

No. 2020-1201

IN THE
United States Court of Appeals for the Federal Circuit

VALEANT PHARMACEUTICALS INTERNATIONAL,
SALIX PHARMACEUTICALS LTD., COSMO TECHNOLOGIES LIMITED,

Plaintiffs-Appellants,

v.

ACTAVIS LABORATORIES FL., INC.,
ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES LTD.,

Defendants-Appellees.

On Appeal from the United States District Court for the
District of Delaware, No. 1:18-cv-1288-LPS (Stark, J.)

APPELLEES' RESPONSE BRIEF

John T. Bennett
Samuel Sherry
Gerard J. Cedrone
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, NW
Washington, DC 20036
(202) 346-4000

Elizabeth Holland
GOODWIN PROCTER LLP
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

June 12, 2020

Counsel for Appellees

CERTIFICATE OF INTEREST

Counsel for Appellees certifies the following:

1. The full name of every party represented by me is:

Actavis Laboratories FL., Inc.; Actavis Pharma, Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

Actavis Laboratories FL., Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.

Actavis Pharma, Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.

Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.

Teva Pharmaceutical Industries Ltd.; None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Phillips, Goldman, McLaughlin & Hall, P.A.; John C. Phillips, Jr.; David A. Bilson

Goodwin Procter LLP; Todd Marabella; Shaobo Zhu

5. The title and number of any case known to me to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal are:

None.

June 12, 2020

/s/ William M. Jay

William M. Jay

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GLOSSARY

'698 patent	U.S. Patent No. 10,143,698 (Appx63-72)
'799 patent	U.S. Patent No. 10,172,799 (Appx87-101)
'878 patent	U.S. Patent No. 10,064,878 (Appx43-52)
ANDA	abbreviated new drug application
FDA	U.S. Food and Drug Administration
PTO	U.S. Patent and Trademark Office
Savastano	U.S. Patent No. 5,681,584
<i>Uceris I</i>	<i>Cosmo Techs. Ltd. v. Actavis Labs. FL, Inc.</i> (D. Del. No. 15-cv-164-LPS) (Fed. Cir. No. 18-1335)

STATEMENT OF RELATED CASES

The same parties were previously before this Court in an appeal from a related civil action in the same district court. *Cosmo Techs. Ltd. v. Actavis Labs. FL, Inc.*, 748 F. App'x 331 (2019) (No. 18-1335). No appeal in or from the same civil action has previously been before this or any other appellate court. Counsel is aware of no other case pending in this or any other court or agency that will be affected by this Court's decision in the pending appeal.

INTRODUCTION

This lawsuit is Appellants’ brazen attempt to wipe the slate clean and start over. Appellants Cosmo, Valeant, and Salix (collectively, Cosmo) are the owners and licensees of a number of patents covering Uceris, a drug that treats ulcerative colitis. Appellees Actavis and Teva (collectively, Actavis) market a generic version of the drug. In a prior round of litigation (*Uceris I*), the district court found that Actavis’s generic product does not infringe several of Cosmo’s patents, and this Court summarily affirmed. *See Cosmo Techs. Ltd. v. Actavis Labs. FL, Inc.*, No. 15-cv-164-LPS, 2017 WL 7185967 (D. Del. Oct. 27, 2017) (Appx1211-1232), *aff’d*, 748 F. App’x 331 (Fed. Cir. 2019). Dissatisfied with the outcome of the trial, Cosmo returned to the PTO and secured additional patents—patents with the same named inventors and materially *identical* specifications to those at issue in *Uceris I*. Armed with those “new” patents, Cosmo brought the present infringement action, insisting that the claims-in-suit are meaningfully different from the ones it previously litigated. But Cosmo’s arguments in this case are squarely contradicted by the positions it took before, both in *Uceris I* and during prosecution of the patents-in-suit. And its reading of the disputed claim terms ultimately fails under traditional claim-construction principles. The district court rightly rejected Cosmo’s about-face, and this Court should affirm the judgment of non-infringement.

The key feature of Cosmo’s claimed pharmaceutical composition is the homogeneity of its tablet core: the active ingredient and other compounds are combined and uniformly distributed throughout the core. Cosmo embraced this aspect of its invention in *Uceris I*, affirmatively arguing that a disputed claim term—“matrix”—required homogeneity. Indeed, both before and after *Uceris I*, Cosmo also relied on the homogeneity of its claimed tablet core to distinguish the prior art, which discloses various non-homogeneous systems containing distinct regions of ingredients. But that element of homogeneity led to the decision in *Uceris I*: Actavis’s generic product was found not to infringe the claims at issue in *Uceris I* because it contained visibly distinct, non-homogenous regions in the tablet core.

Unwilling to accept the loss its own claim construction produced, Cosmo now reimagines the scope of its invention, arguing that a homogeneous core is not an element after all. In this case, Cosmo has zeroed in on three specific claim terms: “matrix,” “mixture,” and “compressed blend.” Before the district court, Cosmo argued that *none* of these terms connoted homogeneity. The district court disagreed. With respect to “matrix,” the court noted that Cosmo’s position is diametrically opposed to the construction it advanced for the same term in *Uceris I*. Yet nothing affecting the meaning of that term has changed since *Uceris I*: the specifications of the old and new patents are identical in all relevant respects, and Cosmo’s “only new intrinsic evidence” consists of self-serving statements it made to the examiner *after*

the allowance of the claims-in-suit. Appx9. As for the terms “mixture” and “compressed blend,” the court examined the intrinsic evidence and held that those terms are used “in substantially the same way as . . . the term matrix”—and that in these patents, “all three terms refer to a homogeneous structure.” Appx13.

The district court’s holdings were correct. Notably, Cosmo has abandoned its challenge to the district court’s determination that “matrix” in these patents connotes homogeneity. *See* Cosmo Br. 2 n.1. Instead, Cosmo tries to sever the connection with “matrix” and doubles down on its interpretation of “mixture” and “compressed blend.” But it ultimately fails to reconcile its construction of those terms with the underlying evidence.

With respect to the term “mixture,” Cosmo’s interpretation is impossible to square with its representations to the examiner and with the ways in which the patents themselves use the term. During prosecution, Cosmo specifically added the word “mixture” to two of the patents-in-suit to overcome rejections based on non-homogeneous systems disclosed in the prior art. Cosmo stressed that this addition of the term “mixture” distinguished those earlier, non-homogeneous systems. The examiner allowed the claims on exactly that basis, explaining that Cosmo’s use of the term “mixture” meant “that any components in the core are in a homogeneous mixture.” Appx3717. After allowance, Cosmo submitted a filing saying that it disagreed with the examiner’s statement—though it accepted the patent and did not

amend the claims. The district court properly gave little weight to that post-allowance submission—a transparent, after-the-fact effort to pad the record. In context, the term “mixture” is used interchangeably with “matrix”—and “matrix,” Cosmo no longer disputes, requires homogeneity. The intrinsic evidence thus confirms the examiner’s understanding.

Cosmo’s construction of “compressed blend” is similarly unavailing. Cosmo affirmatively argues that the terms “blend” and “mixture” are “synonymous,” *see* Cosmo Br. 36-37, so “compressed blend” requires homogeneity for at least the same reasons that “mixture” does. But there is more: the language of the patent’s specification, pertinent aspects of the prosecution history, and applicable dictionary definitions confirm that the term “compressed blend” *independently* requires homogeneity. Cosmo relegates its discussion of that term to the tail end of its brief, in a transparent attempt to bury the overwhelming evidence in support of the district court’s construction. But its nothing-to-see-here approach cannot disguise the fact that this term also describes a homogeneous structure. Indeed, Cosmo’s principal argument on “compressed blend” makes the case for affirming the district court’s construction of “mixture” even stronger, given its argument that “mixture” and “blend” are “synonymous.” Cosmo Br. 36.

In the end, Cosmo’s interpretations of the disputed claim terms are little more than gerrymanders. Rather than starting with the intrinsic evidence and working

forward to a definition of “mixture” and “compressed blend,” Cosmo has instead started with its preferred result (*i.e.*, skirting the prior art while still sweeping in Actavis’s generic product) and worked backward to come up with new definitions that conveniently achieve that litigation-inspired end. In doing so, Cosmo ignores the underlying evidence—not to mention its own positions in *Uceris I*. The district court rightly rejected that effort. This Court should affirm.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held, consistent with Cosmo’s own arguments in prior litigation, that the term “mixture” in U.S. Patent Nos. 10,064,878 and 10,143,698 includes only homogeneous structures.

2. Whether the district court correctly held, consistent with Cosmo’s own arguments in prior litigation, that the term “compressed blend” in U.S. Patent No. 10,172,799 includes only homogeneous structures.

STATEMENT OF THE CASE

I. Cosmo Loses Its Infringement Suit In *Uceris I*, After Arguing That Its Claimed Invention Requires A Homogeneous Tablet Core.

Cosmo markets Uceris, an oral tablet containing 9 mg of the active ingredient budesonide for the treatment of mild to moderate ulcerative colitis. Appx2053. In 2013, Actavis submitted an abbreviated new drug application (ANDA) seeking FDA approval to market a generic, bioequivalent version of Uceris. Appx2160; *see* 21 U.S.C. § 355(j). Cosmo responded by filing *Uceris I*, arguing that Actavis’s generic

product would infringe several Cosmo patents directed to formulations containing budesonide. *See generally* 2016 WL 4697953 (D. Del. Sept. 7, 2016) (Appx1043-1060). The asserted patents came from two families—the “Villa I” family, which claimed priority to a 2000 application, and the “Villa II” family, which claimed priority to a 2011 application. *See* Appx2 n.1, Appx1026, Appx1035, Appx1108, Appx1114, Appx3837-3838. The specifications for both families’ patents are identical in all material respects. *See* Appx3837-3838; *see also* Appx3844.

