

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS  
IRELAND CO., LTD., and ASTELLAS  
PHARMA GLOBAL DEVELOPMENT,  
INC.,

Plaintiffs,

v.

ASCENT PHARMACEUTICALS, INC.,

Defendant.

**CIVIL ACTION NO. 23-486-JFB-CJB**  
**MEMORANDUM AND ORDER**

**I. INTRODUCTION**

This matter is before the Court on parties' motions for claim construction regarding an action for patent infringement of United States Patent No. 10,842,780 ("the '780 Patent"). [D.I. 49](#) and [D.I. 50](#); see [D.I. 1](#); [D.I. 12](#). Defendant, Ascent Pharmaceuticals Inc. ("Ascent"), and Plaintiffs, Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (jointly, "Astellas"), have filed a Joint Claim Construction Chart and Appendix, Joint Claim Construction Brief and Appendix, and separate Supplemental Claim Construction Briefs. [D.I. 39](#); [D.I. 40](#); [D.I. 45](#); [D.I. 46](#); [D.I. 47](#); [D.I. 63](#); [D.I. 64](#); [D.I. 65](#); [D.I. 66](#). The Court adopts Astellas's proposed claim construction. The Court concludes the disputed terms should be given their plain and ordinary meaning.

## II. BACKGROUND

### A. Prosecution History

Astellas obtained the '780 Patent in November 2020. [D.I. 46-1 at 25](#). It claims a time-release formula for the popular bladder-control drug, Myrbetriq®. [D.I. 45 at 8](#).

Astellas filed the '780 Patent application on February 14, 2017. [D.I. 46-2 at 6](#). Claim 6 in the initial application included six polymers and stated, "The pharmaceutical composition for modified release according to Claim 1, wherein the hydrogel-forming polymer is one compound, or two or more compounds selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer." [Id. at 11](#). Claim 7 likewise claimed, "The pharmaceutical composition for modified release according to Claim 6, wherein the hydrogel-forming polymer is one compound, or two or more compounds selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, and hydroxypropyl cellulose." [Id. at 11–12](#).

The Patent Examiner ("Examiner") responded on October 18, 2017, with a restriction and an election requirement. [D.I. 46-2 at 18–20, 73–74](#). First, the Examiner required Astellas to select from three different sets of claims because each set was directed to a different invention under 35 U.S.C. 121. [Id. at 20](#); [D.I. 45 at 30](#). The Examiner restricted Astellas to select one of the following inventions:

- I. Claims 1-15 and 19-20, drawn to pharmaceutical compositions for modified release comprising 2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, an additive, and a hydrogel forming polymer, classified in CPC A61K 31/381.
- II. Claims 16-18, drawn to a method of manufacturing a composition comprising (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, an additive, and a hydrogel forming polymer, classified in CPC A61K 31/381.

- III. Claims 21-37, drawn to methods of reducing an effect of food intake by administering a composition comprising 2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, an additive, and a hydrogel forming polymer, classified in CPC A61K 31/381.

D.I. 46-2 at 20. Next, regardless of the invention selected, the Examiner required Astellas to elect a single disclosed species from the six proposed polymers. *Id.* at 23–25. The Examiner stated,

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-20 are generic to at least one species.

D.I. 46-2 at 25–27, 80–82.

On April 16, 2018, Astellas responded to Restriction Requirement in the October 18, 2017, filing. D.I. 46-2 at 30, 86. Astellas selected the Group I invention without traverse, and elected polyethylene oxide as the species of polymer but did so *with* traverse and for search purposes only. *Id.* at 40, 96. Astellas's response stated,

In response to the restriction requirement, but without conceding the propriety thereof, Applicants elect Group I, claims 1-15, 19-20, and new claims 38-65 without traverse, and without prejudice to the presentation of the claims of the other Groups in later applications.

In addition, Applicants elect “polyethylene oxide” as the hydrogel-forming polymer formulation and “polyethylene glycol” as the additive that ensure penetration of water into the pharmaceutical composition with traverse and for search purposes only.

