UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROXANE LABORATORIES, INC., Plaintiff, v. CAMBER PHARMACEUTICALS INC. et al., Defendants.	Civil Action No. 14-4042 (SRC) **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiff Roxane Laboratories, Inc. ("Roxane") and Defendants Camber Pharmaceuticals Inc. and InvaGen Pharmaceuticals Inc. (collectively, "Defendants"). In this patent infringement suit involving a pharmaceutical patent, the parties seeks construction of claims in U.S. Patent No. 8,563,032 ("the '032 patent").

ANALYSIS

I. The law of claim construction

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

The focus of claim construction is the claim language itself:

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

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

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

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
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> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

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

II. Claim construction of the disputed terms

A. "Size 00 or less"

Claim 1 states:

> A calcium acetate capsule formulation comprising flowable granules comprised of a pharmaceutically acceptable amount of calcium acetate along with other pharmaceutically acceptable adjuvants, wherein said granules are filled into and contained within a pharmaceutically acceptable capsule such that 667 mg of said calcium acetate on an anhydrous basis are present in said capsule that is size 00 or less.

The parties dispute the meaning of the phrase, "size 00 or less." Defendants contend that "size 00" means "precisely size 00," and excludes capsules of size 00el. Roxane contends that "pharmaceutically acceptable capsule . . . that is size 00 or less" means "a capsule suitable for oral consumption by a human having the diameter of any capsule designated size '00' or less."

This Court considered this question when it heard the motion for a preliminary injunction in this case, and made a preliminary claim construction ruling in favor of Defendants. Having reexamined the issue, this Court concludes that its original reasoning was sound, and incorporates those reasons into this Opinion.

It appears that the meaning of "size 00" in the context of fillable pharmaceutical capsules is fairly clear. In the "Other Publications" section of the patent specification, there is a reference to a pharmaceutical capsule size chart: "Torpac, http://www.erowid.org/archive/rhodium/pdf/gelcap.sizechart.pdf, 1-3.*" This reference contains various statistics about various capsule sizes. It contains information about size 00 capsules, which are said to have a height of 23.3 mm and a volume of .95 ml. It appears that, in the context of fillable pharmaceutical capsules, "size 00" refers to a capsule of approximately this size, and this is its common and ordinary meaning. It also appears that there is an elongated

version of this capsule which is generally referred to as "size 00el," which has the same diameter but a greater length and volume. The parties do not disagree that, within the context of the pharmaceutical art, "size 00" and "size 00el" refer to particular standard gelatin capsule sizes, and there is no material dispute over what those sizes are. This Court concludes that the claim term at issue, "size 00 or less," refers to size 00 and excludes size 00el.

Roxane has made a concerted effort to inject confusion into this fairly simple and straightforward matter. Roxane contends that "size 00 or less" is "a technical term of art whose ordinary meaning is not plainly apparent to a layperson." (Pl.'s Reply Br. 5 n.5.) As the following discussion will show, this Court disagrees. Furthermore, Roxane points to a variety of pieces of extrinsic evidence which, it contends, support its argument that the skilled artisan would understand "size 00" to include size 00el. Roxane even urges this Court that, given the Supreme Court's recent decision in Teva, it has an obligation to "to look beyond the patent's intrinsic evidence and to consult extrinsic evidence . . ."[1] 135 S. Ct. at 841.

Roxane cites no post-Teva decision by the Federal Circuit that stands for the proposition that the Teva decision altered the established roles of intrinsic and extrinsic evidence in claim construction. In terms of the issues raised by Roxane, it is worth noting that the Federal Circuit, hearing the Teva case on remand from the Supreme Court, held:

[1] Roxane here both misreads and misquotes the Supreme Court, which stated: "In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." Id. Roxane has not shown that this is such a case. Roxane has not persuaded this Court that a greater understanding of the background science is needed to construe the term at issue, nor that the meaning of the term has changed over time such than an investigation into the usage during another time period would be helpful.

