims as common example of claims with limiting preamble).

[14] The applicant acknowledged that "administering an anti-C5 antibody" was limiting. Xencor, 130 F.4th at 1358. The ARP had also noted, as to the method claim, that the specification lacked "any examples of treating patients with [the relevant antibody] or any other written description support even for the single named anti-C5 antibody." Id. at 1356.

antibody" are markedly different: the first is a natural phenomenon, whereas the second is itself an inventive concept. Accordingly, the Court concludes that the limiting preambles here are subject to the written description requirement. To conclude otherwise would permit a patentee to use a limiting preamble to recite even completely unknown claim limitations. See, e.g., Xencor, 130 F.4th at 1362 (cautioning that, "[f]or example, a patentee cannot obtain a Jepson claim with a preamble that says that a time machine is well-known in the art without describing a time machine" because this "would leave the patent system vulnerable to . . . abuse").

Dr. Almagro opined that in these patents, "the genus is constrained to those antibodies that are useful for treating human patients," D. 235-2 ¶ 290, and that, although the claims recite "sclerostin-recognizing antibod[ies]," context indicates that the relevant antibodies must actually be those that "antagonize[] sclerostin" and "operate[] through LRP," id. ¶ 288.[15] Even assuming this construction is correct, added context does not cure the patents of the issues identified above with respect to the '196 patent. Accordingly, the Court allows Amgen's motion for summary judgment for failure of the asserted claims to satisfy the written description requirement.

2. Enablement

Even assuming the written description requirement was satisfied, the Court concludes that the asserted claims are not enabled. A patent specification "must enable a person skilled in the art to make and use the claimed invention." In re Wands, 858 F.2d 731, 735 (Fed. Cir. 1988) (citing 35 U.S.C. § 112). Enablement and written description are distinct requirements, and each can be met even if the other is not. See Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's

[15] Dr. Almagro also opined that a "POSA would have known that there are . . . sclerostin-recognizing antibodies being used to treat the patients in the asserted claims of the '373 and '681 patents." D. 235-2 ¶ 296. His meaning is unclear, as no human had apparently received such treatment as of the priority date. See, e.g., id. ¶¶ 106-10 (discussing clinical development); D. 170-12 at 64 (agreeing that, as of priority date, none of the antibodies were FDA-approved).

Lab'ys Inc., 923 F.3d 1368, 1382 (Fed. Cir. 2019). "Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation." Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380, 1384 (Fed. Cir. 2013). In the enablement requirement, "the law secures for the public its benefit of the patent bargain" by ensuring that when a patent expires, the public can practice the claimed invention over which the patentee was granted a temporary monopoly. See Amgen Inc. v. Sanofi, 598 U.S. 594, 605 (2023). To assess enablement, the Court considers: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Wands, 858 F.2d at 737. For claims that include functional requirements, the enablement inquiry "can be particularly focused on the breadth of those requirements" and should "consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim." Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021), aff'd, 598 U.S. 594. Ultimately, "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art." Amgen, 598 U.S. at 612.

As OMAB points out, see D. 227 at 21, Amgen focuses on cases where the novelty of the claimed invention was the genus of antibodies itself, see Amgen, 598 U.S. at 602 (describing claims to genus of antibodies that bind to specific amino acid residues of particular naturally occurring protein and block same from binding to LDL receptors); Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1363 (Fed. Cir. 2023) (discussing claim to antibody or fragment thereof that binds particular enzyme and increases procoagulant activity), or to a method involving a novel genus of

compositions, see Wyeth, 720 F.3d at 1385 (explaining that "the invention is a new method of use of a known compound (sirolimus) and any other compounds that meet the [claim] construction's structural and functional requirements" (emphasis in original)).[16]