As relevant here, a number of the claims at issue in *Uceris I* were directed to compositions consisting of a “matrix” of budesonide and other ingredients. One representative claim recited:

A controlled release and taste-masking oral pharmaceutical composition comprising:

budesonide as an active ingredient incorporated into a matrix structure consisting essentially of:

a) a lipophilic matrix consisting of lipophilic compounds with a melting point between 40° C. and 90° C. in which the active ingredient is at least partially inglobated;

b) an amphiphilic matrix;

c) an outer hydrophilic matrix consisting of hydrogels in which the lipophilic matrix and the amphiphilic matrix are dispersed; and

a gastro-resistant coating wherein the active ingredient is dispersed both in the hydrophilic matrix and in the lipophilic/amphiphilic matrix, and the composition is in the form of tablets, capsules or minitables.

Appx1121 (11:54-12:13); *see* Appx1114-1121.

Other claims were directed to tablets with cores containing budesonide and other ingredients in a “macroscopically homogeneous composition” (or “macroscopically homogeneous structure”). For example, one such claim recited:

A controlled release oral pharmaceutical composition consisting essentially of:

(1) a tablet core consisting essentially of:

a) budesonide in an amount effective to treat intestinal inflammatory disease; and

b) a macroscopically homogeneous composition comprising at least one lipophilic excipient, at least one amphiphilic excipient, and at least one hydrogel-forming hydrophilic excipient other than a gum, wherein said budesonide is dispersed in said macroscopically homogeneous composition; and

(2) a coating on said tablet core, said coating consisting essentially of a gastro-resistant film.

Appx1041 (10:19-31); *see* Appx1035-1041.

At the claim-construction stage, the parties agreed that *both* categories of claims—“matrix” claims *and* “macroscopically homogeneous composition” claims—required homogeneous tablet cores. Specifically, Cosmo urged the district court to construe the term “matrix” to mean “a macroscopically homogeneous structure in all its volume.” 2016 WL 4697953, at *3-4 (Appx1049-1050). That interpretation was correct, Cosmo said, because the patents’ specification “equate[d] the term ‘matrix’ with ‘a macroscopically homogenous structure in all its volume.’” Appx1074 (Cosmo’s *Uceris I* claim-construction brief). Cosmo pointed to language

in the specification stating that “[t]he compression of the mixture of [the three ingredients of the tablet core] *yields a macroscopically homogeneous structure in all its volume, namely a matrix.*” Appx1074-1075 (emphasis in original).

Cosmo also contrasted its invention with non-homogeneous prior art that used reservoirs to hold the active ingredient. Cosmo noted that “in distinguishing prior art ‘reservoir’ systems from the disclosed three-matrix system, the specification states that reservoirs are ‘not macroscopically homogenous.’” Appx1075. Cosmo invoked the prosecution history of its patents, too, noting that “during prosecution of other patents within this family, [Cosmo] stated that ‘the term “matrix” is a term known in the art and refers to a macroscopically homogenous structure in all its volume.’” Appx1075.

The district court’s claim-construction decision ultimately agreed with the parties that the patents used the term “matrix” to mean “a homogeneous structure in all its volume” (although the court declined to adopt Cosmo’s view that the structure must be *macroscopically* homogeneous). 2016 WL 4697953, at *3-4 (Appx1049-1050).

As relevant here, the parties proceeded to trial on one of the patents reciting a “macroscopically homogeneous” tablet core. 2017 WL 7185967, at *1 (Appx1213). Following Cosmo’s portion of the bench trial, the district court entered a judgment of non-infringement for Actavis under Rule 52(c), finding, among other things, that

Cosmo had not proved that Actavis’s generic budesonide tablet was “macroscopically homogeneous.” *Id.* at *7-9 (Appx1227-1232). This Court affirmed under Circuit Rule 36. 748 F. App’x 331 (2019). The district court subsequently awarded attorney’s fees to Actavis under 35 U.S.C. § 285, citing Cosmo’s “objectively unreasonable” failure of proof and the “substantive weakness of [its] claims of infringement” among the “exceptional circumstances.” *See* Mem. Order 5-8, *Uceris I* (D. Del. March 27, 2019) (Dkt. No. 289).

II. Cosmo Secures The Patents-In-Suit, Which Overlap Substantially With The Patents At Issue In *Uceris I*.

A. Background And Claims Of The Patents-In-Suit.

After the district court’s decision in *Uceris I*, Cosmo obtained six new patents that, in its view, cover *Uceris*. Three are at issue in this appeal—U.S. Patent Nos. 10,064,878 (the ’878 patent), 10,143,698 (the ’698 patent), 10,172,799 (the ’799 patent).

There is extensive overlap between these “new” patents and those at issue in *Uceris I*. Indeed, Cosmo’s counsel conceded at the *Markman* hearing that, with the exception of a single post-allowance statement (*see infra*, at 38-42), “[t]he evidence here is *the same*” as in *Uceris I*. Appx3844 (emphasis added). The patents-in-suit belong to the same two families—“Villa I” and “Villa II”—as the *Uceris I* patents. *See* Appx3837-3838. They have the same four named inventors as the *Uceris I* patents. *Compare* Appx1026, Appx1035, Appx1108, Appx1114, *with* Appx43,

Appx63, Appx87. Their specifications are identical in all material respects to the specifications of the *Uceris I* patents. Appx3837-3838.¹ And they had to overcome the same “reservoir” prior art during prosecution.

In fact, the only real difference between the patents-in-suit and the *Uceris I* patents is that, while the *Uceris I* patent claims recited tablet cores in the form of a “matrix” or “macroscopically homogeneous composition,” the claims of the patents-in-suit recite tablet cores in the form of a “matrix,” “mixture,” or “compressed blend.” *See* Appx51-52, Appx71-72, Appx99-100.

As discussed below (*see infra*, at 19), Cosmo is no longer asserting the “matrix” patents. Of the three patents that remain in live dispute, the ’878 and ’698 patents use the term “mixture” to describe the core of Cosmo’s claimed composition. Claim 1 of the ’878 patent is representative. It claims:

A controlled release oral pharmaceutical composition in the form of a tablet comprising:

(1) a tablet core comprising a mixture of:

- (i) budesonide in an amount effective to treat intestinal inflammatory disease; and
- (ii) a macroscopically homogenous structure comprising:

¹ More specifically, the Villa I patents at issue in this case have “identical” specifications to the Villa I patents at issue in *Uceris I*, while the specifications of the Villa II patents in this case have some additional material regarding pharmacokinetic values that is not pertinent to the “dispute on homogeneity.” Appx3837-3838.

(a) at least one lipophilic compound; and

(b) at least one hydrophilic compound; and

(2) a gastro-resistant coating applied directly to the tablet core that prevents release of budesonide in the stomach,

wherein the budesonide is dispersed in the macroscopically homogenous structure and wherein the macroscopically homogenous structure controls the release kinetics of the budesonide from the tablet in the gastrointestinal tract.

Appx51 (12:37-52).

The '799 patent, meanwhile, claims tablet cores with “compressed blends.”

Claim 22 is representative; it recites, in relevant part:

A tablet consisting essentially of (1) a tableted core, and (2) a gastro-resistant coating on said tableted core, wherein said tableted core consists of a compressed blend of ingredients, said ingredients comprising:

(a) 9 mg of budesonide;

(b) hydroxypropyl cellulose; and

(c) magnesium stearate

Appx100 (21:13-19).

B. Specifications Of The Patents-In-Suit.

As just discussed, the specifications of the patents-in-suit are materially identical to the specifications of the *Uceris I* patents. Those specifications demonstrate that—like the claims at issue in *Uceris I*—the claims-in-suit here require a homogeneous tablet core, which distinguishes them from the reservoir prior art. In particular, they use the terms “matrix,” “mixture,” and “compressed blend”

interchangeably—and use all of those terms to denote structures with homogeneous distributions.

This interchangeability is evident from the very outset of the specification. All three patents begin by describing “[t]he present invention” as one that “relates to” compositions “incorporated in a three-component *matrix* structure.” Appx46 (1:27-30), Appx66 (1:29-32), Appx90 (1:27-31) (emphasis added).

The “Detailed Disclosure of the Invention” section of the ’878 and ’698 patents confirms the point with respect to the term “mixture.” In that section of the specification, every use of the term “mix” or “mixture” refers to the contents or creation of a “matrix.” For example, the section begins by stating, in step (a), that “the active ingredient is first inglobated by simple kneading *or mixing* in a matrix or coating.” Appx47 (3:57-58), Appx67 (3:57-58) (emphasis added). Step (b) then discusses “[t]he *matrix* obtained in a)”—thus equating a mixture and a matrix. Appx47 (3:63), Appx67 (3:63) (emphasis added). And later, in describing an embodiment of the invention, the disclosure discusses how “[t]he resulting inert lipophilic matrix is reduced into granules by an extrusion and/or granulation process, or any other known processes which retain the *homogeneous dispersion* and *matrix structure* of the *starting mixture*.” Appx47 (4:53-56), Appx67 (4:53-56) (emphasis added).

The examples in the '878 and '698 patents likewise demonstrate the interchangeability between the terms “mixture” (or “mix”) and “matrix.” Example 14 is instructive: its language repeatedly switches back and forth between “mixture” and “matrix.” First, the example says, “the *mixture* is kneaded.” Appx50 (10:27), Appx70 (10:10) (emphasis added). Then, “[t]he resulting *matrix* is . . . extruded.” Appx50 (10:29), Appx70 (10:12) (emphasis added). And finally, “[t]he final *mixture* is tabletted.” Appx50 (10:34), Appx70 (10:17) (emphasis added).

The specification of the '799 patent yields a similar conclusion with respect to the term “compressed blend.” The full term—“compressed blend”—does not appear in the specification, and in the proceedings below Cosmo identified just two passages that could provide written-description support for that concept. *See* Appx3813-3814. Both leave no doubt that a homogeneous structure is required. In one, the specification explains that “[t]he compression of the mixture of [the three ingredients of the tablet core] *yields a macroscopically homogeneous structure in all its volume, namely a matrix.*” Appx92 (5:14-18) (emphasis added). In the other, the specification uses the term “mixture” and “matrix” interchangeably in describing the material subject to compression. Appx91 (4:4-14).