> To the extent that Teva argues that the meaning of "molecular weight" in the context of patents-in-suit is itself a question of fact, it is wrong. See *Teva*, 135 S. Ct. at 841-42. A party cannot transform into a factual matter the internal coherence and context assessment of the patent simply by having an expert offer an opinion on it. The internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law. The meaning one of skill in the art would attribute to the term molecular weight in light of its use in the claims, the disclosure in the specification, and the discussion of this term in the prosecution history is a question of law. The district court should not defer to Dr. Grant's ultimate conclusion about claim meaning in the context of this patent nor do we defer to the district court on this legal question. To the extent that Teva argues that this ultimate determination deserves deference, it is in error. To the extent that Teva or the dissent suggests that the specification's disclosure of SEC would "infer" that this claim term, molecular weight, in this patent refers to Mp, such an inference is part of the legal analysis, not a fact finding to be given deference. Determining the meaning or significance to ascribe to the legal writings which constitute the intrinsic record is legal analysis. The Supreme Court made clear that the factual components include "the background science or the meaning of a term in the relevant art during the relevant time period." *Id.* at 841. Teva cannot transform legal analysis about the meaning or significance of the intrinsic evidence into a factual question simply by having an expert testify on it. *Id.* at 841 ("experts may be examined to explain terms of art, and the state of the art, at any given time, but they cannot be used to prove the proper or legal construction of any instrument of writing" (citation omitted)). Determining the significance of disclosures in the specification or prosecution history is also part of the legal analysis.

Teva Pharms. USA, Inc. v. Sandoz, Inc., 2015 U.S. App. LEXIS 10229, *15-*16 (Fed. Cir. June 18, 2015). Similarly, Roxane "cannot transform legal analysis about the meaning or significance of the intrinsic evidence into a factual question simply by having an expert testify on it." Id. at *16.

Roxane contends otherwise:

> The Supreme Court explained that when parties dispute how a POSITA understands the ordinary meaning of a claim term (especially a technical term of art), the district court "will need" to analyze extrinsic evidence, including pertinent references and expert declarations, and resolve those disputes.

(Pl.'s Resp. Br. 3-4.) This is incorrect. Phillips is still good law, and it stands for the proposition

that extrinsic evidence may not be "used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." Phillips, 415 F.3d at 1324. As the following analysis will demonstrate, this Court finds that the meaning of the claim term "size 00 or less" is unambiguous in light of the intrinsic evidence. There is no need to resolve ambiguities of meaning by examining extrinsic evidence.[2]

"Claim construction analysis begins with the intrinsic evidence." Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1299 (Fed. Cir. 2004). It is very difficult to reconcile Roxane's proposed construction with the plain language in the patent itself. There is nothing in the patent that even suggests that the applicants understood "size 00" to mean a family of capsule sizes. To the contrary, the usage of "size 00" in the patent is inconsistent with the family definition that Roxane has proposed. The strongest piece of evidence is the first appearance of the phrase in the specification: "According to one embodiment of the invention, the capsule is a size 00 capsule containing 667 mg of calcium acetate." '032 patent, col.3 ll.29-31. Note the use of the singular in that sentence, which refers to "**one** embodiment," "the capsule," and "**a** size 00 capsule." If size 00 is understood to mean a family of two sizes, this sentence makes little sense. If the applicants intended the family definition, the sentence should read: "According to some embodiments of the invention, the capsules are size 00 capsules containing 667 mg of calcium acetate." In other words, the singular forms in the sentence ought to be plural. The use of the

[2] Roxane asserts that "[t]he claim construction issue in *Teva*, itself, is instructive." (Pl.'s Br. 5.) This is correct, but this Court understands the *Teva* case differently. In *Teva*, the intrinsic evidence alone was insufficient to resolve ambiguities in the meaning of the claim term – so much so that the Federal Circuit, on remand, found Claim 1 invalid for indefiniteness. 2015 U.S. App. LEXIS 10229 at *23-*24. In the instant case, examination of the intrinsic evidence does not leave unsolved questions about the meaning of "size 00 or less."

phrase "one embodiment" is particularly difficult to square with the family theory: it strongly indicates that "size 00" is a set which contains only one element, not two.[3]

The next appearance of "size 00" in the patent is in Example 1: "The final blend was then filled into size 00 capsules using an IMA capsule filling machine wherein the resulting filled capsules had a weight of 880 mg and contained 760 mg of the final blend, including a 667 mg dose of calcium acetate." '032 patent, col.5 ll.53-57. In this instance, "capsules" is a plural form, and yet the capsules are said to have "**a** weight of 880 mg." Again, this is very difficult to square with the family definition, since, using that definition, it would mean that both a size 00 capsule filled with 760 mg of final blend and a size 00el capsule filled with 760 mg of final blend have the same weight of 880 mg. Presumably, an empty size 00 capsule and an empty size 00el capsule, which share a common diameter but have different heights, have different weights. It would not make sense to assert that capsules with varying weights, when empty, yield capsules with a single weight, when filled with a single amount of final blend.