As the Examiner is aware, restriction is discretionary, and a restriction requirement is made only to avoid placing an undue examination burden on the Examiner and the Patent Office. Here, there is no undue burden to examine all the claims as there is no evidence of record that the searches are of different classes, subclasses or fields. Further, Applicants note that these species were elected in the parent application and have already been examined by Office. Thus, where claims can be examined together without

undue burden, the Examiner must examine the claims on the merits, even if they are directed to independent and distinct inventions. M.P.E.P. § 803.

D.I. 46-2 at 40, 96. Astellas amended Claim 6 but did not remove the six polymers. *Id.* at 32, 88. Astellas also amended Claim 7 to but did not remove the reference to Claim 6 or the listed polymers. *Id.*

The Examiner performed the first prior art search in August and September 2018. D.I. 40-2 at 185–90. The Examiner’s search notes show the Examiner limited the first prior art search to the elected species “polyethylene oxide.” *Id.*

On November 19, 2018, the Examiner acknowledged the elections made by Astellas in the April 16 filing. D.I. 40-2 at 99–123. The Examiner stated, “Applicant’s election without traverse of Group I (Claims 1–15, 19–20, 38–65), as well as polyethylene oxide as the species of hydrogel forming polymer and polyethylene glycol as the species of additive in the reply filed on April 16, 2018[,] is acknowledged.” *Id.* at 102. The Examiner analyzed the prior art and the claimed invention with the elected species of polyethylene oxide, and stated Claims 1–3, 6–7, and 47 to be unpatentable over prior art. *Id.* at 108–19. The Examiner further rejected dependent Claims 4–5, 19, 20, 38–41, 42–45, 46, 48–55, 56–60, and 61–65 because they were unpatentable over prior art. *Id.* at 119–20. The Examiner concluded that no claims were allowed. *Id.* at 122.

On May 13, 2019, Astellas filed an Amendment, Petition for Extension of Time, and Statement of the Substance of the Interview. D.I. 64 at 150. Astellas amended Claims 1–4, 6, 46, and 61; cancelled Claims 16–18, 21–41, 43–45, 47–60, and 62–65; and added new Claims 66 and 67. D.I. 46-2 at 42–46, 128. Astellas again amended Claim 6 but did not remove the six polymers. *Id.* at 43. Astellas did not amend Claim 7. *Id.*

On December 26, 2019, the Patent Office reassigned the application to a new Examiner, who “acknowledged and entered” the “Applicant’s amendments filed May 13, 2019.” [D.I. 46-2 at 128](#). The new Examiner additionally stated,

Applicant’s election without traverse of Group I (Claims 1-15, 19-20, 38-65), as well as polyethylene oxide as the species of hydrogel forming polymer and polyethylene glycol as the species of additive in the reply filed on April 16, 2018[,] is acknowledged. Claims 8-15 stand withdrawn for the reasons set forth in the Office Action dated October 18, 2017.

[D.I. 46-2 at 128](#). The Examiner maintained and reiterated the rejection of claims under [35 U.S.C. § 103](#) as being unpatentable over prior art. *Id.* [at 138–39](#). The Examiner concluded that “no claims are allowed in this application” and “Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, this action is made final. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).” [D.I. 46-2 at 156–57](#) (citation omitted).

On February 18, 2020, Astellas filed an amendment under [37 C.F.R. § 1.116](#) in response to the December 26, 2019, letter. [D.I. 46-2 at 47](#). Astellas did not amend Claims 6 and 7. *Id.* [at 49](#).

On March 2, 2020, the Examiner filed an advisory action in response to Astellas’s amendments in the February 18 filing. [D.I. 46-2 at 191](#), 290. The Examiner did not enter the proposed amendments and stated the amendment “removing the phrase ‘an additive that ensures penetration of water’ would overcome the 112, 2nd paragraph rejection of record; however, by removing this requirement, the instant claims would encompass a number of compositions comprising only mirabegron and a hydrogel-forming polymer.” *Id.* [at 193](#), 292.

On March 10, 2020, Astellas had a phone interview with the Examiner. [D.I. 40-2 at 193–94](#). On March 16, 2020, Astellas filed a submission under [37 C.F.R. § 1.114](#) and statement of the substance of the interview in response to the December 26 filing, and further to Astellas’s amendments in the February 18 filing. [D.I. 46-2 at 53](#). Again, Astellas did not amend Claims 6 and 7. [Id. at 55](#).