The use of the term “blend” in the '799 patent’s specification similarly supports a reading that requires a homogeneous structure. Example 3, for example, describes ingredients being “blended until an homogeneous powder dispersion is

obtained.” Appx97 (15:4-5). Examples 4 and B, meanwhile, describe use of a “blender” to knead material that is later referred to as “*matrix granules*.” Appx97 (15:25-36, 16:20-29) (emphasis added). Like the term “mixture,” the term “blend” is also linked with homogeneity.

C. Prosecution History Of The Patents-In-Suit.

As with the *Uceris I* patents, Cosmo was required to distinguish the claims in the patents-in-suit from “reservoir” systems found in the prior art. Such reservoir systems—including, for example, the system disclosed in U.S. Patent No. 5,681,584 (Savastano)—contain distinct regions of ingredients that are visible when observing the interior of a tablet. The specifications of the patents-in-suit expressly define these reservoir systems by reference to their lack of homogeneity: a “reservoir,” they explain, is “not macroscopically homogeneous along all the symmetry axis of the final form.” Appx46 (2:34-36), Appx66 (2:36-38), Appx90 (2:29-31). Cosmo emphasized that line of distinction before the examiner, making clear that these prior-art systems are different by virtue of their non-homogeneity.

For example, the examiner initially rejected the applications that led to the ’878 and ’698 patents as obvious over, and anticipated by, Savastano. Appx2361-2369, Appx2387-2395. Cosmo subsequently amended the claims to add the word “mixture,” specifying that the claimed tablet core must “consist[] of a mixture” of certain ingredients. Appx2357 (underline omitted); *see* Appx2357-2360,

Appx2383-2386.² Cosmo stressed that because the core of its claimed composition consisted of a “mixture,” it was saved from obviousness over, and anticipation by, Savastano. Appx2361-2369, 2387-2395. Its statements made clear that it saw homogeneity as the distinguishing factor. In describing the amended claims in the patent application that issued as the ’878 patent, for example, Cosmo stressed that “[t]he core comprises a mixture of budesonide and other recited components in the form of a **macroscopically homogeneous structure which controls the release of the budesonide from the tablet in the gastrointestinal tract.**” Appx2389 (emphasis in original).

The examiner agreed. In allowing the claims that issued as the ’698 patent, the examiner expressly relied on Cosmo’s argument that the addition of the term “mixture” limited the tablet core to homogeneous compositions. According to the examiner, the inclusion of that term meant “that any components in the core are in a homogeneous mixture.” Appx3717.³

² The proposed claims that ultimately issued in the ’878 patent were amended to recite a tablet core “*comprising* a mixture of” certain ingredients. Appx2383 (emphasis added) (underline omitted). But Cosmo’s written comments clarified: “Although the ‘comprising’ language with respect to the controlled release oral pharmaceutical composition [in] the form of a tablet may include additional elements, . . . any such elements could not be included in the core if the such elements are not in a mixture.” Appx2388.

³ Cosmo submitted post-allowance comments disagreeing with the examiner’s statement and expressly disavowing—for the first time—any homogeneity

The prosecution history of the '799 patent—the “compressed blend” patent—tells a similar story. The application for that patent initially contained only two claims, and the independent claim required a “matrix” structure. Appx3747; *see* Appx3721-3748. Cosmo withdrew those claims and replaced them with virtually identical claims using the term “compressed blend.” Appx2407-2412. Cosmo expressly asserted that “no new matter [was] added” by the amendment. Appx2413. And in support of the amendment and its “compressed” element, Cosmo cited paragraph 38 of the draft specification, *see* Appx2413, which provides that “[t]he compression of the mixture of [the three ingredients of the tablet core] yields a *macroscopically homogeneous structure in all its volume, namely a matrix,*” Appx3727 (emphasis added). Thus, the prosecution history of the '799 patent leaves no doubt that Cosmo understood its claims to require homogeneity.

It is also worth reiterating the timing of these prosecutions: Cosmo’s addition of the claim terms “mixture” and “compressed blend” came only after its loss at the *Uceris I* trial. *See* Appx2357-2360, Appx2383-2386, Appx2407-2412.

III. Armed With The Patents-In-Suit, Cosmo Seeks A Do-Over Of *Uceris I*.

The FDA approved Actavis’s ANDA to market its generic version of *Uceris* on July 3, 2018, after Cosmo lost the *Uceris I* trial. Appx2160-2164. Cosmo then

requirement. Appx2603; *see infra*, at 38-42 (explaining why these comments are not probative).

filed the present lawsuit, arguing that Actavis's generic product infringes its newly issued patents. Cosmo asserted six patents: the three patents at issue in this appeal, as well as three other patents with claims reciting a "matrix" structure. *See* Appx2050-2053; *see supra*, at 9.⁴

Seeking to avoid the same result as *Uceris I*, Cosmo altered its argument in one critical respect. This time around, it argued that the patents-in-suit do *not* require homogeneity. *See* Appx3784. And it advanced definitions of the disputed claim terms consistent with that newfound interpretation. Most notably, while Cosmo had argued (and persuaded the Court) in *Uceris I* that "matrix" should be construed as "a macroscopically homogeneous structure in all its volume," Cosmo now claimed that a "matrix" should be understood to mean "a structure for controlling the release of an active ingredient that does not have layers." Appx6-11. Cosmo took a similar tack with respect to "mixture" and "compressed blend," arguing that they should mean "a composition of two or more substances that have been mixed" and "a composition of two or more substances that have been mixed and compressed,"

⁴ Cosmo's initial complaint asserted one patent; it filed amended complaints asserting additional patents as those patents issued. *See* Appx129, Appx202, Appx2044. Cosmo also brought a *third* lawsuit, asserting two additional patents in the same family. *See generally* Compl., *Cosmo Techs. Ltd. v. Actavis Labs. FL, Inc.*, No. 18-cv-1006 (D. Del. July 6, 2018) (Dkt. No. 1). Cosmo dismissed that suit after this Court's affirmance in *Uceris I*. *See generally* Stip. & Proposed Order, *Cosmo Techs. Ltd.*, No. 18-cv-1006 (D. Del. March 11, 2019) (Dkt. No. 13).

respectively. Appx11-14. Cosmo's gamesmanship was not lost on the district court: as the court noted at the *Markman* hearing, if Cosmo's current arguments were correct, then its arguments in *Uceris I* had been "evidently misleading." Appx3843.

Actavis, by contrast, explained that the intrinsic evidence supported defining the terms "matrix" and "compressed blend" as "a homogenous composition of two or more substances" and "a compressed matrix (or homogeneous structure in all its volume)," respectively. Appx11-14.

The district court rejected Cosmo's attempted about-face and adopted Actavis's proposed constructions of the three disputed terms. With respect to the term "matrix," the court "agree[d] with [Actavis] that the intrinsic evidence supports a homogeneity limitation, just as it did in *Uceris I*." Appx9. As the district court explained, "[t]he only new intrinsic evidence" that Cosmo had identified was its "post-allowance statements." Appx9. But the court concluded that "their timing—post-allowance and after [Cosmo's] loss in *Uceris I*—significantly reduce[d] their weight." Appx9. In the end, Cosmo's "'post-allowance commentary' contradict[ed] [Cosmo's] position in *Uceris I* and broaden[ed] the scope of the allowed claims in a way that benefit[ed] [Cosmo's] position in this litigation." Appx9. In the court's view, the "strongest evidence" in favor of Cosmo's interpretation of "matrix" was "the specification's silence as to homogeneity in certain examples." Appx11

(quotation marks omitted). But that “silence [did] not persuade the Court that [Cosmo’s] new interpretation [was] correct.” Appx11.

With respect to “mixture” and “compressed blend,” meanwhile, the district court canvassed the intrinsic and extrinsic evidence and concluded that it favored a homogeneity limitation. Appx11-14. As the court explained, “[t]he specifications use the terms mixture and compressed blend in substantially the same way as they use the term matrix—and, importantly, all three terms refer to a homogenous structure.” Appx13. The court also relied on the prosecution history—including the examiner’s comments in the notice of allowance. Appx13-14. The court again discounted Cosmo’s “self-serving” post-allowance statement. Appx14.

The parties agreed that the district court’s resolution of the claim-construction issues in Actavis’s favor foreclosed Cosmo’s infringement claims, compelling a judgment for Actavis. Appx25. The district court entered the parties’ stipulated judgment, Appx24-28, and this appeal followed. Cosmo limits this appeal to the three “mixture” and “compressed blend” patents—its opening brief waives any appeal of the district court’s construction of “matrix” or its judgment as to the three “matrix” patents. *See* Cosmo Br. 2 n.1; *see also id.* at x (statement of the issues).

SUMMARY OF THE ARGUMENT

I. The district court correctly construed the term “mixture,” as used in the ’878 and ’698 patents, to mean “a homogeneous composition of two or more

substances.” The patents’ specifications—the “single best guide to the meaning of a disputed term,” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)—consistently use the term “mixture” and “matrix” interchangeably. In fact, everything from the opening description of the invention to the “Detailed Disclosure of the Invention” to the discussion of various embodiments and examples demonstrates that “mixture” carries the same meaning as “matrix.” And that interchangeable usage is fatal to Cosmo’s proposed construction: Cosmo no longer challenges the district court’s conclusion that “matrix” refers to a homogeneous structure. Cosmo Br. 2 n.1. Nor could it, given its own position in *Uceris I*.

