

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES,  
L.P. and GALDERMA S.A.,

Plaintiffs,

v.

MEDINTER US LLC, MEDINTER  
LTD., ANTECO PHARMA LLC,  
ATTWILL MEDICAL SOLUTIONS,  
INC., ATTWILL VASCULAR  
TECHNOLOGIES LP and  
DERMAVANCE  
PHARMACEUTICALS, INC., and  
MEDGRAFT MICROTECH, INC.,

Defendants

Civil Action No. 18-1892-CFC

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**MEMORANDUM ORDER**

Before me is the matter of claim construction of three terms found in two patents asserted in this case: U.S. Patent Nos. 6,716,251 (the #251 patent) and 7,731,758 (the #758 patent). Oral argument regarding claim construction was held on November 20, 2020. A supplemental evidentiary hearing was held on July 6, 2021.

**TERM 1:** “reconstitutable” in claims 1–6, 9–10, 12 of the #758 patent

1. Galderma’s proposed construction: “Capable of being reconstituted.”

2. Defendants' proposed construction: "Capable of being constituted or formed again. For example, to be reconstitutable to a gel or a hydrogel, the composition that is freeze-dried would need to be in the form of a gel prior to freeze drying."
3. Court's Construction: "**Capable of being reconstituted to a prior form of the composition. For example, to be reconstitutable to a gel or a hydrogel, the composition would had to have been a gel or hydrogel before it was freeze-dried.**"

The shared written description of the #251 and #758 patents does not contain the word "reconstitutable." During prosecution of the #758 patent, the applicant made the following statement to distinguish the Sander prior art reference: "To be reconstitu[t]able to a gel or more especially to a hydrogel, the composition that is freeze dried would need to be in the form of a gel prior to the freeze drying." D.I. 175-3 at 952. Because the Sander reference teaches the mixing of two powders to form a moldable putty for treating bone defects, rather than adding water to a dried composition to create a gel, *see* D.I. 175-3 at 1002 (5:15, 5:19–25), I stated at oral argument that I did not find this statement by itself to constitute a clear and unequivocal definition of reconstitutable.

The parties agree that as a general matter "reconstitution" means in the pharmaceutical sciences the restoration of a freeze-dried composition to a fluid form. D.I. 175 at 8, 9; *see also* Evidentiary Hearing Tr. at 165: 4–8. It seems clear from both parties' experts that this general understanding of the term comes from the fact that pharmaceutical compositions that are freeze-dried for later reconstitution generally begin as fluids. Dr. Heilshorn, however, credibly testified

that she has experience in designing hydrogels that are freeze-dried into a xerogel and then reconstituted into a hydrogel, Tr. 90, and that to reconstitute something into a gel, you have to start with a gel, Tr. 128. I am persuaded by the combination of the applicant's statement quoted above and Dr. Heilshorn's testimony that an artisan of ordinary skill would understand that to reconstitute a composition to a gel, the composition would had to have been a gel before it was freeze-dried.

Accordingly, I will construe "reconstitutable" to mean: "Capable of being reconstituted to a prior form of the composition. For example, to be reconstitutable to a gel or a hydrogel, the composition would had to have been a gel or hydrogel before it was freeze-dried."

**TERM 2: "said reconstitutable product comprises a freeze-dried composition of" / "a freeze-dried composition of" in claim 1 of the #758 patent**

1. Galderma's proposed construction: The reconstitutable product comprises the listed components.
2. Defendants' proposed construction: The freeze-dried composition consists only of the listed components and no others.
3. **Court's Construction: The freeze-dried composition consists essentially of the listed components.**

Claim 1 of the #758 patent recites:

A reconstitutable product, which upon the addition of water becomes a bioresorbable, injectable implant product, wherein said reconstitutable product comprises a freeze-dried composition of:

microparticles of at least one polymer of non-animal origin selected from the group consisting of

lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a hydrogel precursor consisting essentially of materials of non-animal origin, wherein said precursor forms a hydrogel upon the addition of water.

#758 patent at claim 1. The parties dispute whether the claimed “freeze-dried composition” is open-ended or closed-ended.