Importantly, the parties disagree about the role of background knowledge in the enablement inquiry, See D. 227 at 20-22; D. 264 at 7-8. In Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997), which Amgen cites, see D. 264 at 8, the court ruled both that background knowledge can fill in only "minor details" omitted from a specification but also implied that same could supply any "[non-]novel aspects of an invention." Genentech, 108 F.3d at 1366. Subsequent cases have reiterated that a "specification must reasonably teach how to make and use [the novel] aspect of the invention." McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1102 (Fed. Cir. 2020); see Brita LP v. Int'l Trade Comm'n, 156 F.4th 1326, 1339 (Fed. Cir. 2025); Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1283 (Fed. Cir. 2007); see also Pharmacyclics LLC v. Alvogen, Inc., No. 2021-2270, 2022 WL 16943006, at *11 (Fed. Cir. Nov. 15, 2022).[17] The Federal Circuit has further explained: "[W]ith respect to enablement the relevant inquiry lies in the relationship between the specification, the claims, and the knowledge of one of ordinary skill in the art. If, by following the steps set forth in the specification, one of ordinary skill in the art is not able to replicate the claimed invention without undue experimentation, the claim has not been enabled[.]" Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). In turn, to ascertain whether undue experimentation would be

[16] OMAB also so characterizes Idenix Pharmaceuticals LLC v. Gilead Sciences Inc., 941 F.3d 1149 (Fed. Cir. 2019). See D. 227 at 21. Although the court in Idenix noted the patentee's expert testimony "that the field was new and unpredictable," this was only one factor in the court's analysis. See Idenix, 941 F.3d at 1161.

[17] Enablement's focus on novelty aligns with novelty's patentability role. See 35 U.S.C. § 102.

required to practice the full scope of the claims, courts frequently look to the Wands factors, which themselves account in various ways for background knowledge. See Wands, 858 F.2d at 737. The Court does not understand the "novel aspect of the invention" language in the Federal Circuit's enablement precedent to conflict with the requirement that the "full scope" of a claimed invention be enabled. See Wyeth, 720 F.3d at 1384.

If the parties agreed about the state of the prior art, it follows that they would be in agreement about what was not in the prior art (i.e., what aspects of the claimed invention were novel), and the enablement inquiry would appropriately focus on what they agreed was novel. Here, however, the parties disagree about the state of the prior art, meaning that they disagree about what aspects of the invention are novel. In either circumstance, the aim of the enablement analysis is to determine whether a POSA could practice the claimed invention without undue experimentation. See Nat'l Recovery Techs., 166 F.3d at 1196.[18]

a) '196 Patent

As previously discussed, to practice representative claim 8 of the '196 patent, a POSA must administer to a human patient a composition comprising an anti-sclerostin, sclerostin-inhibiting antibody, followed by an antiresorptive drug. See D. 170-2 at 18, 22. With the above framework

[18] The Court is not persuaded by OMAB's suggestion that antibodies recited in the Patents-in-Suit are somehow irrelevant to the enablement inquiry. See D. 227 at 22 (citing In re Biogen '755 Pat. Litig., No. 10-cv-2734-CCC-JBC, 2018 WL 3586271, at *7 (D.N.J. July 26, 2018)). In Biogen, the court relied upon the reasoning in Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co., No. 15-cv-1202-WCB, 2016 WL 6138124 (E.D. Tex. Oct. 21, 2016) ("UroPep"), discussing the written description requirement in the context of method-of-treatment claims, and noted that court's recognition that this framework might have less force if less was known about the compounds at issue. See Biogen, 2018 WL 3586271, at *7 & n.13. The UroPep court refined this reasoning in a later stage of UroPep, see 276 F. Supp. 3d at 648-50, and the Federal Circuit later observed, in rejecting a party's reliance upon UroPep, that it involved "hundreds of known [species of] the type of compound at issue, and the patent identified the compounds by chemical name and structural drawings," and they "also shared a common physical structure to fit the active site of the [relevant] enzyme to inhibit its activity." Juno, 10 F.4th at 1339 n.3.

in mind, this claim is enabled if a POSA could practice its full scope without undue experimentation. See Wyeth, 720 F.3d at 1384.

Dr. Almagro offered opinions on each of the Wands factors. See D. 235-2 ¶¶ 347-70. With respect to the nature of the invention and breadth of the claims, Dr. Almagro disputed Dr. Hale's calculation of the size of the relevant class of anti-sclerostin antibodies. See id. ¶ 349. Dr. Almagro generally did not estimate the size of the genus, instead electing to disagree with Dr. Hale's opinion. See, e.g., id. ¶¶ 201 ("significantly more limited than Dr. Hale's portrayal"), 203 ("Dr. Hale grossly exaggerates the size"), 205 ("[t]he actual number would be a tiny fraction of what Dr. Hale suggests"), 280 ("[e]ven if the theoretical number of possibilities appears large, the reality is unlikely to match Dr. Hale's unconstrained theory"), 349 ("significantly more limited than Dr. Hale's portrayal"). Even Dr. Almagro, however, hypothesized that the genus could include 35,000 species minus those that fail to appropriately antagonize sclerostin, "which may give a calculable and manageable figure in the context of biotech development." Id. ¶ 203 n.20. For reasons discussed above regarding written description, there can be no genuine dispute that the claims involve a broad, functionally defined genus of antibodies. See Amgen, 987 F.3d at 1087.

