

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC. and
GENTIUM S.R.L.,

Plaintiffs,

v.

ALMAJECT, INC., ALVOGEN, INC., and
ALVOGEN PB RESEARCH AND
DEVELOPMENT LLC,

Defendants.

Civil Action No. 25-2785 (SRC)
Civil Action No. 26-2629 (SRC)

OPINION & ORDER

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Jazz Pharmaceuticals, Inc. and Gentium S.R.L. (collectively, “Jazz”) and Defendants Almaject, Inc., Alvogen, Inc., and Alvogen PB Research & Development LLC (collectively, “Almaject”). The parties request claim construction of two disputed claim terms in U.S. Patent Nos. 11,085,043 (“the ’043 patent”), 11,236,328 (“the ’328 patent”), 11,746,348 (“the ’348 patent”), 12,529,052 (“the ’052 patent”), and 12,534,722 (“the ’722 patent”) (collectively, “the patents-in-suit”).

ANALYSIS

I. The law of claim construction

A court’s determination “of patent infringement requires a two-step process: first, the

court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). “[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law.” Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’ We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art 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. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art.

Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

A. “Defibrotide”

The parties dispute the meaning of the term, “defibrotide,” which appears in every claim in every patent at issue. Claim 1 of the ‘043 patent is representative:¹

1. A defibrotide formulation consisting of defibrotide, sodium citrate, and water for injection, having a potency of 25 to 35 IU/mg, and a concentration of at least 80 mg/mL, wherein the defibrotide potency is determined by a method comprising the steps of:
 - a) bringing into contact defibrotide, mammalian euglobulin and a substrate specific for plasmin which, by reaction with plasmin, provides a measurable product; and
 - b) measuring the amount of product formed at successive times, to thereby determine the potency of the defibrotide.

Plaintiffs propose that “defibrotide” means “a substance of natural origin which is obtained by extraction from animal organs and which is constituted by the sodium salt of polydeoxyribonucleotides having a low molecular weight.” Defendants propose that the term means: “defibrotide containing less than 10% double stranded DNA.”

¹ The parties agree that all patents at issue share a common specification. For convenience, both parties cited to the specification of the ‘043 patent in the briefs, and this Court follows suit in this Opinion.

This dispute over the construction of the claim term, “defibrotide,” arises from a dispute over Defendants’ contention that, during prosecution, the applicants surrendered a significant part of the scope of this term in order to overcome an obviousness rejection; Defendants argue that, under Federal Circuit law, the doctrine of prosecution disclaimer prevents Plaintiffs, as the current owners of the patents-in-suit, from now recapturing the surrendered claim scope.

The prosecution history of the ‘043 patent shows the following.² The five patents-at-issue all descended from a common parent application, 14/408,272, via a continuing application, 16/816,741, which matured into the ‘043 patent. On April 8, 2020, the USPTO issued an office action which rejected all claims for lack of written description and as anticipated and/or obvious over Bonomini.³ On July 8, 2020, the applicants filed amended claims, adding sodium citrate to the defibrotide formulation so as to distinguish this formulation from the Bonomini defibrotide formulation. On September 15, 2020, the USPTO issued an office action with a rejection of all claims as obvious over Bonomini, in view of Osterberg. On December 15, 2020, the applicants refiled the claims, along with remarks that argued that the defibrotide in the claimed formulations differed from the prior art defibrotide based on aspects of structure and composition.

On January 22, 2021, the USPTO issued an office action with a rejection of all claims as

² The parties each submitted selected documents from the ‘043 file wrapper, and this Court took judicial notice under Fed. R. Evid. 201(b) of the entire ‘043 file wrapper, which is a public record available on the USPTO website (<https://patentcenter.uspto.gov/>). See Mobility Workx, LLC v. Unified Patents, LLC, 15 F.4th 1146, 1151 (Fed. Cir. 2021) (documents published on the USPTO’s website may be judicially noticed under Fed. R. Evid. 201(b)).

³ The Bonomini reference is U.S. Patent No. 4,649,134; claim 1 of this patent claims “[a] method of treating acute renal insufficiencies in a patient . . . comprising administering to said patient an effective amount of defibrotide.”

obvious over Fedeli,⁴ in view of Bonomini and Osterberg. The examiner explained the obviousness rejection, in part, as follows:

Fedeli et al. disclose defibrotide is defined as a sodium salt of low molecular weight nucleotidic fractions obtained by extraction from animal organs and has known therapeutic properties, including as treatment of acute renal insufficiency (to US 4649134; Bonomini) . . . Fedeli et al. do not explicitly teach a composition comprising the defibrotide with pharmaceutical excipients, for injection. . . .