The prosecution history supports the same conclusion. During its prosecution of the ’698 and ’878 patents, Cosmo was required to distinguish the reservoir systems of the prior art, including the reservoir system disclosed in Savastano. It did so on the basis of their non-homogeneity. Indeed, uniquely probative intrinsic evidence confirms the point. The examiner expressly allowed the ’698 patent on the ground that the inclusion of the term “mixture” meant “that any components in the core are in a homogeneous mixture.” Appx3717. Cosmo now argues that it really distinguished Savastano on the ground that the claimed invention lacks “layers,” not on the ground that the claimed invention is homogeneous. But that is just another litigation-inspired attempt to change the scope of the patent after allowance. Cosmo also points to a post-allowance statement in which it asserted that the term “mixture”

only refers to a lack of layers. But that self-serving statement, as the district court recognized, is minimally probative.

Cosmo raises several other arguments—claiming that a Wikipedia definition supports its construction, or that the district court’s construction violates various canons of interpretation—but these contentions fail to rescue Cosmo’s proposed interpretation. In the end, Cosmo’s construction of “mixture” is inconsistent with its own representations in *Uceris I* and with the intrinsic and evidence in this case. The term “mixture,” as used in the ’878 and ’698 patents, refers to a homogeneous structure.

II. The district court also correctly held that the term “compressed blend,” as used in the ’799 patent, refers to “a compressed matrix (or homogeneous structure in all its volume).” Cosmo affirmatively argues that the terms “blend” and “mixture” mean the same thing, Cosmo Br. 36-37, so the Court could end its analysis there: “compressed blend” requires homogeneity for at least the same reasons that “mixture” does.

In fact, there is *additional* evidence—unique to the term “compressed blend”—that informs its meaning. While the term “compressed blend” does not appear in the ’799 patent’s specification, the portions of the specification that discuss either “compression” or “blending” all involve homogeneous structures. The prosecution history also demonstrates that the term “compressed blend” requires

homogeneity: in amending its claims during prosecution, Cosmo agreed that a claim covering a “compressed blend” was equivalent to—and supported by the specification’s disclosure of—homogeneous matrices. Dictionary definitions support the district court’s construction, too, making clear that the term “blend” connotes a homogeneous structure. *See* Appx2797, Appx2880, Appx3640. And again, because Cosmo affirmatively argues that “mixture” means the same thing as “blend,” the strong intrinsic evidence that “compressed blend” connotes homogeneity is also further evidence that Cosmo’s construction of “mixture” is incorrect.

ARGUMENT

Cosmo was clear in *Uceris I* that the tablet core of its claimed invention consisted of a homogeneous structure. It pressed an interpretation of the relevant claim language supporting that result, arguing that the key claim term—“matrix”—meant “a macroscopically homogeneous structure in all its volume.” 2016 WL 4697953, at *3-4 (Appx1049-1050); *see* Appx1074-1076. And it expressly “distinguish[ed] prior art ‘reservoir’ systems from the disclosed three-matrix system” on the ground that “reservoirs are ‘not macroscopically homogenous.’” Appx1075.

The patents-in-suit claim the same invention, with the same homogeneous tablet core, as the patents in *Uceris I*. There is no dispute that their specifications

are materially *identical* to those of the *Uceris I* patents. Appx3837-3838; *see* Appx3844. And they cover the same three-matrix system as the *Uceris I* patents. Cosmo’s efforts to undo the *Uceris I* litigation by re-imagining the scope of its claims relies on little more than semantic games.

As this Court has repeatedly explained, “the words of a claim are generally given their ordinary and customary meaning”—*i.e.*, “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (*en banc*) (quotation marks omitted). Importantly, “the ordinary meaning of the term” does not exist “in a vacuum.” *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). “Rather, [the court] must look at the ordinary meaning *in the context of the written description and the prosecution history.*” *Id.* (emphasis added) (quotation marks omitted). Here, those sources of intrinsic evidence support only one conclusion: Both disputed claim terms—“mixture” and “compressed blend”—require a homogeneous tablet core.

I. The District Court Correctly Construed The Term “Mixture” In The ’878 And ’698 Patents To Mean “A Homogeneous Composition Of Two Or More Substances.”

As discussed above, the ’878 and ’698 patents both recite claims with tablet cores in “mixture” form—a term the district court understood to mean “a homogeneous composition of two or more substances.” That interpretation was

correct. The specifications of the '878 and '698 patents use the term “mixture” interchangeably with “matrix,” which indisputably refers to a homogeneous structure. And the prosecution history confirms the point. Cosmo distinguished the prior art by pointing to the *homogeneous* nature of its invention, and the examiner allowed the claims on exactly that basis. Cosmo now offers a different (and inconsistent) gloss on the specification and a skewed account of the prosecution history. But the record does not bear out its arguments.

A. The Specifications Demonstrate That The Term “Mixture” Requires Homogeneity.

A patent’s “specification ‘is always highly relevant to the claim construction analysis.’” *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Indeed, “it is the single best guide to the meaning of a disputed term.” *Id.* (quoting *Vitronics*, 90 F.3d at 1582). Here, the specifications of the '878 and '698 patents equate the term “mixture” with “matrix”—and the latter term, as Cosmo no longer disputes, refers to a homogeneous structure. The district court’s construction of “mixture” is well grounded in the specification; Cosmo’s latest construction is not.

1. The Specifications Use The Terms “Mixture” And “Matrix” Interchangeably, And Cosmo No Longer Disputes That “Matrix” Requires Homogeneity.

Throughout the specifications, “mixture” and “matrix” are synonymous. In the “Detailed Disclosure of the Invention” section, for example, *every* use of the

term “mix” or “mixture” refers to the contents or creation of a “matrix.” Consider the steps for preparing the invention detailed at the outset of that section. Step (a) instructs that “the active ingredient is first inglobated by simple kneading *or mixing*,” and step (b) then refers to “[t]he *matrix* obtained in a.” Appx47 (3:57-58, 63), Appx67 (3:57-58, 63) (emphasis added). In other words, in this description the product of “mixing” is a “matrix.” The “Technological Background” section provides similar indications, describing an earlier patent “in which a small amount of a hydrophilic polymer is *mixed* with the substances forming an inert *matrix*.” Appx46 (2:21-23), Appx66 (2:23-25) (emphasis added).

That accords with the specifications’ summary of the invention. Both the ’878 patent and the ’698 patent begin by explaining that “[t]he present invention relates to controlled release and taste-masking compositions containing one or more active principles incorporated in a three-component *matrix* structure.” Appx46 (1:27-30), Appx66 (1:29-32) (emphasis added).

The specifications’ discussion of various embodiments of that “present invention” confirms this interchangeable use of the terms “mixture” and “matrix.” For example, the specification discusses how “[t]he resulting inert lipophilic matrix is reduced into granules by an extrusion and/or granulation process, or any other known processes which retain the *homogeneous dispersion* and *matrix structure* of the *starting mixture*.” Appx47 (4:53-56), Appx67 (4:53-56) (emphasis added).

Along similar lines, Example 14 switches back and forth between the terms “mixture” (or “mix”) and “matrix.” Over the span of just three sentences, the example explains that a “mixture” is kneaded, the “resulting matrix” is extruded, and the “final mixture” is tableted. Appx50 (10:27-34), Appx70 (10:10-17).

In short, the specifications of the '698 and '878 patents consistently demonstrate that “mixture” carries the same meaning as “matrix.” *See, e.g., Semitool, Inc. v. Dynamic Micro Sys. Semiconductor Equip. GmbH*, 444 F.3d 1337, 1347-1348 (Fed. Cir. 2006) (holding that a patent’s “specification treat[ed] the three terms processing bowl, processing chamber, and processing vessel synonymously,” thus “mak[ing] it clear” that the claim terms “processing vessel” and “processing chamber” should be “interpreted to be coextensive”). That interchangeable usage is fatal to Cosmo’s proposed construction. Again, Cosmo has expressly waived any challenge to the district court’s construction of “matrix.” Cosmo Br. 2 n.1. The district court’s ruling that a “matrix” is “a homogeneous structure in all its volume” is thus a settled issue. Appx5; *see, e.g., Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1363 (Fed. Cir. 2001) (“Since [Appellant] has presented no argument to us directed particularly to claim 26, the question of the proper construction of that claim has been waived.”).

Nor could Cosmo reasonably challenge that interpretation of “matrix.” Cosmo argued in *Uceris I* that the term “matrix” requires homogeneity. *See* 2016

WL 4697953, at *3-4 (Appx1049-1050); Appx1074-1075. And this Court “previously construed ‘matrix’ to mean ‘a macroscopically homogeneous structure in all its volume’ in a different patent from the same inventor featuring the same language in the specification in a litigation to which . . . Cosmo was a party.” Appx8-9; *see Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1365 (Fed. Cir. 2015); *see also* Appx9 n.7 (finding *Shire* “instructive”).⁵ As the district court rightly recognized, there was no basis to reach a different result here: Cosmo “already undertook the analysis in *Uceris I* of how a [skilled artisan] would interpret the intrinsic record”—including the nearly identical specifications—“and, in the [district court’s] continuing view, [Cosmo] got it right in *Uceris I*.” Appx11 n.10; *see supra*, at 18-19.⁶

⁵ In the proceedings below, Cosmo dismissed *Shire* as “not probative” because it “involved different claims from a different patent in a different patent family covering a different drug with a different specification and different prosecution history.” Appx3793. But by this point it should come as little surprise that Cosmo took the opposite position in *Uceris I*. There, Cosmo argued that, despite any differences, *Shire* shed light on the meaning of “matrix” because this Court “rel[ied] in part on the same language cited above appearing in a different patent specification.” Appx1075.

⁶ Cosmo repeatedly characterizes the *Uceris I* litigation as involving “different patents.” Cosmo Br. 1, 7-8, 10. But it cannot wish *Uceris I* away so easily. As mentioned, the patents-in-suit belong to the *same* families, have the *same* four inventors, and contain the *same* written disclosures in all material respects as the *Uceris I* patents. *See supra*, at 9-10; *Semitoool*, 444 F.3d at 1346-1347 (referring to “the clear definition of . . . language in the claims of the earlier . . . parent application” to construe the language in “the continuation . . . application which issued as the” patent-in-suit); *Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1350 (Fed. Cir.