As to the three Wands factors focused on the art, Dr. Almagro opined that the level of skill was "very high" and included familiarity with techniques for generating, characterizing and humanizing antibodies and drug development, D. 235-2 ¶ 353; that "the state of the art was advanced and mature," including because of Paszty, id. ¶¶ 355-56; and that generating anti-sclerostin antibodies was routine and generating, characterizing and humanizing antibodies was conventional, id. ¶¶ 358-63.

Further, Dr. Almagro opined that the specification provides sufficient guidance to allow a

POSA to generate, humanize, identify and characterize the antibodies recited in the claims. Id. ¶¶ 364-68. Dr. Almagro opined that Dr. Hale's opinion regarding the amount of effort required for regulatory approval and commercialization did not provide "compelling evidence of undue experimentation," id. ¶ 369, and he opined that he understood working examples were unnecessary but that the patents included such examples of anti-sclerostin antibodies, id. ¶ 370. Dr. Almagro's opinions regarding the steps a POSA would need to undertake to practice the method claimed in the '196 patent, however, merely demonstrate that the method is akin to those claims determined non-enabled by the Federal Circuit and Supreme Court:

> [I]t is undisputed that to practice the full scope of the claimed invention, skilled artisans must make candidate antibodies and screen them to determine which ones perform the claimed functions. This is the definition of trial and error and leaves the public no better equipped to make and use the claimed antibodies than the inventors were when they set out to discover the antibodies over which they now have an exclusive right.

Baxalta, 81 F.4th at 1367 (citation omitted). OMAB understates the exclusive right it has obtained over the use of anti-sclerostin antibodies. Because OMAB has not enabled the full scope of its claimed method, it is not entitled to that exclusivity, and no reasonable jury could conclude otherwise. Accordingly, Amgen is entitled to summary judgment as to the asserted claims in the '196 patent.

b) '373 and '681 Patents

While the Court agrees with Amgen that the limiting preambles define the scope of the claims in the '373 and '681 patents, see CFMT, Inc. v. YieldUp Int'l Corp., 349 F.3d 1333, 1336-40 (Fed. Cir. 2003), Amgen has not identified any case holding that a limiting preamble must be enabled. See D. 264 at 12. Instead, Amgen contends that the reasoning of Xencor extends to enablement, because "both requirements stem from [§] 112." Id. Regardless of whether Xencor extends beyond written description, "the more a party claims, the broader the monopoly it

demands, the more it must enable." Amgen, 598 U.S. at 613. For the same reason that the written description requirement properly applies to the limiting preambles here, OMAB cannot avoid the enablement requirement. Accordingly, the Court concludes that the same enablement requirement applies to the '373 and '681 patents, and Amgen is entitled to summary judgment on this ground for the reasons stated with respect to the '196 patent. D. 167. Although the Court need not reach Amgen's remaining summary judgment motions, D. 168-69, in light of this ruling, it does so in the interest of completeness.

B. Failure to Describe the Claimed Methods

In its second summary judgment motion, D. 168, Amgen argues that the Patents-in-Suit are invalid because the specification does not demonstrate that Dr. Ellies possessed the claimed methods of treatment as of the priority date. D. 190 at 5, 11-17.[19] Specifically, Amgen contends that the specification improperly "assert[s], without any scientific basis or data or examples or experiments or embodiments, that the sequential administration of anti-sclerostin antibodies and antiresorptive drugs actually increases or hasten[s] bone formation." Id. at 11. Amgen argues that the Patents-in-Suit are invalid as a matter of law because, in its view, OMAB "contends that a skilled artisan would not have thought the claim methods would work and yet the specification offers no theory or explanation for how or why they would." Id. at 16 (citation omitted).

