IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 14-1203-LPS
	:	
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC.,	:	
	:	
Defendants.	:	
	:	

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MEMORANDUM OPINION

November 3, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

On September 17, 2014, Plaintiff Reckitt Benckiser LLC ("Reckitt" or "Plaintiff") filed suit against Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. ("Aurobindo" or "Defendants") alleging infringement of U.S. Patent Nos. 6,372,252 (the "'252 patent"), 6,955,821 (the "'821 patent"), and 7,838,032 (the "'032 patent").[1] The patents are directed to controlled-release formulations of the drug guaifenesin.

The parties submitted claim construction briefs (D.I. 50, 51, 59, 61) and Aurobindo submitted a technology tutorial (D.I. 49). The Court held a claim construction hearing on August 8, 2016. (*See* D.I. 102 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in

[1]After the claim construction hearing, Reckitt dropped its claims related to the '252 patent. (*See* D.I. 111)

question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be

read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "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." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of

the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. "portion"[2]

Plaintiff "a part of a whole, either separated or integrated with it"
Defendants "a discrete part of the product"
Court "a distinct formulation"

The Federal Circuit previously construed "portion" in the context of the (now non-asserted) '252 patent. *See Reckitt Benckiser Inc. v. Watson Laboratories, Inc.*, 430 Fed. App'x 871(Fed. Cir. 2011). The '252 patent issued from U.S. Application Serial No. 09/559,542 ("the '542 application"). Defendants urge the Court to adopt the same construction of "portion" in the context of the '032 patent-in-suit, because the '032 patent issued from an application that is a continuation-in-part of the '542 application.

"It is settled that prosecution disclaimer attaches to progeny continuation in part applications where the same claim limitation is at issue." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1335 (Fed. Cir. 2003). When evaluating whether two claim limitations are the same, the "appropriate focus is on the scope of the claim element, not the meaning of particular words in isolation." *Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 943 (Fed. Cir. 2013).

Defendants argue that the portion limitations of the claims of the '252 patent that were construed by the Federal Circuit are the same as the portion limitations of the asserted claims of

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[2]This term appears in claim 1 of the '032 patent.

the '032 patent because both appear in the context of a claim to a product "having two portions": an "immediate release form" ("IR") and a "sustained release form" ("SR"). Moreover, the claims in both patents have similar structure. After setting out the "two-portion" limitation, both patents' claims describe the concentrations of guaifenesin the claimed product must deliver to the body.

The nearly-identical language and structure of the "portion"-containing limitations in the '252 and '032 patents suggest that the "portion" limitation should be construed the same in both patents. That is, as the Federal Circuit explained in its discussion of the term, the two-portion limitation distinguishes the claimed products, which contain distinct IR and SR formulations, from products that contain a single formulation.[3] *See Watson*, 430 Fed. App'x at 876. While not limiting the claims to embodiments in which the sustained and immediate release portions of the drug have a particular spatial relationship, the Federal Circuit's construction does require that the sustained and immediate release "portions" of the product comprise two distinct formulations.[4] This distinction is consistent with the description of the invention of the '032 patent as set forth in its specification. *See* '032 pat. col. 3:66-4:6 (explaining that invention may relate to

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[3]In *Watson*, the issue was whether during prosecution the patentees had "disavowed claim coverage of sustained release tablets," even if those tablets "release some guaifenesin immediately upon ingestion." *Watson*, 430 Fed. App'x at 876.

[4]The Federal Circuit affirmed the lower court's "discrete part" construction on the basis that it "excludes single-formulation SR tablets." *Watson*, 430 Fed. App'x at 877. The Court also noted that the "discrete part" construction "accurately encompass[ed] the three embodiments of two-portion tablets and capsules disclosed in the specification" of the '252 patent, but did not suggest that the construction was meant to limit the claims to those embodiments or others like them. *Id.*; *see also* '252 pat. col. 3:57-60, 9:46-56 (describing three disclosed embodiments: bilayer tablets having an IR portion on one face and an SR portion on the other; bilayer tablets having an SR portion in the center that is coated and surrounded by an IR portion; and guaifenesin capsules containing beads of the IR formulation and beads of the SR formulation).