Bonomini discloses the pharmaceutical compositions comprising defibrotide are prepared for administration in a pharmaceutically suitable form . . . Bonomini does not explicitly teach that the composition for injection comprises only defibrotide (200 mg), trisodium citrate dihydrate, and water (2.5 mL). . .

It would have been obvious to one of ordinary skill in the art at the time of the invention to arrive at a defibrotide formulation consisting of defibrotide (200 mg), sodium citrate, and water for injection (2.5 mL), where the liquid defibrotide formulation has a concentration of at least 80 mg/mL, where the defibrotide has substantial uniformity and reasonably has a potency of about 25 to about 35 IU/mg and a pH from about 7-8. One of ordinary skill would have a reasonable expectation that the defibrotide prepared by the process of Fedeli et al. and formulated as a composition for injection has a potency of about 25 to about 35 IU/mg and a pH from about 7-8 since Fedeli et al. disclose a defibrotide that is or appears structurally the same as the claimed defibrotide and can be formulated in a pharmaceutical composition including 200 mg defibrotide and 2.5 mL water for injection (instant claims 21-39).

(‘043 patent file wrapper, Office Action dated 1/22/21 at 3-5.)

On April 22, 2021, the applicants filed a response to the Office Action, offering both responsive arguments and a declaration signed by two named inventors. On June 30, 2021, the USPTO issued a Notice of Allowance and, on July 21, 2021, the ‘043 patent issued.

Almaject argues that the two documents filed by the applicants on April 22, 2021 constitute intrinsic evidence sufficient to meet the Federal Circuit standard for finding that

⁴ The Fedeli reference is U.S. Patent No. 4,985,552; claim 1 of this patent claims a process for producing defibrotide.

prosecution disclaimer has narrowed the scope of the claim terms at issue. The Federal Circuit has summarized the key principles of the prosecution disclaimer analysis as follows:

“[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). This doctrine of prosecution disclaimer “precludes patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.” *CUPP Computing AS v. Trend Micro Inc.*, 53 F.4th 1376, 1382 (Fed. Cir. 2022).

Key here, “[w]hen the prosecution history is used solely to support a conclusion of patentee disclaimer, the standard for justifying the conclusion is a high one.” *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016). A patentee will only be bound to a disavowal that is both “clear and unmistakable.” *CUPP Computing AS*, 53 F.4th at 1382. Thus, where “the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations, we have declined to find prosecution disclaimer.” *Avid Tech., Inc.*, 812 F.3d at 1045.

Maquet Cardiovascular LLC v. Abiomed Inc., 131 F.4th 1330, 1339 (Fed. Cir. 2025). In short, Almaject contends that, in order to overcome the obviousness rejection in the Office Action dated 1/22/21, the applicants made a clear and unmistakable disavowal of the scope of the claim term, “defibrotide,” thus permanently narrowing its meaning, and that the disclaimed territory cannot now be recaptured through claim construction.

In its opening claim construction brief, Almaject begins its argument by pointing to the obviousness rejection in the Office Action dated January 22, 2021, noting that the Examiner wrote: “the defibrotide of Fedeli et al. can be deemed to have similar structure and/or composition as the defibrotide of the present invention and a potency of about 25 to about 35 IU/mg when measured by the intended method steps recited in the claims.” (Defs.’ Op. Br. at 6, quoting ‘043 patent file wrapper, Office Action dated 1/22/21 at 7.) Almaject then turns to the applicants’ response to the rejection, dated April 22, 2021, pointing to these statements:

As explained in the Inventor Declaration submitted herewith (“Declaration”), the structure and composition of the art defibrotide and the claimed defibrotide differ and would not be expected to have the same biological activity. Declaration at ¶ 5. Indeed, Fedeli explicitly teaches that the structure of the claimed defibrotide would not have the recited activity. *Id.* at ¶¶ 6-7.

(Defs.’ Op. Br. at 7, quoting ‘043 patent file wrapper, Response to Office Action dated 4/22/21 at 5-6.) Almaject then states that the cited paragraphs of the Inventor Declaration

“unmistakably identify double-stranded DNA content as the structural difference between the defibrotide taught by Fedeli and that claimed in the Asserted Patents.” (Defs.’ Op. Br. at 7.) In support, Almaject’s opening brief then quotes the Inventor Declaration as follows:

5. As explained below, the defibrotide formulations in Fedeli differ from that described in the present application. Importantly, these formulations differ in the structure of the defibrotide. These differences render the Fedeli defibrotide and the current defibrotide as not equivalent or similar to each other.

6. Fedeli teaches defibrotide compositions that have an amount of double stranded DNA (i.e. heterochromicity) between about 10% and 20%. *See* column 2, lines 32-33. Importantly, Fedeli teaches that defibrotide compositions having below 10% double stranded DNA will be inactive. *See* column 3, lines 9-16. Fedeli teaches that pharmacologically active defibrotide compositions for therapeutic uses must have about 15% double stranded DNA. *Id.*

7. In contrast, as explained below, the defibrotide in the compositions taught in this application contain less than 10% double stranded DNA, which according to Fedeli should render the compositions inactive. Yet these defibrotide compositions are biologically active.