2. Cosmo Misreads The Specifications And Misunderstands Their Implications.

Cosmo insists that the specification supports its interpretation, but it presents no valid basis to reach that conclusion.

Cosmo's principal argument is that the specification used the adjective "homogeneous" numerous times, suggesting (according to Cosmo) that "mixture" alone is not enough to connote a homogeneous composition. *See* Cosmo Br. 17-22. But the examples Cosmo cites cut *against* its interpretation: they draw an express link between the term "mixture" (or "mix" or "mixing") and homogeneity. Take Example 1, which Cosmo features heavily. *See* Appx48 (6:41-62), Appx68 (6:41-62). Cosmo asserts that the example describes two separate steps: "Substances are mixed," Cosmo says, "*then* homogenized." Cosmo Br. 18. But Cosmo has no basis to conclude that "mixing" and "homogenization" are separate steps. To the contrary, a later sentence in the same paragraph confirms that it is the process of "mixing" that produces homogeneous results; that sentence describes "a first mixing step *for homogenously dispersing the powders.*" Appx48 (6:50-51), Appx68 (6:50-51) (emphasis added). The other examples on which Cosmo relies similarly undermine its position. Example 2, for example, clarifies that "mixing" takes place until "complete homogenization" or "until homogeneous dispersion." Appx49 (7:1-2, 12-

2004) ("Any statement of the patentee in the prosecution of a related application as to the scope of the invention would be relevant to claim construction . . .").

13), Appx69 (7:1-2, 12-13). Example C contains similar statements. *See* Appx51 (11:39-59), Appx71 (11:24-44).

Cosmo attempts to draw a contrast with Examples 3, 4, 6, and 8-14; those examples, it argues, “say nothing at all about homogeneity.” Cosmo Br. 19 (emphasis omitted). But those examples consistently describe the production of a “matrix” without *any* step expressly describing “homogeneous” mixing or “homogeneous” dispersion. *See* Appx49-50. To take just one instance, Example 14 describes a process of kneading a “mixture” and adding lecithin to produce a “matrix”—without ever using the word “homogeneous.” Appx50 (10:25-36), Appx70 (10:8-19); *see supra*, at 13, 26. Recall that Cosmo no longer disputes that the term “matrix,” either alone *or* modified by the term “homogeneous,” refers to a homogeneous composition. *See supra*, at 26. Thus, Cosmo is simply wrong to assert that the specification uses “homogeneous” as the sole label of a homogeneous composition—*i.e.*, that a composition is “homogeneous” if and only if the specification says so expressly. Nor is it unusual that the specification did not always reiterate the term “homogeneous” where it was clear from context. While there is a general presumption that a patent’s *claim* does not use redundant or superfluous language (*see infra*, at 46), there is no similar presumption for a patent’s *specification*. After all, the purpose of the two differs: “Claims define and circumscribe,” while “the written description discloses and teaches.” *Ariad Pharm.*,

Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc); *cf. Reiter v. Sonotone Corp.*, 442 U.S. 330, 341 (1979) (making a similar point as between judicial opinions and statutes, *i.e.*, “the language of an opinion is not always to be parsed as though we were dealing with language of a statute”).

Cosmo also attempts to blunt the force of the specification by arguing that the district court improperly relied on a description of an *embodiment* of the invention in construing the claims. *See* Cosmo Br. 31-34. Cosmo points in particular to column 5, lines 15-20, where the specification describes an embodiment of the invention by stating that “[t]he compression of the mixture of [the three ingredients in the tablet core] yields a macroscopically homogeneous structure in all its volume, namely a matrix.” Appx48, Appx68. According to Cosmo, “to the extent the district court apparently relied on this passage . . . to support its imposition of a homogeneity limitation on the construction of ‘mixture,’ it is an impermissible importation of a limitation from an embodiment into the claims.” Cosmo Br. 33. But Cosmo’s argument fails for two reasons.

First, this description of an embodiment is *not* the only part of the specification that equates a mixture with a homogeneous composition. *See supra*, at 12, 24-25. This case is thus on all fours with *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361 (Fed. Cir. 2007). There, the patentee argued that the district court improperly “limit[ed] the invention to particular embodiments” when it construed

the disputed claim term (“composite composition”) as limited to compositions in “pellet and linear extrudate forms.” *Id.* at 1367. As this Court explained, however, the district court did not adopt that construction “on the ground that those are the only disclosed embodiments”; rather, it “construed the claims in that way because the patents use the term ‘composite composition’ restrictively,” and because the “specification repeatedly states that the steps of linear extrusion or pelletization are not merely embodiments, but are essential features of the claimed composite composition.” *Id.* The Court noted in particular that the specification stated at the outset that “the invention relates to a composition comprising a polymer and wood fiber composite that can be used in the form of a linear extrudate or thermoplastic pellet to manufacture structural members.” *Id.* (brackets and quotation marks omitted). This case is the same in every material respect: through repeated references in the specification—including a key line at the very outset of the specification—the patents-in-suit make clear that “mixture” means “matrix.”

Second, the language that Cosmo now faults Actavis and the district court for quoting is language that *Cosmo itself emphasized* in advancing its claim-construction argument in *Uceris I*. Cosmo pointed to that language as its *lead argument* in support of its proposed construction of “matrix.” Specifically, Cosmo’s claim-construction brief in *Uceris I* argued that “[i]n describing an embodiment of the invention, the specification equates the term ‘matrix’ with ‘a macroscopically

homogenous structure in all its volume,’ stating, ‘The compression of the mixture of [the three ingredients of the tablet core] *yields a macroscopically homogeneous structure in all its volume, namely a matrix.*’” Appx1074-1075 (emphasis in original). That language—and, indeed, the full surrounding language—is *identical* to the language Cosmo now dismisses. *Compare* Appx1117 (4:50-58) (patent at issue in *Uceris I*), *with* Appx48 (5:16-23), Appx68 (5:16-23) (patents-in-suit). What’s sauce for the goose is sauce for the gander: Cosmo cannot claim this language is relevant only when it supports Cosmo’s position, but reject it when it forecloses Cosmo’s preferred construction.

B. That A “Mixture” Requires Homogeneity Is Demonstrated By Cosmo’s Efforts To Distinguish The Prior-Art Reservoir Systems.

“[T]he record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims.” *Vitronics*, 90 F.3d at 1582. “[A]n examination of the prior art cited” in the record is often particularly probative, because “the prior art cited in the file wrapper gives clues as to what the claims do *not* cover.” *Id.* at 1583 (emphasis added) (quotation marks omitted); *see also, e.g., SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018) (“In construing the scope of claims, we give considerable weight to statements made by patent applicants during prosecution in order to overcome examiner rejections.”). Here, an analysis of the prosecution history—and, in particular, of the prior art discussed

during prosecution—yields exactly this type of insight with respect to the term “mixture.”

During its prosecution of the '698 and '878 patents, Cosmo was required to distinguish the reservoir systems of the prior art, including the reservoir system disclosed in Savastano. *See supra*, at 14-15. The record makes clear that the defining characteristic of those reservoir systems was their lack of homogeneity. One need look no further than the specifications of the patents-in-suit: all three expressly describe reservoir systems by reference to the fact that they are *not* homogeneous, stating that their “structure is a ‘reservoir’, i.e. is not macroscopically homogeneous along all the symmetry axis of the final form.” Appx46 (2:34-36), Appx66 (2:36-38), Appx90 (2:29-31); *see, e.g., Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009) (“[T]he specification’s use of ‘i.e.’ signals an intent to define the word to which it refers”). Or one can look to Cosmo’s own words in *Uceris I*, where it told the district court that “reservoirs are ‘not macroscopically homogenous.’” Appx1075. Against this backdrop, there can be no doubt that Cosmo’s strategy to overcome the prior art was to distinguish it on the ground that it disclosed non-homogeneous systems.⁷

⁷ Indeed, this argument was made repeatedly during earlier prosecutions of related applications. *See, e.g.,* Appx11 n.10 (citing Appx3994); *see also* Appx3996.

Cosmo drew that distinction in the '698 and '878 patents by employing the term “mixture.” As discussed above, the examiner initially rejected the applications for those patents on obviousness and anticipation grounds, citing Savastano’s reservoir system. Appx2361-2369, Appx2387-2395; *see supra*, at 14-15. In response, Cosmo amended the claims to add the word “mixture.” Appx2357-2359, 2383. The revised language, Cosmo argued, clarified that “elements could not be included in the core if the such elements are not in a mixture.” Appx2388. In other words, it was the term “mixture” that allowed the '698 and '878 patents to overcome the non-homogeneous prior art.

One of Cosmo’s arguments to the examiner is particularly telling on this point. In describing its amendments to the '878 patent (in which it added the term “mixture”), Cosmo wrote:

[T]he controlled release oral pharmaceutical composition in tablet form of claim 1 comprises (1) **a tablet core comprising a mixture** of recited components and (2) **a gastro-resistant coating applied directly to the core**. In claim 1, the tablet core comprises budesonide in an amount effective to treat intestinal inflammatory disease and a macroscopically homogeneous structure comprising at least one lipophilic compound and at least one hydrophilic compound. The core comprises a mixture of budesonide and other recited components in the form of a **macroscopically homogeneous structure which controls the release of the budesonide from the tablet in the gastrointestinal tract**.

Appx2389 (emphasis in original). As the final sentence makes clear, the “mixture” that makes up the “core”—both the active ingredient budesonide *and* the lipophilic

and hydrophilic compounds—is in a “macroscopically homogenous structure which controls the release of the budesonide.” Appx2389 (emphasis omitted).