preparations "in the form of capsules having beads or granules of both immediate release formulation and beads or granules of sustained release formulation . . . [in which] beads may comprise a mixture of discrete beads each having only one of the SR or IR formulations or may comprise beads containing both SR and IR formulations associated in a single bead, or combinations of the forgoing"). Thus, the Court will construe "portion" as a "distinct formulation."[5]

B. "modified release drug product"[6]

Plaintiff "a dosage form comprising a sustained release ***quantity*** and an immediate release ***quantity***, and having both immediate release and sustained release properties"
Defendants "a dosage form comprising a sustained release ***portion*** and an immediate release ***portion***, and having both immediate release and sustained release properties"
Court "a dosage form comprising a sustained release quantity and an immediate release quantity, and having both immediate release and sustained release properties"

Each of the disputed claim terms is directed to a "modified release drug product"

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[5]The Federal Circuit construed "portion" as "a discrete part of the product." *Watson*, 430 Fed. App'x at 876. Plaintiff in this case argues that adopting the Federal Circuit's claim construction of "portion" in the context of the '032 patent would violate the doctrine of claim differentiation because it would render claim 1 identical to claim 3, which is directed to "[t]he drug product according to claim 1, wherein the first and second portions are discrete." *See Phillips*, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."). The parties have not asked the court to construe the term "discrete" in the context of claim 3 of the '032 patent, so the Court does not reach the issue of whether the meaning of "discrete" in that claim is the same as the meaning of the term "discrete" in the context of the Federal Circuit's construction of the "portion" term of the '252 patent. In order to avoid confusion, however, the Court has (non-substantively) modified the Federal Circuit's construction of "portion" by substituting "distinct formulation" for "discrete part of the product."

[6]This term appears in claims 1, 2, 6-12, 17, 29-30, and 41-42 of the '821 patent.

including at least "a first quantity of guaifenesin in an immediate release formulation . . . [and] a second quantity of guaifenesin" in either a "sustained release form" or a "release-delaying matrix." *See* '821 pat. col. 30:11-16, 32:23-27. The parties agree that the term "quantity" means "amount." (D.I. 50 at 8; D.I. 51 at 16) Defendants argue that this claim term also imposes "important structural limits on the claimed invention." (D.I. 51 at 16) Specifically, Defendants ask the Court to construe "quantity" as "portion," where "portion" refers to a quantity of guaifenesin located in a "physically separate, discrete formulation[]." (*See id.*)

Defendants' argument that the claims are limited to embodiments having physically separate IR and SR formulations is predicated on the patentee's tacit acknowledgment that the claimed products have two "portions," just like the claimed formulations of the '252 patent. (D.I. 51 at 16-18; D.I. 59 at 5-10) During prosecution, the examiner issued an obviousness-type double patenting rejection based on the '252 patent, because both the pending claims and those of the '252 patent "claim modified release tablets having two portions containing guaifenesin in both portions." (*See* D.I. 59 at 6) The patentee did not directly dispute this characterization, acknowledging that both sets of claims "are directed to guaifenesin in immediate release and sustained release formulation." (*Id.*) Defendants argue that the patentees thereby accepted of the examiner's characterization of their invention as having two "portions," and that this acceptance, along with the patentee's subsequent use of the term "portions" to describe its product, indicates that the patentee intended to impose the "portion" limitation from the '252 patent upon the claims of the '821 patent. Plaintiff responds that the patentee could not have intended to impose such a limitation, because the patentee ultimately amended the claims to ***exclude*** the word "portion" and distinguished the claims from the prior art by adding a requirement that the

claimed products include "at least one additional drug" besides guaifenesin. (D.I. 50 at 8)

The plain language of the disputed claims imposes a requirement that the modified release drug product includes two, distinct formulations: an IR formulation and an SR formulation (or release-delaying matrix). Because these formulations are distinct, they are, inherently, physically "separate" to some extent. This is identical to the requirement imposed by the "portion" limitation as construed by the Federal Circuit. (*See supra* Section A) Thus, it is not completely clear what additional limitation Defendants would impose by substituting the word "quantity" for "portion."