(Defs.’ Op. Br. at 8, quoting ‘043 patent file wrapper, Ignoni and Kumar Declaration dated April 15, 2021 at 2.) Almaject contends that these quoted parts of the Inventor Declaration are “explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art [which] may serve to narrow the scope of a claim.” (Defs.’ Op. Br. at 8-9, quoting Spectrum Int’l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998)).

Almaject next points to other statements in the Inventor Declaration that, Defendants

contend, also distinguish the inventive defibrotide compositions from the prior art defibrotide compositions on the basis of the level of double-stranded DNA content:

8. A study we conducted in 2009 measured the percentage of double stranded DNA in Jazz's industrial batches of defibrotide. This study demonstrated that the percentage of double stranded DNA in the defibrotide ranges from 5.72% to 9.7% as shown in the table below.

14. In sum, the Fedeli and current defibrotide compositions differ in the percent of double stranded DNA and guanine content. Thus, the Fedeli and current defibrotide compositions have different structures and are not equivalent.

(See Defs.' Op. Br. at 9, citing '043 patent file wrapper, Ignoni and Kumar Declaration dated April 15, 2021 at 2, 5.) Almaject concludes the review of the '043 prosecution history by pointing to the Notice of Allowance issued June 30, 2021, which states: "In view of Applicants' remarks and the 37 C.F.R. 1.132 declaration filed April 22, 2021, all the previous rejections and/or objections are hereby withdrawn." (Defs.' Op. Br. at 9-10, quoting '043 patent file wrapper, Notice of Allowance dated June 30, 2021 at 2.)

Jazz begins its claim construction argument by pointing to the express definition of "defibrotide" in the specification of the '043 patent: "Defibrotide (Merck Index, 1996, no. 2915) is a substance of natural origin which is obtained by extraction from animal organs and which is constituted by the sodium salt of polydeoxyribonucleotides having a low molecular weight." '043 patent, col.1 ll.18-21. Jazz offers this definition as its proposed construction of "defibrotide."

Jazz's arguments in opposition to Almaject's proposed construction may be summarized in two points: 1) the claims and specification of the '043 patent contain no support for Almaject's proposed construction; and 2) the prosecution history does not show the "clear and unmistakable" disclaimer of claim scope required by the Federal Circuit law of prosecution

disclaimer.

As to the prosecution history, Jazz contends that the applicants' submissions to the PTO in April of 2021 demonstrate not an unmistakable disclaimer of claim scope but, instead, "present a surprising result for 'defibrotide' over Fedeli." (Pls.' Op. Br. at 15.) Jazz agrees with Almaject as to certain fundamental facts: 1) Fedeli taught that defibrotide compositions having below 10% double stranded DNA will be inactive; and 2) the applicants demonstrated that their inventive defibrotide formulations unexpectedly maintained potency, contrary to the teachings of Fedeli.

Jazz, however, disagrees with Almaject's interpretation of the Inventor Declaration, arguing that "[t]he data in the April 15 Declaration confirm that "defibrotide" includes both defibrotide with less than 10% dsDNA and greater than 10% dsDNA." (Pls.' Op. Br. at 15.) Specifically, Jazz references paragraph 10 in the Inventor Declaration, in which the applicants reproduce the table which appears as Table 4 in the '043 patent as issued. This Table contains a list of batch identifiers and the associated potency measurement for each batch. When the table appears in the '043 patent specification as Table 4, no entries have highlighting, but the version of Table 4 included in paragraph 10 of the Inventor Declaration shows highlighting on seven of the rows, but not on the other rows.

In its opening brief, after presenting the table with highlighted rows that appears in the Inventor Declaration, Jazz argues:

Nothing in the April 15 Declaration, much less the intrinsic evidence as a whole, would have informed a POSA that these batches were not covered by the claims. Stein Decl. at ¶¶ 40-45, 34-39.

(Pls.' Op. Br. at 16.) The problem for Jazz is that its brief does not present the table as it

appears in the Inventor Declaration, where the table is introduced with relevant explanatory text.

Jazz has thus omitted crucial explanation of the table which the applicants included. Here is

paragraph 10 of the Inventor Declaration as it appears in its entirety:

10. Moreover, the present defibrotide compositions have demonstrated biological activities that Fedeli teaches are not possible. The specification of the present '541 application [*sic*] demonstrates the biological activity of many of the same batches we tested. Table 4 from the specification is reproduced below with the relevant batches highlighted. All of these highlighted batches contain less than 10% double stranded DNA and demonstrate a biological activity (IU/mg) between 31 and 35.