Cosmo now attempts to downplay this statement, arguing that it “was directed to claim 1 of the application, which expressly recited a limitation that included ‘a macroscopically homogenous structure.’” Cosmo Br. 27. But there are at least two problems with this argument. First, the limitation to which Cosmo refers (reciting a “macroscopically homogeneous structure”) applies only to *some* of the ingredients in the tablet core—namely, the combination of “at least one lipophilic compound” and “at least one hydrophilic compound.” Appx2387. But Cosmo’s statement to the examiner was clearly broader than that: Cosmo stressed that the *whole tablet core*—the “mixture of budesonide *and* other recited components”—is “in the form of a **macroscopically homogeneous structure.**” Appx2389 (first emphasis added). The only claim term that supports that result is “mixture.” *See* Appx2387. Second, Cosmo’s efforts to cabin this statement divorce it from its surrounding context. The statement came on the heels of a discussion whose *entire thesis* was that the word “mixture”—and that word alone—saved claim 1 of the application from rejection in view of Savastano. *See* Appx2388-2399 (“Applicant submits that claim 1 specifies that the claimed controlled release oral pharmaceutical composition in the form of a tablet comprises a tablet core comprising a *mixture* of the recited components and a gastro-resistant coating applied directly to the tablet core.” (emphasis in original)).

Cosmo's theory that the statement had nothing to do with the term "mixture" is an implausible, post hoc recharacterization.

Moving beyond this particular page of the prosecution history, Cosmo argues more generally that its arguments before the examiner distinguished Savastano "not because the claimed inventions were homogeneous, but because the inventions lacked the rate-controlling release *layers* of Savastano." Cosmo Br. 24 (emphasis added). But even if this were a complete and accurate summary of Cosmo's statements—and it is not, for the reasons just discussed—it flies in the face of Cosmo's representations elsewhere. As noted above, Cosmo told the district court in *Uceris I* that reservoir systems are different from its invention precisely because "reservoirs are 'not macroscopically homogenous.'" Appx1075. And Cosmo drafted a written description echoing that point; the specifications of the patents-in-suit expressly define a "reservoir" as a structure that "is not macroscopically homogeneous along all the symmetry axis of the final form." Appx46 (2:34-36), Appx66 (2:36-38), Appx90 (2:29-31). Cosmo's efforts to reframe the prosecution history as focusing on layers rather than homogeneity is little more than a litigation-inspired attempt to circumvent its loss in *Uceris I*.⁸

⁸ To the extent Cosmo augmented its "homogeneity" argument with a "layers" argument, it is important to remember the context: Cosmo featured this argument after its loss in *Uceris I*—*i.e.*, after the district court determined that Cosmo had not

As this Court has explained, “[t]he definition of a claim term can be affected through repeated and definitive remarks” during prosecution. *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1277 (Fed. Cir. 2013) (quotation marks omitted). Cosmo’s “repeated and definitive” remarks during prosecution here, and throughout prosecution of these families, demonstrate that it used the term “mixture” to connote homogeneity—and to distinguish the prior art on that ground.

C. The Examiner Understood The Term “Mixture” To Require Homogeneity And Allowed The Claims On That Basis.

Cosmo did not just *make* these statements to the examiner; it *convinced* the examiner, and the examiner *explained why*. An examiner’s statements in allowing a claim can provide further insight into the meaning of a disputed claim term. *See, e.g., Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) (relying on statements in examiner’s reasons for allowance to construe claim language). That is particularly true where the examiner’s statement “simply repeated the arguments that the patentee had presented.” *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003). And here, the examiner made clear that she understood Cosmo’s repeated arguments about the term “mixture” to require homogeneity.

proven that Actavis’s generic budesonide tablet was “macroscopically homogeneous.” *See supra*, at 8-10.

More specifically, in allowing the application for the '698 patent, the examiner observed that the inclusion of the term “mixture” meant “that any components in the core are in a homogeneous mixture.” Appx3717. In other words, it was on this basis that the examiner allowed the application notwithstanding the prior art. *See* Appx3717. This is uniquely relevant intrinsic evidence—confirming that Cosmo meant what it said about homogeneity during prosecution, and supporting the district court’s construction of the term “mixture” as requiring a homogeneous composition.

Cosmo asks the Court to disregard the examiner’s statement—and, indeed, to disregard the entire corpus of its *own* prior statements—based on a post-allowance statement it made to the examiner. *See* Cosmo Br. 22-24. Specifically, after the examiner allowed the claims and noted that they required a homogeneous core, Cosmo filed a submission in which it argued that the examiner’s “remark is inaccurate” on the theory that “[t]he allowed claims . . . do not include the word ‘homogenous,’” and that Cosmo “did not represent during prosecution . . . that the claimed ‘mixture’ is or must be homogenous.” Appx2378. According to Cosmo, “[t]he claimed ‘mixture’ requires, and only requires, that layers are not present.” Appx2378.

The district court considered this post-allowance statement but found it minimally probative—and rightly so. Appx9-10. As the district court explained,

the timing of the statement “significantly reduce[s] [its] weight.” Appx9. Cosmo made the statement only “after [its] loss in *Uceris I*,” and only after persuading the examiner to allow claims with its desired language. Appx9. And the substance of the statement confirms its “obviously self-serving purpose.” Appx10 n.8. As the district court explained, Cosmo’s “‘post-allowance commentary’ contradicts [its] position in *Uceris I* and broadens the scope of the allowed claims in a way that benefits [its] position in this litigation (i.e., they were not analogous to statements against interest).” Appx9. Cosmo’s statement, in other words, did not shed persuasive light on the meaning of the disputed claim term. Appx10 n.8.

The district court’s decision to give little weight to Cosmo’s statement accords with precedent. This Court has previously declined to adopt an interpretation advanced in post-allowance comments by an applicant who “disagree[d] with the examiner’s construction” but was happy to pocket the patent the examiner was allowing rather than propose further changes. *St. Clair I.P. Consultants, Inc. v. Canon Inc.*, 412 F. App’x 270, 277 (Fed. Cir. 2011). As the Court explained, such post-allowance comments “do not, indeed cannot, change the examiner’s Reasons for Allowance.” *Id.* (brackets omitted) (quoting *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1139 (Fed. Cir. 2003)). Cosmo cites two cases for the proposition that the district court should have assigned greater weight to its post-allowance statements, *see* Cosmo Br. 25-26, but it misunderstands both decisions.

First, citing *Rembrandt Wireless Technologies, LP v. Samsung Electronics Co.*, 853 F.3d 1370 (Fed. Cir. 2017), Cosmo argues that this Court has previously “approved of a construction that relied on a purported ‘self-serving statement in the prosecution history’” that was “made after the examiner had allowed certain claims.” Cosmo Br. 25-26 (quoting *Rembrandt*, 853 F.3d at 1376). But the statements at issue in *Rembrandt* concerned a limitation that “the applicant inserted . . . into its claims after the examiner had already issued a notice of allowance.” 853 F.3d at 1376. In other words, the applicant’s statement was “contemporaneous” with the addition of the disputed claim term. *Id.* As the Court explained, “the clearest statement in the intrinsic record regarding the meaning of the [disputed] limitation is the descriptive statement the applicant made to the examiner *when he inserted the limitation into the claims.*” *Id.* (emphasis added). The same principle applies here: the clearest indication of what Cosmo meant by the term “mixture” is what it said *when it added that term to the claims*—not its post hoc efforts to capture a different meaning. The applicant in *Rembrandt* did what Cosmo (and the applicant in *St. Clair*) did not: write its new interpretation into the claims after allowance.

Second, Cosmo cites *3M Innovative Properties Co. v. Tredegar Corp.*, 725 F.3d 1315 (Fed. Cir. 2013), for the proposition that “a patentee’s statements during prosecution are more relevant than an examiner’s responses.” Cosmo Br. 26. But the examiner’s statements in *3M* arose in the context of reexamination proceedings,

and conflicted with statements the applicant had made “during the course of the original prosecution.” 725 F.3d at 1332. Under circumstances like those, “an examiner’s statement during reexamination,” the Court explained, “was, at most, representative of how one of skill in the art would understand the term.” *Id.* This case arises in a meaningfully different posture. Here, the examiner’s statement came in the reasons for allowance—that is, they shed light on the basis for which the patent was allowed in the first place. Cosmo is pointing to statements that came, not “during the course of the original prosecution,” *id.*, but after allowance.

Perhaps recognizing that post-allowance comments that do not change the claims do not change the *meaning* of the claims, Cosmo claims that this case involves not just unilateral comments by the applicant, but implicit ratification of those comments by the examiner. Advancing an argument it raised for the first time at oral argument below, Cosmo suggests that if the examiner had disagreed with Cosmo’s post-allowance comments, she could have withdrawn the allowance under 37 C.F.R. § 1.313. *See* Cosmo Br. 26; *see also* Appx10 n.9 (“This provision was first mentioned at oral argument.”). But the inference Cosmo draws from the examiner’s silence is foreclosed as a matter of law. The applicable rule is clear: “Failure by the examiner to respond to any statement commenting on reasons for allowance does not give rise to *any* implication.” 37 C.F.R. § 1.104(e) (emphasis

added). The burden is not on the *examiner* to squelch attempts by patentees to change their claim scope after allowance; quite the contrary.

Trying a variation on the same implicit-ratification argument, Cosmo notes that the examiner was required to approve Cosmo's filing of post-allowance amendments to its claims. *See* Cosmo Br. 26 (citing 37 C.F.R. § 1.312). That is a non sequitur. The examiner's permission was required only for Cosmo's *amendments*, not its separate (and separately titled) *comments* on the examiner's reasons for allowance. *See* 37 C.F.R. § 1.104(e) (providing that "[t]he applicant or patent owner may file a statement commenting on the reasons for allowance," without requiring the examiner's leave); *compare* Appx2373-2376 ("Amendments to the Claims"), *with* Appx2378-2380 ("Comments on Statement of Reasons for Allowance").

In sum, the examiner's reasons for allowance provide yet another indication that the term "mixture," as used in the '698 and '878 patents, connotes a homogeneous structure.