The only other place in the patent in which "size 00" appears is claim 1.

A similar analysis may be performed on the Uraizee declaration. Dr. Uraizee's main point in the declaration was that granules prepared by the Nakai process did not fit in a size 00 capsule. There appears to be no dispute that a size 00 capsule and a size 00el capsule have different fill capacities.[4] There is nothing in the writing of the declaration that suggests that Dr.

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[3] If Roxane's proposed construction is correct, we are left with a patent specification that says "one embodiment" when it means "two embodiments."

[4] Roxane's opening brief presents a table which generally demonstrates this. (Pl.'s Br. 8.) The Lightfoot reference cited in the Uraizee declaration also presents a table which demonstrates this. (Uraizee Decl. at 2 n.1, INVAGEN0003652.)

Uraizee understood the term "size 00 capsule" to encompass a set with two elements with differing fill capacities. The declaration appears to be written from the perspective that a size 00 capsule has a single fill capacity, and that this single fill capacity is insufficient to hold 710 mg of calcium acetate granules prepared by the Nakai process. In particular, Dr. Uraizee states: "Due to the lower bulk density and lower tapped density (0.65 g/cc) of the granules by the Nakai et al. process, only about 592 mg of granules can be comfortably filled into the capsule." (Uraizee Decl. at 2, INVAGEN0003652.) Note that this implies that a size 00 capsule has one fill capacity; there is no suggestion that a size 00 capsule has a range of fill capacities. If Dr. Uraizee understood "size 00" to refer to a set containing two capsules of different volumes, she might have written this sentence differently, such as by using a range, e.g., "about 592 mg to 610 mg can be comfortably filled into size 00 capsules."[5]

Roxane contends that documents relating to the applicants' appeal to the Patent Trial and Appeal Board ("PTAB"), the transcript of which was not included in the record when this Court heard the motion for a preliminary injunction, provide intrinsic evidence which supports Plaintiff's construction. Roxane first points to this statement in the appeal reply brief:

> [It] is apparent to one of ordinary skill that the claimed capsules are administrable to humans for treating hyperphosphatemia, whereas larger capsules of size number 000 are not normally administered to humans.

(Long Dec. Ex. 17 at 4, ROX_CA00000276). Roxane contends that this statement "clearly expressed" that the claim term "size 00" excludes only size 000. (Pl.'s Br. 17.) This is

[5] Roxane has conceded that, in connection to the declaration, Dr. Uraizee tested only the size 00 capsule, and not size 00el, and so that explains why her declaration appears to reflect a single fill capacity. (Pl.'s Resp. Br. 2.) Thus, Roxane takes the position that Dr. Uraizee tested only one size capsule, but wrote a declaration using a term that she understood to refer to two capsules of different volumes, but did not attempt to clarify the matter. This is difficult to credit.

unpersuasive; this sentence says nothing about the scope of the claim term "size 00." Roxane argues that "[t]he Applicants expressly stated that ***only*** the 'larger capsules of size number 000' are outside the scope of the 'claimed capsules,'" but this is not supported by the plain language Roxane has quoted. (Id.) There is no "only" in the original sentence, so it was not expressly stated, nor is "only" implied.[6]

Roxane also attempts to make use of the applicant's correction of a small mistake made by the examiner. According to statements made in the appeal reply brief, in the appeal answer brief submitted by the examiner to the PTAB, the examiner mistakenly asserted that claim 1 covers capsules of size 00 or larger, instead of smaller. (Long Dec. Ex. 17 at 4, ROX_CA00000276). The statements made by the applicants in pointing out and correcting that error do not speak to the issue of whether the applicants used "size 00" to refer to a family.[7]

The appeal reply brief actually provides evidence that works against Roxane's position. It contains the statement: "[t]he Uraizee Declaration only tested size 00 capsules . . ." (Long Dec. Ex. 17 at 5, ROX_CA00000277). There is no dispute that, in the experiment described in that declaration, Dr. Uraizee tested only capsules of size 00, and did not test capsules of size 00el.[8] It is quite clear that, in this appeal reply brief sentence, "size 00" was used to refer to size

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[6] Roxane also cites the transcript for the hearing before the PTAB and claims, once again, that the applicant explicitly stated that ***only*** size 000 capsules are larger capsules. The transcript does not say that. (Long Dec. Ex. 18 at 9:14-20, ROX_CA00050020).