Batch	Potency IU/mg	Potency IU/container of 200 mg
688	31	6200
738	34	6800
785	32	6400
836	30	6000
0406	31	6200
DS0617	35	7000
DV0502*	*	Not Available
DV0601	35	7000
1070010073	32	6400
1080010016	32	6400
1080020018	31	6200
1080030021	31	6200
1080040110	32	6400
1080050114	35	7000
1080060117	34	6800
Mean	33	
Min	30	
Max	35	
RSD (%)	5.4	

In case the highlighting does not show up, in the original Inventor Declaration, the rows for Batch DS0617, DV0601, and the five rows from Batch 1070010073 through 1080040110 are highlighted, a total of seven rows. Jazz asserts that the batches *without* highlighting had double stranded DNA contents greater than or equal to 10%. (Pls.' Br. at 16.)

To return to Jazz’s opening brief, Jazz presented the table above, but without the explanatory text which introduced it, and then asserted: “Nothing in the April 15 Declaration . . . would have informed a POSA that these batches⁵ were not covered by the claims.” (Pls.’ Br. at 11.) The Court reads this sentence to assert that nothing in the Declaration would have informed a POSA that the batches without highlighting were not covered by the claims. The Court disagrees, because the first sentence of paragraph 10 in the Declaration states: “the present defibrotide compositions have demonstrated biological activities that Fedeli teaches are not possible.”

The phrase, “the present defibrotide compositions,” should be interpreted based on its use in the Inventor Declaration as a whole. Briefly, the following statements from the Inventor Declaration inform the reader about how to understand the phrase:

- As explained below, the defibrotide formulations in Fedeli differ from that described in the present application. Importantly, these formulations differ in the structure of the defibrotide. These differences render the Fedeli defibrotide and the current defibrotide as not equivalent or similar to each other. (Inventor Declaration ¶ 5.)
- Fedeli teaches defibrotide compositions that have an amount of double stranded DNA (i.e. heterochromicity) between about 10% and 20%. (Inventor Declaration ¶ 6.)
- In contrast, as explained below, the defibrotide in the compositions taught in this application contain less than 10% double stranded DNA, which according to Fedeli should render the compositions inactive. Yet these defibrotide compositions are biologically active. (Inventor Declaration ¶ 7.)
- Thus, the present defibrotide compositions differ structurally from the

⁵ As just stated, the preceding sentence in Jazz’s opening brief had established that “these batches” refers to the batches without highlighting in the table in paragraph 10, which, according to Jazz, had double stranded DNA contents greater than or equal to 10%.

active defibrotide compositions taught in Fedeli which must contain about 15% double stranded DNA. (Inventor Declaration ¶ 9.)

By the time the reader reaches paragraph 9, the Inventor Declaration has provided a context for understanding the phrase, “the present defibrotide compositions.” The applicants have established that they are distinguishing two groups of defibrotide formulations: 1) the first is the group of defibrotide compositions covered by the Fedeli patent; and 2) the second is the group of defibrotide compositions covered by the claims in the application the applicants were prosecuting, for which the Inventor Declaration was submitted. Thus, the reader has a foundation to understand that, in the first sentence in paragraph 10, referring to “the present defibrotide compositions,” the Inventors mean the second group, the defibrotide compositions covered by the claims in the application presently being prosecuted.

Paragraph 10, after stating that “the present defibrotide compositions” have biological activity that Fedeli taught was not possible, invokes the current patent application (the ‘541 application) and states that the specification presents evidence of that biological activity in Table 4, which is shown below “with the relevant batches highlighted.” Paragraph 10 then states: “All of these highlighted batches contain less than 10% double stranded DNA and demonstrate a biological activity (IU/mg) between 31 and 35.” Then a copy of Table 4, with certain rows highlighted, is presented.

The Court thus considers the highlighted table in paragraph 10 in the context of the statements in paragraph 10 that precede it, as well as the other statements in the Inventor Declaration. In short, the Court finds that, in the Inventor Declaration, the applicants clearly and unmistakably distinguished the group of defibrotide compositions covered by the claims in the patent application under prosecution from the group of defibrotide compositions that Fedeli

taught were biologically active, and did so by drawing a line based on double stranded DNA content, with the present defibrotide compositions all below the line at 10% double stranded DNA.