D. The Dictionary Definitions And Canons Of Interpretation On Which Cosmo Relies Do Not Support A Different Construction Of "Mixture."

Faced with the foregoing evidence, Cosmo offers three linguistic arguments to support its contention that the term "mixture" does not require homogeneity. First, Cosmo asserts that a Wikipedia definition submitted during prosecution

supports its interpretation. *See* Cosmo Br. 14, 22. Second, Cosmo claims that the district court’s interpretation renders certain claim language superfluous. *See id.* at 16. And third, Cosmo argues that the district court’s construction violates the presumption that different claim terms should carry different meanings. *See id.* at 34.

Each of these arguments breaks down upon closer inspection.

1. Cosmo’s Wikipedia Entry Does Not Undermine The District Court’s Interpretation.

Cosmo relies on a Wikipedia definition of the term “mixture,” arguing that the entry reflects the term’s “plain and ordinary meaning.” Cosmo Br. 13-14.⁹ Cosmo specifically emphasizes the first sentence of that definition: “In chemistry, a mixture is a material made up of two or more different substances which are mixed.” Appx2362, Appx2366; *see* Cosmo Br. 14, 22. But Cosmo’s reliance on this sentence, which it adopts nearly verbatim as its proposed claim construction (*see* Cosmo Br. 8, 36), does little to advance its argument. The sentence is circular—a tautology—and it sheds no further insight on the meaning of the term “mixture.” As

⁹ Cosmo’s argument that it advances the “plain and ordinary meaning of ‘mixture’” and that “[no] lexicography or disavowal modified the plain and ordinary meaning of ‘mixture,’” Cosmo Br. 30, directly contradicts its assertions in the district court. *See* Appx3773 (“Here, the patentee has acted as his own lexicographer to clarify the ordinary and customary meaning of the terms ‘matrix’ and ‘mixture’ as not requiring homogeneity.”). Once again, Cosmo has changed its position to suit its present needs.

relevant here, stating that a “mixture” is something that is “mixed” does not answer one way or the other whether the act of mixing produces a homogeneous result. Whether it does so can only be understood from an examination of the intrinsic evidence. *See also* Cosmo Br. 23 (quoting similarly tautological definitions).¹⁰

In fact, dictionary definitions themselves make clear that whether a mixture is homogeneous or heterogeneous depends on context. Appx3820; *see* McGraw-Hill Concise Encyclopedia of Science & Technology 1227 (4th ed. 1998) (stating that a mixture may be “a homogeneous or heterogeneous system”). Cosmo’s Wikipedia definition is a case-in-point. After its first sentence, it goes on to provide that “[a] mixture refers to the physical combination of two or more substances in which the identities are retained and are mixed in the form of solutions, suspensions and colloids.” Appx2362, Appx2366. Solutions and colloids are both homogeneous substances.¹¹ As these definitions show, the determination whether the term

¹⁰ The case cited by Cosmo likewise provides a circular definition. *See Sanders v. Mosaic Co.*, 418 F. App’x 914, 918 (Fed. Cir. 2011) (“[I]t appears the court construed ‘mixture’ to mean ‘a mixture.’ We agree that ‘mixture’ does not require any additional construction.”); Cosmo Br. 13-14.

¹¹ *See* McGraw-Hill Dictionary of Scientific and Technical Terms 431 (6th ed. 2003) (defining “colloid” as “[t]he phase of a colloidal system made up of particles having dimensions of 10-10,000 angstroms (1-1000 nanometers) and which is dispersed in a different phase,” and defining “colloidal system,” in turn, as “[a]n intimate mixture of two substances, one of which, called the dispersed phase (or colloid), is *uniformly distributed in a finely divided state* through the second substance” (emphasis added)); *id.* at 1974 (defining “solution” as “[a] single, *homogeneous* liquid, solid, or gas phase that is a mixture in which the components (liquid, gas, solid, or

“mixture” refers to a homogeneous or heterogeneous structure requires an assessment of surrounding circumstances.

Here, those surrounding circumstances are Cosmo’s statements during prosecution and its disclosures in the specification. For the reasons discussed above, those statements and disclosures point squarely toward an interpretation of “mixture” as a homogeneous composition. *See supra*, at 24-37.

2. The Presumption That All Claim Terms Should, Where Possible, Be Understood To Have Independent Effect Does Not Undermine The District Court’s Interpretation.

Cosmo next argues that “mixture” cannot refer to a homogeneous structure because that interpretation would render part of claim 1 of the ’878 patent superfluous. *See* Cosmo Br. 16. Claim 1 recites a mixture of (i) budesonide and (ii) a macroscopically homogeneous structure comprising at least one lipophilic and one hydrophilic compound, “wherein the budesonide is dispersed in the macroscopically homogenous structure.” Appx51 (12:48-49). According to Cosmo, “[i]f the claimed ‘mixture’ is necessarily homogeneous, then there would be no need to separately require that one of the mixture’s components (budesonide) be ‘dispersed’ in the other component (a macroscopically homogeneous structure).” Cosmo Br. 16.

combinations thereof) are *uniformly* distributed throughout the mixture” (emphasis added)).

“It is true that ‘interpretations that render some portion of the claim language superfluous are disfavored.’” *SimpleAir, Inc. v. Sony Ericsson Mobile Commc’ns AB*, 820 F.3d 419, 429 (Fed. Cir. 2016) (quoting *Power Mosfet Techs., LLC v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004)). But that preference “is not an inflexible rule.” *Id.* Most importantly, “the canon against superfluity assists only where a competing interpretation gives effect to every clause and word.” *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 106 (2011) (quotation marks omitted) (applying the canon in the statutory-interpretation context). In other words, the presumption has no purchase when “no interpretation of [the text]—including the [one] advanced by [the opposing party]—avoids excess language.” *Id.*

That is the case here: even under Cosmo’s interpretation of the term “mixture,” the “wherein” clause is redundant. Before the reader ever reaches the “wherein” clause, the plain language of claim 1 *already* requires the budesonide to be “mix[ed]” into the macroscopically homogenous structure of at least one lipophilic compound and at least one hydrophilic compound. Appx51 (12:37-52). So regardless of whose construction of “mixture” is right, there is no need to “*separately* require that one of the mixture’s components (budesonide) be

‘dispersed’”—*i.e.*, mixed—“in the other component (a macroscopically homogenous structure).” Cosmo Br. 16 (emphasis added).¹²

In fact, the redundancy produced by the “wherein” clause is easily explained. That clause is simply an artifact of the history of claim amendments. As discussed above, this claim originally called for “a tablet core comprising” the recited ingredients, rather than “a tablet core comprising *a mixture of*” the recited ingredients. *Compare* Appx2639, *with* Appx51 (12:37-39); *see supra*, at 14-15. The examiner rejected that earlier claim in view of Savastano. Appx2645-2653; *see supra*, at 14-15. Cosmo attempted to traverse this argument without amendment. In particular, Cosmo argued that “the language ‘gastro-resistant coating **applied directly** to the tablet core’ specifically excludes the presence of additional elements between the tablet core and the gastro-resistant coating.” Appx2651 (emphasis in original). The examiner rejected the claim again, noting that the claim language did not exclude elements in addition to the recited ingredients (*i.e.*, elements in addition to the budesonide and lipophilic and hydrophilic compounds) from the core. Appx2387-2395. Cosmo then added “a mixture of” to the claim, and argued that it

¹² Cosmo’s superfluity argument is also impossible to reconcile with another one of its key arguments. The premise of Cosmo’s assertion of superfluity is that the “wherein” clause requires the budesonide to be *homogeneously* dispersed in the macroscopically homogeneous structure of at least one lipophilic and one hydrophilic compound. *See* Cosmo Br. 16. But elsewhere Cosmo insists that “[w]here homogeneity is necessary, it is specified” expressly. *Id.* at 18.

excluded anything from the core not in a mixture. Appx2383; *see supra*, at 14-15. In making that adjustment, Cosmo simply failed to delete the “wherein” clause, though it is now redundant.

3. The Presumption That Different Claim Terms Should Carry Different Meanings Does Not Undermine The District Court’s Interpretation.

Finally, Cosmo argues that the district court improperly conflated the terms “mixture” and “matrix.” *See* Cosmo Br. 34-36. According to Cosmo, “it is presumed that different claim terms have different meanings.” *Id.* at 34 (citing *Andersen*, 474 F.3d at 1369). But the very case on which Cosmo relies, *Andersen*, clarifies that the inference does not apply in the face of “evidence to the contrary.” 474 F.3d at 1369-1370. Like this case, *Andersen* involved a group of several patents sharing a common specification. *Id.* at 1364, 1366. The patentee argued that because the patents used three different claim terms (“pellets,” “linear extrudates,” and “composites”), “the third category must be assumed to be different from the first two.” *Id.* at 1370. The Court disagreed, explaining that “the written description and prosecution history over[came] any presumption” that different terms carried different meanings. *Id.* (quotation marks omitted); *see also, e.g., St. Clair*, 412 F. App’x at 275 (finding that different claim terms carried the same meanings in related patents that “share[d] the same specification and use[d] similar, and often identical, terminology”). The Court reached a similar conclusion in *Semitool*, discussed

above, in which it held that a specification's interchangeable use of the terms "processing bowl," "processing chamber," and "processing vessel" made it clear that, as used in the claims, "processing vessel" and "processing chamber" should be "interpreted to be coextensive." 444 F.3d at 1347-1348. The same result is warranted here, for the same reasons: the specification and prosecution history overcome any inference that "mixture" carries a different meaning than "matrix." *See supra*, at 24-42.

That conclusion is bolstered by Cosmo's own concessions. Cosmo agrees that "the terms 'blend' and 'mixture' *are* used interchangeably." Cosmo Br. 36 (emphasis in original). Cosmo has no account for why these two terms would have an *identical* definition as one another, while at the same time carrying a *different* definition from a third term (matrix). Its argument to that effect is yet another litigation-driven attempt to have it both ways. The more coherent explanation is the one already revealed by the prosecution history and specification: all three terms are synonyms; they simply offer different ways to refer to homogeneous structures.