On June 26, 2020, Astellas filed a Preliminary Amendment. [D.I. 46-2 at 59](#). Astellas amended Claim 1 by adding the six polymers recited in Claim 6 to Claim 1, and cancelled Claim 6. [Id. at 60–61](#). Astellas amended Claim 7 to reference the newly amended Claim 1 but did not remove the listed polymers. [Id. at 61](#). Claim 7 became Claim 5 in the final patent. [Id. at 66](#). Astellas’s remarks state, “claims 1 and 69 being independent” and “Claims 2 and 6 have been cancelled without prejudice or disclaimer and their features have been incorporated into claim 1.” [Id.](#)

The Examiner performed the final prior art search in July 2020. [D.I. 40-2 at 199–204](#). The Examiner expanded the final prior art search to encompass all “hydrogels” prior to allowing the patent. [Id.](#) On July 22, 2020, the Examiner responded and issued a Notice of Allowance to the Claims “1, 3–5, 7–15, 19–20, 42, 46, 61 and 66–72.” [Id. at 67–71, 159–63](#).

## **B. '780 Patent**

Astellas obtained the '780 Patent on November 24, 2020. [D.I. 46-1 at 25](#). Claim 1 in the '780 Patent recites “wherein the hydrogel-forming polymer is at least one compound selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer.” [Id. at 40](#). Claim 22 in the '780 Patent recites “in

a sustained release hydrogel-forming formulation comprising a means for forming a hydrogel.” *Id.* at 41.

Additionally, the Summary of Invention section in the ‘780 Patent explains “[t]he present invention provides” that “the hydrogel-forming polymer is one compound, or two or more compounds selected from the group consisting of polyethylene oxide, hyd[r]oxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer.” D.I. 46-1 at 32. The Summary of Invention goes on to consistently state “[t]hese hydrogel-forming polymers may be used alone, or as an appropriate combination of two or more thereof;” a polymer of which the viscosity (before mixing) is beyond the specific range can be used as an appropriate combination with one or more other polymers;” “examples of the hydrogel-forming polymer in another embodiment include polyethylene oxide, hydroxypropyl methylcellulose, and hydroxypropyl cellulose;” and “[t]he pharmaceutical composition for modified release of the present invention may be prepared by mixing the drug, the hydrogel-forming polymers, and the hydrophilic base, and forming the mixture into a predetermined shape.” *Id.* at 34–35.

### **C. Procedural Posture**

Astellas is the assignee of the asserted patent, the ‘780 Patent. D.I. 46-1 at 25. Astellas alleges patent infringement of the ‘780 Patent by Ascent. D.I. 1; D.I. 12. Ascent asserts it did not infringe on the ‘780 Patent and one or more claims of the ‘780 Patent are invalid and/or unenforceable. D.I. 12. The parties have now submitted their briefs for claim construction.

### III. DISCUSSION

Ascent set out two claim terms for construction by the court, “a hydrogel-forming polymer” appearing in independent Claim 1 and “means for forming a hydrogel” appearing in independent Claim 22. [D.I. 39 at 2–6](#); [D.I. 45 at 9](#). Astellas proposes the claim terms should be given their plain and ordinary meaning. [D.I. 39](#); [D.I. 45 at 9](#). Ascent contends that during prosecution Astellas restricted the claim terms to polyethylene oxide only as their elected species. [D.I. 39](#); [D.I. 45 at 11](#). The Court has reviewed the parties’ claim-construction filings, [D.I. 39](#); [D.I. 45](#); [D.I. 46](#); [D.I. 47](#), the transcript of the *Markman* hearing, and both parties’ supplemental claim construction filings, [D.I. 63](#); [D.I. 64](#); [D.I. 65](#); [D.I. 66](#).