The Court now turns back to this statement in Jazz’s opening brief: “Nothing in the April 15 Declaration . . . would have informed a POSA that these batches were not covered by the claims.” (Pls.’ Br. at 11.) As just discussed, this Court finds that the Inventor Declaration, read as a whole, and in particular paragraph 10, clearly and unmistakably inform a POSA that defibrotide formulations below the 10% double stranded DNA line *are* included in the group of the “present defibrotide compositions,” and that defibrotide formulations at or above the 10% double stranded DNA line, the batches *not* highlighted in the paragraph 10 table, *are not* included in the group of the “present defibrotide compositions.”⁶

In support of its interpretation of the relevant prosecution history documents, Jazz offers the declaration of its expert Dr. Stein, but does not address the legal issue of the role of extrinsic evidence in claim construction under Federal Circuit law. The documents in the patent file wrapper, showing the prosecution history, are intrinsic evidence, while declarations of experts are extrinsic evidence. The Federal Circuit has held:

Expert testimony, one type of extrinsic evidence, may be useful in claim construction “to provide background on the technology at issue, to explain how an invention works, to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the

⁶ Furthermore, the applicants’ response to the obviousness rejection states: “As explained in the Inventor Declaration submitted herewith, the claimed defibrotide compositions *contain* less than 10% double stranded DNA.” (‘043 patent file wrapper, Response to Office Action dated 4/22/21 at 6) (emphasis added). This is a clear and unmistakable disavowal of claim scope, limiting the claims to defibrotide compositions which contain less than 10% double stranded DNA. Jazz has not suggested any viable alternative reading of this clear statement.

pertinent field.” *Phillips*, 415 F.3d at 1318 (citations omitted). However, expert testimony may not be used to diverge significantly from the intrinsic record. *See, e.g., id.* (“[A] court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.” (citation and quotation marks omitted)); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (“[E]xpert testimony . . . may not be used to vary or contradict the claim language. Nor may it contradict the import of other parts of the specification.” (citation omitted)); *Aqua-Aerobic Sys., Inc. v. Aerators Inc.*, 211 F.3d 1241, 1245 (Fed. Cir. 2000) (stating that expert testimony “may not correct errors or erase limitations or otherwise diverge from the description of the invention as contained in the patent documents”); *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1332 (Fed. Cir. 2003) (“Yet, Omega submits its expert declarations not to shed light on this field of art, but to rewrite the patent’s specification and explicitly provide for the laser splitting device, lenses, and prisms to strike the center of the energy zone. That we cannot accept.”); *U.S. Indus. Chems. v. Carbide & Carbon Chems. Corp.*, 315 U.S. 668, 678, 62 S. Ct. 839, 86 L. Ed. 1105, 1942 Dec. Comm’r Pat. 751 (1942) (“It is inadmissible to enlarge the scope of the original patent by recourse to expert testimony to the effect that a process described and claimed in the reissue, different from that described and claimed in the original patent, is, because equally efficacious, in substance that claimed originally.”).

Accordingly, the intrinsic record “must be considered and where clear must be followed.” *See Mantech Env’t Corp. v. Hudson Env’t Servs., Inc.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998); *see also Vitronics*, 90 F.3d at 1584 (“[W]here the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight.”). “Any other rule would be unfair to competitors who must be able to rely on the patent documents themselves, without consideration of expert opinion that then does not even exist, in ascertaining the scope of a patentee’s right to exclude.” *Vitronics*, 90 F.3d at 1584. Reliance on expert testimony regarding the claim interpretation is thus permissible where the testimony is “consistent with [the interpretation] required by the intrinsic evidence.” *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1166 (Fed. Cir. 2004).

Genuine Enabling Tech. LLC v. Nintendo Co., 29 F.4th 1365, 1373 (Fed. Cir. 2022). *Jazz* does not address these guidelines on the use of extrinsic evidence during claim construction.

In its responsive brief, Almaject argues that the Court should not even consider the Stein Declaration, citing the Federal Circuit’s nonprecedential decision in Finjan: “Where, as here, ‘an analysis of the intrinsic evidence alone will resolve any ambiguity in [the] disputed claim term,’

it is ‘improper to rely on extrinsic evidence,’ such as expert testimony, to introduce ambiguity.” Finjan, Inc. v. Cisco Sys., 837 F. App’x 799, 806 (Fed. Cir. 2020) (quoting Vitronics, 90 F.3d at 1583). This quote from Finjan is remarkably apt. In the instant case, Jazz points to paragraph 10 in the Inventor Declaration and suggests an interpretation of the table that is unsupported by the clear language of paragraph 10, in the context of the rest of the Inventor Declaration. Jazz then offers Dr. Stein’s Declaration in an attempt to support Jazz’s interpretation. If Dr. Stein’s expert opinion is accepted and credited, ambiguity is injected into paragraph 10, the Inventor Declaration, and the construction of the claim term, “defibrotide.” The Court finds that, as to the meaning of the term, “defibrotide,” there is no ambiguity in the Inventor Declaration, so there is no ambiguity for the Court to resolve, and, therefore, following both Finjan and the legal framework set forth in Genuine Enabling, it is improper to rely on Jazz’s proffered extrinsic evidence, the Stein Declaration, in its attempt to bolster its argument that ambiguity arises from the table in paragraph 10.⁷