E. The Extrinsic Evidence Further Confirms That A "Mixture," As Used In These Patents, Is A Homogeneous Structure.

The Court can resolve this case on the intrinsic evidence. *See Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003). But if the Court were to turn to extrinsic evidence, Actavis's expert, Dr. Alexander Mullen, confirmed that "a person of skill in the art would understand 'mixture,'" as used in the patents-in-suit,

“to require a homogeneous system.” Appx3638 (capitalization omitted). As Dr. Mullen explained, “statements made by both the applicant and the examiner during the prosecution of these patents” demonstrate that “the applicant intended that the term ‘mixture’ mean ‘a homogeneous composition of two or more substances.’” Appx3638. Cosmo, for its part, highlights the declaration of its expert Dr. Leah Appel. *See* Cosmo Br. 28. But Dr. Appel’s opinion is contradicted by that of Cosmo’s own expert in *Uceris I*, Dr. Stanley Davis. *Compare* Appx2814-2815 (reflecting Dr. Appel’s view that a skilled artisan “would have understood that a matrix . . . would not necessarily require absolute homogeneity”), *with* Rebuttal Decl. of Prof. Stanley S. Davis at 8, *Uceris I* (D. Del. Feb. 25, 2016) (Dkt. No. 75) (reflecting Dr. Davis’s opinion that a skilled artisan would have understood the term “matrix” to refer to a macroscopically homogeneous structure). And, of course, Dr. Appel’s opinion is also inconsistent with the district court’s construction of “matrix,” to which Cosmo has now abandoned any challenge.

* * *

In the end, Cosmo’s interpretation of “mixture” requires it to walk back most of what it said in *Uceris I* and during prosecution. Indeed, if its current arguments about the intrinsic evidence are correct, then its arguments in *Uceris I* were—to quote the district court—“evidently misleading.” Appx3843. And even putting aside Cosmo’s flip-flopping, the interpretation it now advances is inconsistent with

the intrinsic and extrinsic evidence. The term “mixture,” as used in the ’878 and ’698 patents, refers to a homogeneous structure.

II. The District Court Correctly Construed The Term “Compressed Blend” In The ’799 Patent To Mean “A Compressed Matrix (Or Homogeneous Structure In All Its Volume).”

Cosmo concedes that the terms “blend” and “mixture” mean the same thing—“compressed blend” is just another way of saying “compressed mixture.” Cosmo Br. 36-37. That is the end of Cosmo’s argument: for the same reasons that “mixture” requires homogeneity, “compressed blend” does, too. *See supra*, at 23-51.

But even putting aside all the evidence discussed above, there is *additional* evidence—unique to the term “compressed blend”—that informs its meaning. Cosmo breezes through its discussion of the term “compressed blend.” *See* Cosmo Br. 36-39. That cursory approach ignores compelling indications that this term, too, requires homogeneity.

A. The Specification Demonstrates That The Term “Compressed Blend” Requires Homogeneity.

The term “compressed blend” does not appear in the specification of the ’799 patent. But the instances that *do* discuss compression or blending support the conclusion that a “compressed blend” is a homogeneous mixture.

In the principal passage discussing compression, the specification describes how “[t]he compression of the mixture of lipophilic and/or amphiphilic matrix, hydrogel-forming compound and, optionally, active ingredient not inglobated in the

lipophilic matrix, *yields a macroscopically homogeneous structure in all its volume, namely a matrix.*” Appx92 (5:14-18) (emphasis added). That passage leaves no doubt that the product of compression here is a homogeneous structure. The specification of the ’799 patent also discusses compression at column 4, lines 6-7, in which it discusses compression of a mixture. Appx91. That discussion, too, supports Actavis’s interpretation because the passage uses “matrix” and “mixture” interchangeably in the context of “compression.”

Quoting the examples of the ’799 patent, Cosmo argues that “as with ‘mixture,’ where the inventors wanted to describe a blend as homogeneous in the specification, they did so explicitly.” Cosmo Br. 37. But as with “mixture,” these examples cut *against* Cosmo’s proposed interpretation, because they repeatedly link the concept of blending an homogeneity. Example 3, as Cosmo notes, describes ingredients being “blended until an homogeneous powder dispersion is obtained.” Appx97 (15:4-5); *see* Appx96 (14:61-62). Examples 4 and B, meanwhile, describe use of a “blender” to knead granules that are later referred to as “*matrix* granules.” Appx97 (15:25-36, 16:20-29) (emphasis added). Cosmo notes that Example 1 discusses a “final blending” step without an express “mention of homogeneity.” Cosmo Br. 37. But, as explained above, the specification cannot be read in a way that marks a composition as “homogeneous” if and only if the specification says so expressly. *See supra* at 29-30. Ultimately, the claimed invention of the ’799 patent,

too, is a “composition[] containing budesonide as active ingredient incorporated in a three-component *matrix* structure.” Appx90 (1:27-31) (emphasis added). And “matrix” connotes homogeneity without needing to say so each time.

B. The Prosecution History Demonstrates That The Term “Compressed Blend” Requires Homogeneity.

The prosecution history of the '799 patent likewise confirms the understanding that a “compressed blend” is a homogeneous structure. As discussed above, the application for the '799 patent initially contained only two claims, and the sole independent claim required a “matrix” structure. Appx3747; *see* Appx3721-3748. Cosmo withdrew those claims and replaced them with virtually identical claims using the term “compressed blend.” Appx2407-2412. Cosmo expressly asserted that “no new matter [was] added” by the amendment. Appx2413. And in support of the amendment and its “compressed” element, Cosmo cited paragraph 38 of the draft specification—*i.e.*, the passage providing that “[t]he compression of the mixture of [the three ingredients of the tablet core] yields a *macroscopically homogeneous structure in all its volume, namely a matrix.*” Appx3727 (emphasis added); *see* Appx2413. In short, Cosmo agreed that a claim covering a “compressed blend” was equivalent to—and supported by the specification’s disclosure of—homogeneous matrices.¹³

¹³ Actavis’s proposed construction also is supported by Cosmo’s submission of a post-issuance certificate of correction. The '799 patent originally issued with

Seeking to draw a different conclusion from the prosecution history, Cosmo argues that this amendment “reflects a difference in meaning between the two terms.” Cosmo Br. 38. But the events leading up to that amendment—which post-dated both the decision in *Uceris I* and the institution of Cosmo’s current lawsuit (see Appx2407)—suggests a far more plausible explanation: Cosmo was seeking to claim the same invention without using the term on which it had already lost, “matrix.”

C. Dictionary Definitions And Other Extrinsic Evidence Confirm That The Term “Compressed Blend” Requires Homogeneity.

As with the term “mixture,” the Court need not consult extrinsic evidence to resolve the meaning of “compressed blend.” But if it does, that evidence confirms Actavis’s interpretation.

Dictionaries, for example, make clear that the term “blend” connotes a homogeneous structure. One dictionary defines a “blend” as “[a] mixture so combined as to render the parts *indistinguishable* from one another.” Appx2797 (emphasis added). Another defines it, in pertinent part, as “[a] *uniform* combination

independent claim 22, which recites a tablet with a core consisting of a “compressed blend” of ingredients, and dependent claim 23, which reads: “The tablet of claim 22, wherein said *matrix* further comprises starch or a starch derivative.” Appx100 (emphasis added). Cosmo later changed “matrix” in claim 23 to “ingredients.” Appx101. This original typo and subsequent correction offers further confirmation that Cosmo had no meaningful distinction between the terms “mixture,” “matrix,” and “compressed blend.”

of two or more materials.” Appx3640 (emphasis added). Still another defines the verb “blend” as “mix *thoroughly*.” Appx2880 (emphasis added). Both individually and in combination, these definitions foreclose Cosmo’s proposed interpretation.

Actavis’s expert evidence likewise confirmed that a “compressed blend” is a homogeneous structure. In view of the specification, prosecution history, and common usage, Dr. Mullen opined that a person of ordinary skill in the art would understand the term “compressed blend,” as used in the ’799 patent, to describe a homogeneous system. Appx3638-3641. That, too, reinforces the district court’s construction of the term.¹⁴

* * *

Again, the foregoing evidence is evidence that applies specifically to the term “compressed blend.” It confirms—without more—that the term “compressed blend” requires homogeneity. But of course there *is* more: all of the evidence pertaining to the term “mixture.” As the record intrinsic evidence shows, the patents-in-suit use the terms “mixture,” “compressed blend,” and “matrix” synonymously to refer to a homogeneous system. Once the Court is satisfied that this is true of either “compressed blend” *or* “mixture,” Cosmo itself argues that the other term must be given the same meaning.

¹⁴ Cosmo cites the testimony of Dr. Appel, *see* Cosmo Br. 39, but, as noted above, her testimony contracts the district court’s now-settled construction of “matrix” *and* the construction offered by Cosmo’s own expert in *Uceris I*. *See supra*, at 50.

Even taking each term separately, Cosmo’s arguments are impossible to square with the record—not to mention its own previous statements. The Court should reject its attempted do-over.

CONCLUSION

The judgment of the district court should be affirmed.

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John T. Bennett
Samuel Sherry
Gerard J. Cedrone
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Respectfully submitted,

/s/ William M. Jay
William M. Jay
GOODWIN PROCTER LLP
1900 N Street, NW
Washington, DC 20036
(202) 346-4000

Elizabeth Holland
GOODWIN PROCTER LLP
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Counsel for Appellees

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

/s/ William M. Jay
William M. Jay

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 32(a) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b), it contains 12,789 words.

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word 2016 (Version 1803) in 14-point Times New Roman, a proportionally spaced typeface.

June 12, 2020

/s/ William M. Jay
William M. Jay