According to Amgen, OMAB has only identified two passages in the specification that describe the claimed methods. D. 288-1 ¶ 15. The first recites:

> The antagonist may be coadministered or serially administered with an antiresorptive drug if desired to increase or hasten bone formation. For example, the antiresorptive drug may be a bisphosphonate (i.e. fosamax, actonel), a PTH or

[19] Amgen moved for leave to file a notice of supplemental authority in connection with this motion, D. 290, and OMAB moved for leave to respond to same, D. 292. The Court allows the motions, *nunc pro tunc*, and reviewed same in considering the summary judgment motion.

> analog (i.e. Forteo), calcitonin or analog (i.e. Miacalcic), Vitamin D or analog, SERM or analog (i.e. Evista).

Id. ¶ 16 (citing D. 170-3 at 16). The second recites:

> The methods of the present invention include application of SOST antagonists in cocktails including other medicaments, for example, antibiotics, fungicides, and anti-inflammatory agents. Alternatively, the methods may comprise sequential dosing of an afflicted individual with a SOST antagonist and one or more additional medicaments to optimize a treatment regime. In such optimized regimes, the medicaments, including the granulation inhibitor may be applied in any sequence and in any combination.

Id. ¶ 17 (citing D. 170-3 at 20). OMAB disputes Amgen's assertion, pointing to OMAB expert Dr. Mone Zaidi's opinion that the disclosures in the specification, read as a whole from the perspective of a POSA, describe the claimed methods. Id. ¶¶ 15-17; see D. 235-3 ¶¶ 588-648. OMAB also directs the Court to the passage in the specification stating that one embodiment of the claimed invention "relates to promoting new bone by systemic administration of a Sost or Wise antagonist in combination with an antiresorptive agent." D. 170-3 at 12; see D. 288-1 ¶ 14.

As an initial matter, Amgen's focus on whether a POSA "would . . . know whether the claimed methods work" falls flat. See D. 190 at 5; id. at 12 (arguing that "OMAB admits that, until Amgen's research and development work on Evenity . . . no one had demonstrated that the claimed methods of treatment were effective at all"). The written description requirement "is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue." Alcon Rsch. Ltd. v. Barr Lab'ys, Inc., 745 F.3d 1180, 1191 (Fed. Cir. 2014). That said, adequate written description is not "necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification." Nuvo, 923 F.3d at 1380 (internal quotation marks and citation omitted); see Ariad, 598 F.3d at 1350.

1. '196 Patent

Here, the Court accepted the parties' construction of "effective amount" in claim 1 of the '196 patent to mean "[a]n amount that achieves the claimed result of systemically increasing bone density." See D. 69-1 at 5; D. 99 at 1 n.1. Federal Circuit "case law does not require experimental data demonstrating effectiveness." Nuvo, 923 F.3d at 1380; cf. Biogen, 18 F.4th at 1343 (upholding determination "that a skilled artisan would not have recognized, based on the single passing reference to a DMF480 dose in the disclosure, that DMF480 would have been efficacious in the treatment of MS, particularly because the specification's only reference to DMF480 was part of a wide DMF-dosage range and not listed as an independent therapeutically efficacious dose"). Moreover, a specification need not include a "theory or explanation of how or why a claimed composition will be effective," and "the invention does not actually have to be reduced to practice." Nuvo, 923 F.3d at 1380. Even so, the Federal Circuit has required more descriptive support where efficacy is claimed and the specification or other evidence shows that a POSA would not have expected efficacy. See id. at 1384 (invalidating claim to use of uncoated medicine to raise gastric pH by a specific amount, where therapeutic effectiveness was not adequately described, and "a person of ordinary skill in the art reading the specification would not have otherwise recognized . . . that it would be efficacious because he or she would not have expected uncoated PPI to raise gastric pH"); Brita, 156 F.4th at 1332-36 (affirming agency decision of inadequate written description where invention claimed particular efficacy using "any filtration media type with activated carbon and a lead scavenger" but, *inter alia*, specification disclosed that only carbon-block filters were capable of meeting functional limitation, experts agreed that only working examples were carbon-block filters, specification discussed disadvantages of other filter media and agency found that inventors admitted they only possessed carbon-block filters).