Jazz points to the table in paragraph 10 of the Inventor Declaration and argues that it

⁷ Furthermore, the Court has reviewed the Stein Declaration and finds it unhelpful for the purpose of claim construction, as well as inadmissible under F.R.E. 702(a), because it does not help the trier of fact to understand an issue. The issue presently before this Court is whether the applicants, during prosecution, clearly and unmistakably disavowed a certain meaning of a claim term in order to overcome an obviousness rejection and obtain the ‘043 patent. In the Declaration, Dr. Stein discusses the Inventor Declaration without awareness of the core question of the negotiation between the applicants and the USPTO over patentability. Dr. Stein does not show awareness that the legal question here is what a POSA would understand about what the applicants communicated to the USPTO about claim scope in order to overcome the obviousness rejection and obtain their patent. Dr. Stein does not address this issue and the Stein Declaration does not help the Court to better understand the negotiation between the applicants and the USPTO during prosecution that resulted in the issuance of the patent. As the Federal Circuit held in Vitronics Corp. v. Conceptronic, 90 F.3d 1576, 1583 (Fed. Cir. 1996), “where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.”

shows that “defibrotide” includes *all* the compositions shown in the table, not just the highlighted ones. Jazz here offers an interpretation of the table entirely free of context, as if neither the highlighting has significance, nor does the fact that the table appears in the specification without highlighting and in the Inventor Declaration with it.

In brief, the Court views the table, which appears in the specification without highlighting and in the Inventor Declaration with highlighting, as a visual expression of the surrender of claim scope that occurred during prosecution. Table 4 in the specification appears within an example and shows the results of assays for potency performed on 15 different batches of defibrotide; there is no highlighting. Table 4 is reproduced in paragraph 10 of the Inventor Declaration with highlighting of nine of the fifteen batches. The text in paragraph 10 states: “All of these highlighted [*sic*] batches contain less than 10% double stranded DNA and demonstrate a biological activity (IU/mg) between 31 and 35.” (‘043 patent file wrapper, Ignoni and Kumar Declaration dated April 15, 2021 at ¶ 10.) The fact that the applicants highlighted only 9 of the 15 batches in the table is a visual representation of the surrender of claim scope, narrowing the scope of the claims to a subset of defibrotide compositions: *only* defibrotide compositions containing less than 10% double stranded DNA.

Jazz’s main argument in opposition to Almaject’s prosecution disclaimer argument is that the applicants’ responses which attempt to overcome the obviousness rejection during prosecution are “amenable to multiple reasonable interpretations.” (Pls.’ Resp. Br. at 4, quoting Avid Tech., Inc. v. Harmonic, Inc., 812 F.3d 1040, 1045 (Fed. Cir. 2016)). Jazz has failed to persuade this Court that there is any other reasonable interpretation of any of the relevant statements constituting disclaimer in the prosecution history as cited by Almaject. Jazz has

failed to persuade this Court that, in the context of the intrinsic record in its entirety, there is any ambiguity relevant to prosecution disclaimer that requires an inquiry into extrinsic evidence; the Court has nonetheless considered the Stein Declaration and, as already explained, finds that it is not helpful and does not propose any alternative, reasonable interpretation of the key statements in the prosecution history. This Court has found only one reasonable interpretation of the relevant statements in the prosecution history, and it is the interpretation proposed by Almaject.

Jazz suggests as well that, because Almaject submitted no declaration from a POSA, Dr. Stein's "conclusions remain unchallenged." (Pls.' Resp. Br. at 4.) In Markman, the Supreme Court held:

The question here is whether the interpretation of a so-called patent claim, the portion of the patent document that defines the scope of the patentee's rights, is a matter of law reserved entirely for the court, or subject to a Seventh Amendment guarantee that a jury will determine the meaning of any disputed term of art about which expert testimony is offered. We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.

Markman v. Westview Instruments, 517 U.S. 370, 372 (1996). Furthermore:

[A]s we have recently re-emphasized, extrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language. Nor may it contradict the import of other parts of the specification. Indeed, where the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight.

Vitronics Corp. v. Conceptiontronic, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (citations omitted.) This Court has found the relevant statements in the prosecution to be clear and unmistakable; the patent documents are unambiguous, and Dr. Stein's Declaration is entitled to no weight.