#### A. Principles of Claim Construction

The claims of a patent define the scope of the patent. [Phillips v. AWH Corp.](#), 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The claims of a patent are of primary importance in determining what is patentable and the function and purpose of a claim is to “delimit the right to exclude.” *Id.* The purpose of claim construction is to “determin[e] the meaning and scope of the patent claims asserted to be infringed.” [Markman v. Westview Instruments, Inc.](#), 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). A claim construction order will dictate how the court will instruct the jury regarding a claim’s scope. [O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., Ltd.](#), 521 F.3d 1351, 1359 (Fed. Cir. 2008). Claim construction falls “exclusively within the province of the court,” not that of the jury. [Teva Pharm. USA, Inc. v. Sandoz, Inc.](#), 135 S. Ct. 831, 837 (2015) (quoting [Markman v. Westview Instruments, Inc.](#), 517 U.S. 370, 372 (1996)). It is proper for courts to “treat the ultimate question of the proper construction of the patent



as a question of law in the way that [courts] treat document construction as a question of law.” *Id.* at 837.

The process of construing a claim term begins with the words of the claims. *Phillips*, 415 F.3d at 1312–14; *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[A]bsent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis.” *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008) (citing *N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1295 (Fed. Cir. 2000)). However, the claims “must be read in view of the specification, of which they are a part.” *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979); see *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) (stating in claim construction, the court “gives primacy to the language of the claims, followed by the specification”). Additionally, the prosecution history, while not literally within the patent document, serves as intrinsic evidence for purposes of claim construction. See *Phillips*, 415 F.3d at 1317. If a claim term remains ambiguous after an examination of intrinsic evidence, the court may resort to extrinsic evidence. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1332 (Fed. Cir. 2001).

“[A] district court is not obligated to construe terms with ordinary meanings, lest trial courts be inundated with requests to parse the meaning of every word in the asserted claims.” *O2 Micro Int’l Ltd.*, 521 F.3d at 1360. However, when the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute. See *id.*

The words of a claim are generally given their ordinary and customary meaning, which is the meaning a term would have to a person of ordinary skill in the art in question at the time of the invention. [Phillips, 415 F.3d at 1313](#). The inquiry into how a person of ordinary skill in the art understands a term provides an objective baseline for which to begin claim interpretation. *Id.* “In some cases, the ordinary meaning of claim language ... may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

## **B. The Disputed Claim Terms**

### **a. “a hydrogel-forming polymer”**

The first disputed term, “a hydrogel-forming polymer,” appears in independent Claim 1 and is recited or incorporated by reference into dependent Claims 2 through 21. [D.I. 39](#).

Astellas proposes the term should be given its plain and ordinary meaning, “consistent with the intrinsic evidence for this patent.” [D.I. 45 at 14](#). Astellas argues the claim term should be construed to include all six polymers listed in the claims, including combinations, because the claim term is fully described in the '780 Patent, including the patent specification and claims themselves. *Id.* at 15. Additionally, Astellas argues its response to the election of species was clear and unmistakable, because it elected polyethylene oxide with traverse and for search purposes only. *Id.* at 18; [D.I. 46-2 at 40, 96](#); [D.I. 65 at 13](#). Astellas further argues that at no point during prosecution did it agree with the species election or to otherwise “amend claims to limit the claims to polyethylene oxide.” [D.I. 45 at 18](#); [D.I. 65 at 9](#).

Ascent contends the term “a hydrogel-forming polymer” is restricted to polyethylene oxide only because Astellas clearly and unmistakably disavowed the other polymers via the species election. [D.I. 39 at 2](#); [D.I. 45 at 25](#); [D.I. 63 at 7](#). Ascent argues the species election became final when Astellas did not comply with the requirements for traversing the species election and the response was treated as being without traverse; the Patent Office reiterated the restriction requirement and the elected species in the next two office actions; and Astellas failed to file a petition with the Director after the November 2018 office action. [D.I. 45](#); [D.I. 63 at 5–9](#).