The parties dispute whether a POSA would have expected the claimed method to have any efficacy. OMAB dismisses Amgen's argument, explaining that a POSA would have known that each component treatment was effective to increase bone density, and therefore "would have expected at least some systemic increase in bone density." D. 231 at 18 (emphasis in original). It is well settled, however, that "a description that merely renders the invention obvious does not satisfy the [written description] requirement." Ariad, 598 F.3d at 1352.

Moreover, setting aside the claimed efficacy, the Court concludes that on this record, no reasonable juror could find that the specification reasonably conveys to a POSA that Dr. Ellies had possession of the claimed methods as of the priority date. See id. at 1351. The written description requirement varies based on the nature and scope of the invention. See Capon, 418 F.3d at 1357. The asserted claims in the '196 patent cover methods of treatment involving, at least, an enormous number of possible combinations of numerous antibodies with numerous species of antiresorptive agents. See D. 170-2 at 18.[20]

It is undisputed that the specification does not include any working examples of the claimed methods. See D. 235-3 ¶ 681; Bos. Sci., 647 F.3d at 1364 (explaining that "[a]lthough examples are not always required to satisfy the written description requirement, the lack of any disclosure of examples may be considered when determining whether the claimed invention is adequately

[20] Dr. Zaidi disagreed with such characterization, opining with respect to certain asserted claims that there are "one of two possible combinations: antisclerostin antagonist followed by antiresorptive drug OR antiresorptive drug followed by antisclerostin antagonist." D. 235-3 ¶ 631. As to claim 8 of the '196 patent and the asserted claims of the '373 and '681 patents, he opined that "there is just one combination—the patient is treated with a sclerostin-recognizing antibody first, and then the antiresorptive drug is administered." Id. Such opinion does not change the language of the claims that govern here which allow for numerous combinations. See, e.g., Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996) (noting that expert testimony "may not be used to vary or contradict . . . claim language" and that "where the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight").

described"). Dr. Ellies testified that as of the priority date, she could not have named any antibody that binds sclerostin and that, when administered with an antiresorptive, systemically increases bone density. See D. 288-1 ¶ 22; Nuvo, 923 F.3d at 1381 (explaining that "[a]lthough inventor testimony cannot establish written description support where none exists in the four corners of the specification," it may "illuminate[] the absence of critical description"); Seagen Inc. v. Daiichi Sankyo Co., 160 F.4th 1322, 1331 (Fed. Cir. 2025) (same). Apart from repeating the passages in the specification stating what the invention is, Dr. Zaidi largely points to information disclosed in the specification about the individual components of the methods (i.e., antibodies and antiresorptive agents). See D. 235-3 ¶¶ 597-600, 607-17, 623-28. His opinion that serial and sequential administration are adequately described rests on assertions that a POSA would have understood what the claim language meant and how to effectively administer the components. See id. ¶ 631. Taken together, the expansive nature of the method claims and the dearth of illuminating information in the specification compel a conclusion that the asserted claims are not adequately supported as a matter of law.

2. '373 and '681 Patents

OMAB contends that Amgen's argument fails with respect to the '373 and '681 patents because they do not claim efficacy. See D. 231 at 15. Amgen disagrees because as construed, the claims in these patents must be performed with the "intent" to increase bone density or formation. D. 265 at 12. The Court agrees with OMAB that the asserted claims do not include efficacy limitations. See Xencor, 130 F.4th at 1359. Despite the drafting differences between the patents, however, the Court concludes that Amgen has met its burden for the (non-efficacy-related) reasons stated above. The Court, therefore, allows Amgen's second motion for summary judgment, D. 168.

C. Obviousness of or Failure to Describe the Claimed Methods Where Vitamin D Is the Antiresorptive

In its third summary judgment motion, D. 169, Amgen argues that eleven of the sixteen asserted claims, which contemplate vitamin D as the antiresorptive (the "Vitamin D Claims"), are invalid as obvious or for inadequate written description.[21] D. 192 at 10. Amgen first asserts that the Vitamin D Claims must be construed to include concurrent administration of the anti-sclerostin antibody and antiresorptive drug, rendering them obvious. Id. Alternatively, Amgen contends that if the claims exclude concurrent administration, they are inadequately described. Id.