To the extent the parties' dispute centers on whether the IR and SR formulations ***must be*** "physically separate," as in, for example, a bi-layered tablet (*see* D.I. 61 at 8-10), the Court finds that the claims do not impose limitations regarding the spatial orientation of the two. The Court recognizes that the two different formulations of guaifenesin in the claimed products are inherently physically "separate" because they are distinct formulations. However, the intrinsic record does not support additional structural or spatial limitations being imposed by the word "portion." Given this lack of evidence, the Court adopts Plaintiff's proposed construction.

C. "release-delaying matrix"[7]

Plaintiff "pharmaceutical preparation that incorporates the active pharmaceutical ingredient dispersed within a dosage form and releases the active pharmaceutical ingredient in a controlled fashion"
Defendants "a combination of hydrophilic and water insoluble polymers of the sustained release formulation which gels when exposed to a media of low pH"

[7]This term appears in claim 1 of the '821 patent.

Court
"a combination of hydrophilic and water insoluble polymers of the sustained release formulation which gels in the stomach"

The parties agree that the claimed "release-delaying matrix" comprises a combination of hydrophilic and water insoluble polymers. They disagree, however, about whether those polymers must "gel when exposed to a media of low pH." Defendants contend that the patentee added this limitation by being its own lexicographer. (D.I. 59 at 20)

The specifications of both patents unambiguously state that the polymers of the claimed inventions gel when placed in "aqueous acidic media." *See, e.g.* '252 pat. col. 3:34-31, 5:65-6:23; '821 pat. col. 7:18-39. This tendency to gel is described as an inherent property of the claimed polymers: diffusion of guaifenesin from the gelled polymers is the mechanism by which the claimed invention achieves a sustained release. For this reason, the claims are limited to combinations of polymers that gel at low pH. However, the specification does not specify the meaning of "low pH' or "acidic," but instead only defines the pH level at which the polymers gel by reference to the pH of the stomach. *See, e.g.*, '252 pat. col. 3:34-37; '821 pat. col. 3:47-51 ("When a tablet comprising the sustained release formulation is exposed to an aqueous medium of low pH, such as that found in the stomach, the polymer combination gels causing guaifenesin and the drug ingredient to diffuse from the gel."). Hence, the Court will construe the term to specify that the formulation gels "in the stomach."

D. "immediate release formulation wherein the guaifenesin becomes bioavailable in a subject's stomach"[8]

Plaintiff "a form intended to rapidly release in the stomach guaifenesin for absorption"
Defendants "a form intended to rapidly release in the stomach substantially all of the guaifenesin for absorption"
Court "a form intended to rapidly release in the stomach guaifenesin for absorption"

The parties disagree about whether this term requires that "substantially all" of the guaifenesin in the immediate release formulation must become bioavailable in a subject's stomach. Defendants find such a requirement in the disputed term. Plaintiff counters that this cannot be correct because other claims in the patent refer to immediate release formulations in which the guaifenesin becomes "***fully*** bioavailable" in the stomach. (D.I. 50 at 18-19) Indeed, in prior litigation over the '252 patent, the Federal Circuit construed the term "an immediate release formulation which becomes ***fully*** bioavailable in a subject's stomach" as a formulation in which "substantially all" of the formulation becomes bioavailable in the stomach. *See Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1290 (Fed. Cir. 2010).

Defendants argue that the specification limits the claims to embodiments that have an immediate release formulation in which "substantially all" of the guaifenesin quickly becomes bioavailable in the stomach, because the claims require the guaifenesin to reach a concentration profile identical to that of a standard immediate release formulation. (D.I. 59 at 22-23) Defendants have not, however, pointed to intrinsic or extrinsic evidence to substantiate this

[8]This term appears in claims 1 and 29 of the '821 patent.

contention. Defendants also note that the parties have stipulated that the relevant portion of the concentration profile outlined in the '821 patent is identical to the concentration profile created by embodiments of claims in the '252 patent, which refer to guaifenesin becoming "fully bioavailable." However, Defendants have not explained why this necessarily means that the embodiments of the '821 patent must achieve that profile by making "substantially all" of their guaifenesin available in the stomach (as opposed to, for example, having a larger amount of guaifenesin in the immediate release formulation, and releasing only some of it).

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.