Ascent’s argument is based on prosecution disclaimer. However, “for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.” [Wyeth, LLC v. Intervet, Inc.](#), 771 F. Supp. 2d 334, 345 (D. Del. 2011) (alteration in original) (quoting [Omega Eng’g, Inc. v. Raytek Corp.](#), 334 F.3d 1314, 1325–26 (Fed. Cir. 2003)); see also [Raindance Techs., Inc. v. 10X Genomics, Inc.](#), No. 1:15-CV-00152-RGA, 2017 WL 382235, at \*6 (D. Del. Jan. 26, 2017) (“I do not find the restriction requirement to be a persuasive reason to narrow the construction of this term.”). However, the “election of a species provides no basis for limiting the language [of a claim because] it is no clear and unmistakable disavowing statement.” [Wyeth](#), 771 F. Supp. 2d at 346 (citation omitted). Absent clear intent, courts refuse to read the claims of the patent restrictively. *Id.*

Based on a full review of the record, including the claim language, the specification, and the intrinsic evidence, the Court agrees with Astellas that the claim term should be given its plain and ordinary meaning. While Ascent argues Astellas disavowed the

polymers other than polyethylene oxide, the patent's intrinsic evidence does not demonstrate a clear and unmistakable disclaimer. In response to the Examiner's election of species requirement, Astellas elected polyethylene oxide but did so with traverse and for search purposes only. Additionally, Astellas provided a response with its traverse, and the Examiner did not object or state in the record the response was insufficient or that the species election was made final. In arguing the species election was made either without traverse or was made final, Ascent conflates the requirement for restriction (which Astellas complied with without traverse) and the election of species (which Astellas responded to *with* traverse).

Although the Examiner's letters discuss the requirement for restriction and election of species at the same time resulting in some confusion over which portion of the letter references which element, the regulations are clear that these are distinct processes. *Compare* [37 C.F.R. § 1.142](#) (discussing requirement for restriction), *with* [37 C.F.R. § 1.146](#) (discussing election of species as a separate process). Moreover, the Examiner examined the entire scope of hydrogels before granting claims, in accordance with the Manual for Patent Examining Procedure, and the final patent continues to list all six polymers. Overall, this record is not adequate to say that there was a clear and unmistakable disavowal of the other polymers. The Court therefore adopts Astellas's proposed claim construction that the term "a hydrogel-forming polymer" should be given its plain and ordinary meaning.

**b. “means for forming a hydrogel”**

The second disputed claim term, “means for forming a hydrogel,” appears in independent Claim 22 and is incorporated by reference into dependent Claims 23–25. [D.I. 39](#).

Astellas proposes the term should be given its plain and ordinary meaning based on the claims, the specification, and the intrinsic record. [D.I. 45 at 48](#). Additionally, Astellas argues extrinsic evidence supports the specification. [Id. at 49–50](#). Moreover, Astellas argues there is no clear and unmistakable disclaimer of the claim term, or any lexicography that would limit it to polyethylene oxide. [Id. at 50](#).

Ascent again contends the term is limited to polyethylene oxide only with no equivalents. [D.I. 45 at 51](#). Ascent argues Astellas disclaimed other “means for forming a hydrogel” during prosecution of the '780 Patent. [Id. at 51–52](#).

As previously discussed above, Ascent’s argument is again prosecution history disclaimer. However, “for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.” [Wyeth, 771 F. Supp. 2d at 345](#). Furthermore, the “election of a species provides no basis for limiting the language” because “it is no clear and unmistakable disavowing statement.” [Id. at 346](#) (citations omitted). Absent clear intent, courts refuse to read the claims of the patent restrictively. [Id.](#)

Based on a full review of the record, including the claim language, the specification, and the intrinsic evidence, the Court agrees with Astellas that the claim term should be given its plain and ordinary meaning. As with the first claim term, the record is not adequate to say that Astellas made a clear and unmistakable disclaimer of the claim term

limiting it to polyethylene oxide. Furthermore, because the claim can be construed on the unambiguous intrinsic evidence, the Court need not examine extrinsic evidence. See *Interactive Gift Express*, 256 F.3d at 1332. The Court therefore adopts Astellas's proposed claim construction that the term "means for forming a hydrogel" should be given its plain and ordinary meaning.

#### **IV. CONCLUSION**

For the reasons given above, the Court will construe the terms of the '780 Patent consistent with this Memorandum and Order.

THEREFORE, IT IS ORDERED:

1. Plaintiffs' motion for claim construction, [D.I. 49](#), is granted.
2. Defendant's motion for claim construction, [D.I. 50](#), is denied.
3. The disputed claim terms are given their plain and ordinary meaning as set forth herein.

Dated this 15th day of August, 2024.

BY THE COURT:

s/ Joseph F. Bataillon  
Senior United States District Judge