Amgen's obviousness argument is premised on a faulty understanding of the Court's claim construction order. Amgen represents that OMAB "never presented" the argument that serial or sequential administration excluded concurrent administration and that Amgen, therefore, "had no reason or opportunity to respond." D. 266 at 7. In its opening claim construction brief, however, OMAB argued that the "claims that recite 'serially administering' the antiresorptive are limited to non-overlapping treatment," meaning limited to treatment in which the administration of the anti-sclerostin antibody did not overlap with administration of the antiresorptive drug. See D. 78 at 13; see also id. at 16 (arguing that patent abstract "reflects the understanding that when medications are administered sequentially, they are not coadministered 'together,' i.e. the courses of treatment are consecutive and non-overlapping"). In its responsive brief, Amgen argued that the claims did not "dictate that there be two entirely distinct, non-overlapping 'course[s] of treatment.'" D. 89 at 18 (alteration in original); see id. at 21 (arguing that certain extrinsic evidence "does not address whether sequential administration means non-overlapping courses of treatment"). Finally, OMAB

[21] Amgen's argument applies to claims 8 and 10 of the '196 patent; claims 15 through 19, 21 and 22 of the '373 patent; and claims 12 and 29 of the '681 patent. D. 169 at 2; D. 192 at 20. Amgen appears to take no position on claim 27 of the '681 patent. See D. 192 at 7 & n.2.

explained during the Markman hearing that "concurrent" combination therapy meant "when two drugs are given at the same time" and that "sequential" therapy was "where a patient receives one drug and then another" with a transition period in between the two courses of treatment. D. 97 at 12. Amgen argued that "serial" did not mean that "two things happen separately." Id. at 52; see id. at 53-54 (arguing that OMAB did not "say what we are claiming is finish the course of treatment with the antibody and then give the antiresorptive," but rather "[w]hat they say they invented is a combination of one treatment with two drugs, whether you give them on the same day or you alternate them or you give one of them in series"); id. at 90 (arguing that "you can[not] understand what this means by looking to extrinsic evidence of how two drugs are given in sequential separate courses of treatment," because the '373 patent "is not a patent about two consecutive courses of treatment").

In these circumstances, the Court will not permit relitigation of claim construction arguments. See Apple, Inc. v. Samsung Elecs. Co., No. 12-cv-00630-LHK, 2014 WL 252045, at *4 (N.D. Cal. Jan. 21, 2014) (explaining that "local rules and this Court did not set out a particular process for resolving claim construction disputes only to let the parties make additional arguments at the summary judgment phase untethered to those carefully structured rules"); DNA Genotek Inc. v. Spectrum Sols. L.L.C., 671 F. Supp. 3d 1105, 1119-20 (S.D. Cal. 2023) (concluding party waived argument raised at summary judgment where it argued during claim construction that term did not require construction), aff'd sub nom. DNA Genotek Inc. v. Spectrum Sols. LLC, No. 2023-2017, 2025 WL 502040 (Fed. Cir. Feb. 14, 2025). In any event, the Court does not agree with Amgen's attempt to cast the exclusion of concurrent administration from serial or sequential administration as a negative claim limitation. See D. 192 at 12-18. Amgen's interpretation would frustrate the construction of serial and sequential and, in any event, ignores that claims can be

limited in specific ways without necessarily featuring negative limitations. Where claim language requires a method to be performed in a particular sequence, for instance, that is not analyzed as a negative limitation. See, e.g., Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1369-70 (Fed. Cir. 2003) (explaining how to determine whether steps of method claim that do not recite order must be performed in order in which they are written); Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp., 540 F. Supp. 2d 1233, 1251 (M.D. Fla. 2008) (concluding that based on "the claim language, there [was] no reason why the formation of the polymer core material and the alteration of the surface of the core material must be consecutive steps; the language of the claim [did] not exclude the possibility that the two steps occur simultaneously or concurrently"). Thus, the Court addresses only Amgen's written description argument.[22]

As to written description, Amgen argues that the Vitamin D Claims are invalid because the Patents-in-Suit do not demonstrate that Dr. Ellies "had possessed that the use of vitamin D only after (and not also during) treatment with an anti-sclerostin antibody would somehow increase bone density." D. 192 at 18. Although the premise of Amgen's argument seems to be that the written description standard is heightened whenever prior art teaches away from the claimed invention, it has not directed the Court to any case holding same. See id. at 19-20; D. 266 at 12-13. Nevertheless, the Court agrees that Amgen is entitled to summary judgment that the Vitamin D Claims are invalid as inadequately described.[23]

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[22] OMAB filed a related motion, D. 175, seeking to "exclude Amgen from advancing inadmissible claim construction arguments guised within invalidity [expert] opinions in support of any motion or at trial," D. 176-1 at 4. At oral argument, Amgen's counsel conceded that if the Court concluded "Amgen's view of the claims [was] incorrect," the expert would not offer such testimony. D. 294 at 57. In light of the Court's conclusion regarding Amgen's claim construction argument, the Court denies OMAB's expert motion, D. 175, as moot.