In *AFG Industries, Inc. v. Cardinal IG Co.*, the Federal Circuit construed the transition phrase “composed of” “in light of the specification to determine whether open or closed claim language is intended.” 239 F.3d 1239, 1245 (Fed. Cir. 2001) (citing MPEP § 2111.03 (7th ed. rev.1 Feb. 2000)). The court found “based on the specification and other evidence . . . that the term ‘composed of’ in [that] case was not completely closed.” *Id.* The court then adopted the construction “consisting essentially of,” in other words, “exclud[ing] ingredients that would materially affect the basic and novel characteristics of the claimed composition.” *Id.* (quoting *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1259, 1274 (Fed. Cir. 1984)) (internal quotation marks omitted). Several district courts have adopted this semi-closed construction of the transitional phrases “composed of” or “of.” *See, e.g., Bd. of Regents v. Ethicon, Inc.*, Case No. 1-17-CV-1084-LY, 2018 WL 6313295, at \*3–\*4 (W.D. Tex. Nov. 30, 2018) (construing “composed of” to be open to unlisted ingredients that do not materially affect the basic and novel

properties of the invention); *Sebela Int'l Ltd. v. Actavis Labs. FL, Inc.*, Civil Action No.: 17-4789-CCC-MF, 2017 WL 4782807, at \*4 (D.N.J. Oct. 20, 2017) (construing “of” to be a closed or mostly closed term); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 810 F. Supp. 2d 578, 585 (S.D.N.Y. 2011) (construing “composed of” and “of” to mean “consisting essentially of”).

Galderma argues that a closed-ended construction of this term would exclude from claim 1 an embodiment of the invention wherein a “freeze-drying medium” contains a gelling agent, a cryoprotecting agent, and a surfactant. #758 patent at 3:52–4:22, 4:61–5:3. Furthermore, claims 4 and 9, which depend from claim 1, recite a “hydrogel precursor compris[ing]” additional ingredients and a “reconstitutable product . . . further comprising a surfactant.” In light of these examples from the #758 patent, I agree that the “freeze-dried composition” was not intended to be closed to just the claimed “microparticles” and “hydrogel precursor.”

Defendants’ expert testified credibly that an artisan of ordinary skill would infer that a surfactant is part of the “hydrogel precursor” included in the freeze-dried composition, and therefore the transition need not be open-ended to include the desired embodiment. But Defendants’ essential argument—that the term should be closed *unless* the desired embodiment would be read out of the claims—

is stricter than the guidance of *AFG Industries*. Accordingly, I will construe “freeze-dried composition” as “consisting essentially of” the claimed ingredients.

**TERM 3: “water for injection” in claim 16 of the #251 patent**

1. Galderma’s proposed construction: “Water suitable for injection.”
2. Defendants’ proposed construction: “Water that is substantially ion-free and apyrogenic, making it suitable for human injection.”
3. Court’s Construction: “**Water suitable for human injection.**”

The parties initially disputed whether “water for injection” can contain any solutes, added substances, excipients, or contaminants. D.I. 175 at 54–57. I initially adopted Galderma’s construction, “water suitable for injection,” because “[n]othing in the patents or prosecution history require that the water be distilled or solute-free.” Tr. at 147:6–14. But I allowed the parties to provide extrinsic evidence on whether “there really can be contaminants” in “water for injection.” Tr. at 149:25–150:6.

It has become clear that parties dispute not whether “water for injection” can contain solutes, but what level of solutes “water for injection” can contain. Defendants’ expert opined that the standard of compendial Water for Injection—a term of art, according to Defendants—varies based on “*what specific ion levels are tolerable* and what methods of preparation are acceptable.” D.I. 215-3, Ex. 38 ¶ 39 (emphasis added). The parties also agree that “water for injection” is generally understood to exclude fever-inducing contaminants. *See* D.I. 214 at 82 n.10. Thus, I adopt the construction “water suitable for human injection,” with the

understanding that “water for injection” may include some tolerable level of excipients.

NOW THEREFORE, at Wilmington on this Twenty-seventh day of July in 2021, the Court adopts the claim constructions set forth above.



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COLM F. CONNOLLY  
CHIEF JUDGE