Jazz also argues that Almaject's proposed construction "seeks to read several preferred embodiments out of the claim." (Pls.' Br. at 13.) Jazz does not identify which particular

embodiments this refers to, but the preceding sentences in the brief indicate that this refers to the batches in Table 4 that were not highlighted in paragraph 10 of the Inventor Declaration. The '043 specification contains only one use of the phrase, "preferred embodiment," and that phrase is applied to a description of a process by which samples of defibrotide are processed to determine "the unknown activities of the defibrotide samples." '043 patent, col.7 ll.8-23. Furthermore, in the paragraph in Jazz's opening brief which comes just before the assertion about reading preferred embodiments out of the claim, Jazz states:

Third, the lone example in the specification discloses a potency test and the results for 14 batches of defibrotide. Ex. 1, '043 patent at 7:45-11:45, Table 4. Notably, neither that example, nor the specification as a whole, reports any physico-chemical characteristic, including dsDNA content, of any batch of defibrotide.

(Pls.' Br. at 12.) Thus, the earlier paragraph acknowledges that the specification reports no physico-chemical characteristic for any batch in Table 4, and then the next paragraph makes every batch a preferred embodiment. On what basis would a POSA understand all those batches in Table 4 – with no known or reported physico-chemical characteristics, Jazz says – to be preferred embodiments?⁸ Jazz has provided no support for this assertion.

⁸ Moreover, the Federal Circuit has, in at least two cases, found that the evidence of prosecution disclaimer overcame the general rule disfavoring constructions which exclude preferred embodiments:

We also reject Slip Track's argument that our claim construction is wrong because it excludes the preferred method of assembly. This is because, while recognizing the general rule disfavoring a claim construction that excludes a preferred embodiment, the prosecution disclaimer in this case provides "highly persuasive evidentiary support" for our construction.

Slip Track Sys. v. Metal Lite, Inc., 113 F. App'x 930, 938 (Fed. Cir. 2004). Also:

[W]e have previously explained that limitations may be construed to exclude a

Had Jazz argued that Almaject's proposed construction excludes embodiments, rather than excludes preferred embodiments, the Court would have found this to be a bit misleading. The intrinsic evidence shows that, during prosecution, the applicants narrowed the scope of the claims and thereby surrendered coverage of some defibrotide compositions that had previously been considered to be embodiments. Once the applicants narrowed the claim scope, these defibrotide compositions no longer came within the scope of the claims. It is thus misleading to say that Almaject's proposed construction excludes embodiments; it is more accurate to say that the applicants narrowed the scope of the claims during prosecution and therefore surrendered coverage of some compositions that had previously been within the scope of the claims. Almaject's proposed construction does not exclude embodiments.

As to the dispute over the claim term, "defibrotide," the Court finds that Almaject has demonstrated that the scope of all claims in the '043 patent has been narrowed under the doctrine of prosecution disclaimer. Under Federal Circuit law, "where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Having examined the intrinsic evidence, the Court concludes that the applicants for the '043 patent unequivocally disavowed a certain meaning of "defibrotide" to obtain their patent.

preferred embodiment if the prosecution history compels such a result. *Elekta Instruments S. A.*, 214 F.3d at 1308. For the reasons explained above, in this case, it does. As the district court recognized, the fact that claims do not cover certain embodiments disclosed in the patent is compelled when narrowing amendments are made in order to gain allowance over prior art.

N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1346 (Fed. Cir. 2005).

In summary, the basis for this conclusion is as follows. During prosecution, the PTO rejected all claims submitted as obvious over the Fedeli reference. In the Office Action dated January 22, 2021, the Examiner explained the obviousness rejection in part with this statement: “the defibrotide of Fedeli et al. can be deemed to have similar structure and/or composition as the defibrotide of the present invention and a potency of about 25 to about 35 IU/mg when measured by the intended method steps recited in the claims.” (‘043 patent file wrapper, Office Action dated 1/22/21 at 7.) In response, the applicants distinguished the defibrotide compositions of Fedeli from the defibrotide compositions covered by the claims in the application on the basis of the amount of double stranded DNA content in the defibrotide in the two sets of compositions. In short, the applicants argued that, “[a]s explained in the Inventor Declaration submitted herewith (“Declaration”), the structure and composition of the art defibrotide and the claimed defibrotide differ and would not be expected to have the same biological activity.” (‘043 patent file wrapper, Response to Office Action dated 4/22/21 at 5-6.) The applicants further stated:

Fedeli teaches that defibrotide compositions having below 10% double stranded DNA will be inactive . . . As explained in the Inventor Declaration submitted herewith, the claimed defibrotide compositions contain less than 10% double stranded DNA. Declaration at ¶ 7.

(‘043 patent file wrapper, Response to Office Action dated 4/22/21 at 6.) Paragraph 7 of the Inventor Declaration states:

[T]he defibrotide in the compositions taught in this application contain less than 10% double stranded DNA, which according to Fedeli should render the compositions inactive. Yet these defibrotide compositions are biologically active.