[23] To the extent OMAB contends that the claims cannot be invalid because the Court construed disputed terms, see D. 233 at 23-24, the authority it relies upon does not so hold. See In re Entresto, 125 F.4th 1090, 1098 (Fed. Cir. 2025) (explaining that claim construction concerns

As both parties largely rely upon their arguments regarding Amgen's second motion for summary judgment, see D. 192 at 18-19; D. 233 at 24 n.5; D. 266 at 13, the Court incorporates that analysis here. OMAB's other arguments do not compel a different outcome. OMAB contends that Amgen's motion fails because it "assumes that the claims have efficacy limitations such that the specification must describe a particular level of effectiveness," that such is not true of the claims in the '373 and '681 patents and that Amgen has not shown that a POSA would expect serial administration of vitamin D in the '196 patent to be totally ineffective. See D. 233 at 24-25. OMAB relies upon United Therapeutics to argue that any written description issue with vitamin D would not automatically invalidate the claims, id. at 25, but United Therapeutics does not support this argument. In rejecting the argument that limited utility in a subset of patients having a variant of a particular disease would render written description covering those patients insufficient, the court specifically noted that a "subset of unresponsive patients is not analogous to unsupported species in a generic claim to chemical compounds." United Therapeutics, 74 F.4th at 1371. Here, by contrast, the method claims involve use of any antiresorptive, including, as disclosed in the specification, the "species" vitamin D. See D. 170-3 at 16. Moreover, to the extent OMAB relies upon the inherent disclosure doctrine, it has not developed any argument to support the application of same here, see D. 233 at 25, and the case it cites at the end of its brief is distinguishable here, see Yeda Rsch. & Dev. Co. v. Abbott GMBH & Co. KG, 837 F.3d 1341, 1345 (Fed. Cir. 2016) (concluding written description was satisfied for priority purposes under inherent disclosure doctrine where it was "undisputed that the invention described in an earlier application was the

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the "scope of what is claimed (and must be adequately described)"); United Therapeutics, 74 F.4th at 1370-71 (remarking that as construed, claimed invention satisfied written description requirement); cf. Seagen, 160 F.4th at 1333 (concluding claim that included limitation construed broadly by district court was not enabled).

exact invention claimed by the later patent"). Accordingly, the Court concludes that Amgen is entitled to summary judgment that the Vitamin D Claims are invalid. D. 169.[24]

VI. Conclusion

For the foregoing reasons, the Court ALLOWS Amgen's motions for summary judgment, D. 167; D. 168; D. 169, and DENIES OMAB's motion for partial summary judgment, D. 171, and the parties' respective motions to strike, D. 175; D. 178; D. 181; D. 183; D. 185, as moot.

So Ordered.

/s Denise J. Casper
Chief United States District Judge

[24] In light of its rulings on Amgen's summary judgment motions, the Court need not reach the parties' motions regarding proposed expert testimony. As already discussed, OMAB's motion to exclude certain expert testimony as inconsistent with the Court's claim construction order, D. 175, is denied as moot. See note 22, *supra*. In its remaining expert motions, OMAB seeks to exclude certain opinions of Amgen's experts regarding damages, see D. 178; D. 179-1; D. 294 at 74 (arguing proposed testimony would mislead jury), and United States Patent and Trademark Office ("USPTO") practice, see D. 185; D. 186-1 at 4-5 (contending certain opinions should not be allowed to be offered at trial). Amgen seeks to exclude certain trial testimony of OMAB's experts regarding damages, see D. 183; D. 194 at 4 (arguing testimony would confuse jury), and USPTO practice, see D. 181; D. 195 at 4 (arguing for exclusion of testimony at trial). Because the Court allows Amgen's motions for summary judgment, it denies these motions regarding expert testimony, D. 175; D. 178; D. 181; D. 183; D. 185, as moot.