[7] Similarly, Roxane finds support for its position in a statement to the PTAB that a size 0 capsule was one size smaller, rather than two sizes smaller, than the claimed invention. (Pl.'s Resp. Br. 1.) The problem with this argument is that at issue is the meaning of the claim term "size 00," not the word "size." The parties have not asked for claim construction of the word "size," and the use of "size" outside the context of the claim term at issue does not reliably illuminate the meaning of the claim term.

[8] "Roxane can now confirm that she used a non-elongated version." (Pl.'s Resp. Br. 2.)

00 capsules only, rather than the set of size 00 and size 00el capsules. This is consistent with the usage throughout the intrinsic record.

Roxane has proposed a construction that conflicts with the intrinsic evidence; Defendants have proposed a construction that is consistent with the intrinsic evidence. The intrinsic evidence uniformly demonstrates that "size 00 or less" does exclude capsules of size 00el, and so means "precisely size 00 or less."

B. "Flowable granules"

Defendants contend that the claim term "flowable granules" in Claim 1 excludes any granule produced by a wet granulation process. Roxane contends that there is no such exclusion.

Defendants first point to the fact that the specification describes only a dry granulation production method. It is well-settled that the Federal Circuit "has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004).

Defendants next point to a statement in the appeal decision from the PTAB, observing that the specification describes a dry granulation method. (PTAB decision at 3, ROX_CA00000304). This is a simple statement of fact. The PTAB made no legal conclusions limiting claim scope to granules produced by dry granulation methods.

Lastly, Defendants contend that the applicants disclaimed granules produced by a wet granulation process during prosecution. There is no dispute that the applicants used the Uraizee declaration to overcome an obviousness rejection, and that they distinguished the flowable granules made by the dry granulation process disclosed in the '032 patent specification from the

granules produced by the wet granulation process described in Nakai. As Defendants state, under Federal Circuit law, "where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003).

The key to the analysis is that the applicant must unequivocally disavow a certain meaning of a claim term, and Defendants have not explained what meaning of "flowable granules" has been disavowed. The statements distinguishing the Nakai process do not rise to the level of an unequivocal disavowal of some meaning of "flowable granules." In the declaration, Dr. Uraizee states that, using the granules she produced using the Nakai process, "[t]he capsule fill was part slug and part granules." (Uraizee Decl. at 2, INVAGEN0003652). Defendants have not explained what a slug is, nor what the appearance of slug in the capsule fill has to do with being flowable, nor why this Court should conclude that wet granulation is to blame for the slug.[9] Defendants have failed to persuade this Court that the applicants used "words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002).

[9] It is not at all clear that Dr. Uraizee even relied on the wet/dry granulation distinction to distinguish Nakai. Her main point appears to be about granule density: the inventive process produced granules with a much higher bulk density than did the Nakai process. (Uraizee Decl. at 4, INVAGEN0003654). While she does refer at points to the issue of whether the granules were flowable, as already stated, she makes no clear statement about how the wet/dry production distinction affects granule flowability.

Furthermore, the transcript from the PTAB hearing shows that counsel for the applicants argued: "[The examiner] ignores the declaration evidence that Nakai wasn't able to *consistently* produce flowable granules as claimed." (Long Decl. Ex. 18 at 7:11-12, ROX_CA00050018) (italics added). This appears to concede that the Nakai wet granulation process sometimes produced flowable granules.

The Court agrees with Roxane and concludes that "flowable granules" means "flowable granules."

Also before the Court are two motions seeking to exclude certain extrinsic evidence from consideration during claim construction. This Court has determined that the meaning of the claim terms at issue is unambiguous in light of the intrinsic evidence. It has not needed to rely on extrinsic evidence in claim construction, and these motions will be denied as moot.

For these reasons,

IT IS on this 15th day of July, 2015 hereby

ORDERED that, in U.S. Patent No. 8,563,032, the term "size 00 or less" means "precisely size 00 or less," and "flowable granules" means "flowable granules;" and it is further

ORDERED that Defendants' motion to preclude the testimony of Stuart Silverman (Docket Entry No. 188) is **DENIED** as moot; and it is further

ORDERED that Defendants' motion to strike the declaration of Larry L. Augsburger (Docket Entry No. 207) is **DENIED** as moot.

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