(‘043 patent file wrapper, Ignoni and Kumar Declaration dated April 15, 2021 at 2.) The applicants’ response stated, in conclusion:

Thus, the skilled artisan would not have had a reasonable expectation of success in arriving at the claimed defibrotide compositions based on the teachings of Fedeli. Bonomini and Osterberg do not cure the deficiencies of Fedeli. Neither publication teaches or suggests defibrotide compositions having the same structure and activity as the claimed defibrotide. The pending claims are therefore not obvious over the cited art, and Applicant respectfully requests withdrawal of the instant rejection.

(‘043 patent file wrapper, Response to Office Action dated 4/22/21 at 6.)

The USPTO responded and stated that, based on these arguments, the rejection as obvious over Fedeli had been withdrawn, all claims were allowed, and the ‘043 patent issued.

(‘043 patent file wrapper, Notice of Allowance dated June 30, 2021 at 2.)

The Court finds that, although the specification of the ‘043 patent contains an express definition of defibrotide that does not indicate any limitation based on double stranded DNA content, during prosecution, the applicants clearly and unmistakably surrendered all defibrotide compositions covered by the Fedeli patent except those containing less than 10% double stranded DNA, in order to overcome the obviousness rejection and achieve patentability. The Court rejects Jazz’s attempts to persuade that the relevant statements in the prosecution history are ambiguous; they are clear and unmistakable. The applicants permanently surrendered this claim scope and, under Federal Circuit law, the surrendered subject matter cannot be recaptured in patent litigation. The Court therefore adopts Almaject’s proposed construction of “defibrotide.” “Defibrotide” means “defibrotide containing less than 10% double stranded DNA.”

B. “Consisting of”

The parties appear to agree that the phrase, “consisting of,” has its usual meaning in patent law. Jazz states: “The phrase ‘consisting of’ is a well-established transitional phrase in

patent law that requires no construction beyond its settled legal meaning.” (Pls.’ Br. at 18.)

Jazz contends that no construction of the term is needed. Almaject contends that the phrase has its ordinary meaning, but then adds on different “e.g.” clauses for different patents. The Court thus finds that, on the one hand, the parties have agreed that “consisting of” has its ordinary meaning, but, on the other, Almaject also wants to append “e.g.” clauses, using one example phrase for the ‘043, ‘348, and ‘328 patents, and a different example phrase for the ‘052 patent. If the ordinary patent law meaning is so clear, what need is there for adding in a confusing system of varying examples? Jazz, in opposition, criticizes Almaject’s “e.g.” proposal on two grounds, both of which seem to have merit: 1) “Almaject does not propose a construction that provides any meaningful clarity;” and 2) “Almaject cites no precedent for including its “e.g.” clause.” (Pls.’ Resp. Br. at 11.)

This Court agrees to both points. Almaject has failed to persuade the Court that its “e.g.” clauses are proposed constructions of claim terms under Federal Circuit law, and the “e.g.” clauses appear confusing rather than clarifying. The Court rejects Almaject’s proposed “e.g.” clauses.

As to the ordinary meaning of “consisting of,” the Federal Circuit summarized the law as follows:

The presumption that a claim term set off by the transitional phrase “consisting of” is closed to unrecited elements is at least a century old and has been reaffirmed many times by our court and other courts. We are unaware of any case that has construed a patent claim’s use of “consisting of” to have the same open meaning as “comprising,” and Multilayer points us to none. There may be a scenario where a patent’s specification or prosecution history give “consisting of” the meaning of “comprising”; our decision in *Conoco, Inc. v. Energy & Environmental International* noted that “it is not inconceivable that a patentee could break with conventional claim construction and become his own lexicographer,” so as to give “consisting of” an alternative, less restrictive

meaning. 460 F.3d 1349, 1359 n.4 (Fed. Cir. 2006). But to overcome the exceptionally strong presumption that a claim term set off with “consisting of” is closed to unrecited elements, the specification and prosecution history must unmistakably manifest an alternative meaning.

Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1358-59

(Fed. Cir. 2016). Under Federal Circuit law, the meaning of “consisting of” ordinarily is that the claim is closed to unrecited elements. Jazz has made no case that “consisting of” should be construed in any other way. Almaject proposes an analysis of the prosecution history of the ‘043 patent which, in the end, arrives at the conclusion that “consisting of” should be construed as closed to unrecited elements. Neither party has made a case that it should be construed in any other way.

The Court concludes that the parties have agreed that “consisting of” has its ordinary meaning in patent law, and that, in the absence of any demonstration to the contrary, it is construed as closed to unrecited elements.

In conclusion, the Court construes the terms at issue as follows. The term “defibrotide” means “defibrotide containing less than 10% double stranded DNA.” The term “consisting of” has its ordinary meaning in patent law: it is closed to unrecited elements.

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: October 2, 2026