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

UNSEALED ON
MARCH 7, 2017

March 6, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

I. BACKGROUND

Plaintiff Reckitt Benckiser ("Reckitt") brought this patent infringement action under the Hatch-Waxman Act. Reckitt filed suit against Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), which had submitted an Abbreviated New Drug Application to market a generic version of Mucinex® DM, an extended-release tablet that contains dextromethorphan hydrobromide and guaifenesin. (*See* D.I. 1 at ¶ 23) Reckitt asserts claims 1, 2, 6-12, 14, 17, 29, 30, 41, and 42 of U.S. Patent No. 6,955,821 and claim 1 of U.S. Patent No. 7,838,032. (*See* D.I. 148 at 3 n.1) The patents claim controlled-release formulations of the drug guaifenesin, which contain both immediate-release and sustained-release portions or quantities.

The Court issued a claim construction opinion on November 3, 2016. (*See* D.I. 134) In light of that claim construction, the Court granted Aurobindo's motion for leave to file a motion for summary judgment of non-infringement. (*See* D.I. 138) The parties briefed Aurobindo's summary judgment motion, as well as Aurobindo's motion to exclude certain expert testimony. The Court heard oral argument on the pending motions on February 23, 2017. A five-day bench trial is scheduled to begin on April 17, 2017.

For the reasons stated below, the Court will deny Aurobindo's motion to exclude expert testimony and grant its motion for summary judgment of non-infringement.

II. LEGAL STANDARDS

A. Motion to Exclude

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), the Supreme

Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Rule 702(a) requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d).

There are three distinct requirements for proper expert testimony: (1) the expert must be qualified; (2) the opinion must be reliable; and (3) the expert's opinion must relate to the facts. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

B. Summary Judgment

Under Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the

moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson*, 477 U.S. at 252.

III. DISCUSSION

A. Aurobindo's Motion to Exclude Testimony of Mario A. Gonzalez

Aurobindo moves to exclude the expert opinions of Mario A. Gonzalez, Ph.D., FCP, regarding infringement and invalidity, specifically with respect to (1) the structure or physical make-up of Aurobindo's product and (2) the obviousness of the patents in suit. (*See* D.I. 148 at 1-2)[1] Aurobindo contends that Dr. Gonzalez is not qualified to opine on drug formulation science and that his opinions are neither reliable nor fit the issues in the case. The Court disagrees and will deny Aurobindo's motion.

Dr. Gonzalez is qualified to offer opinions here. Although there is some disagreement as to the identity of a person of skill in the art, Dr. Gonzalez undisputedly meets both sides' definitions. (*See* D.I. 149 Ex. C at ¶¶ 131-32) Dr. Gonzalez has a Ph.D. in pharmacokinetics, with over 50 years of experience in the fields of pharmacy, pharmacology, and pharmacokinetics. (*See* D.I. 152 at ¶ 1) Dr. Gonzalez is not himself a formulator, but he has experience working in research and development of specialized drug-delivery systems, including immediate-release and modified-release dosage forms. (*See* D.I. 141 Ex. F at ¶ 10) Dr. Gonzalez's work includes collaborating with formulators to determine how drug products perform and how they release active ingredients. (*See* D.I. 141 Ex. D at 34-37)

With respect to fit and reliability, Aurobindo contends that Dr. Gonzalez has failed "to particularize his opinions and to link Aurobindo's formulations to each limitation," specifically the requirement for two distinct formulations. (D.I. 148 at 15) In particular, Aurobindo suggests

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[1]Aurobindo did not seek leave to file a motion to strike in conjunction with its motion for summary judgment. (*See* D.I. 94)

that the in vitro and pharmacokinetic data Dr. Gonzalez discusses are not relevant to the structure of Aurobindo's product and cannot show that Aurobindo's product has two distinct formulations. (*See id.*) But Aurobindo does not argue that the data Dr. Gonzalez relies on was collected using an unreliable methodology, and Dr. Gonzalez articulates his reasoning supporting the conclusions that he draws from the data. "The test of admissibility is not whether a particular scientific opinion . . . is demonstrably correct. Rather, the test is whether the 'particular opinion is based on valid reasoning and reliable methodology.'" *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145-46 (3d Cir. 2000) (quoting *Kannankeril v. Terminix Int'l Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). That Aurobindo disagrees with Dr. Gonzalez's conclusions is not reason to exclude his opinions. Dr. Gonzalez's testimony is sufficiently reliable and will assist the trier of fact. Accordingly, the Court will deny Aurobindo's motion.

B. Other Evidence

Aurobindo suggests that in deciding the motion for summary judgment, the Court should not consider any evidence other than the ANDA. (*See* D.I. 140 at 11-12) The Court disagrees. "[S]ection 271(e)(2) 'requires an infringement inquiry focused on what is likely to be sold following FDA approval,' an inquiry that 'must be based on all of the relevant evidence ***including*** the ANDA.'" *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997)). Thus, for example, biobatch test data submitted with an ANDA – based on testing which falls into the safe harbor provision of 35 U.S.C. § 271(e)(1) and, therefore, cannot be a basis for infringement – may be irrelevant and, perhaps, should not be considered. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000). But where additional evidence

supplements the record with respect to characteristics of the proposed commercial product made pursuant to the specifications of the ANDA, courts may consider that evidence. *See Bayer AG. v. Biovail Corp.*, 279 F.3d 1340, 1346-47 (Fed. Cir. 2002). The additional evidence that Reckitt provides here – a dissolution study conducted by a commercial laboratory on Aurobindo's ANDA drug product – falls into this latter category. This testing provides relevant evidence about characteristics of the product Aurobindo will likely sell, and is appropriate to consider.[2]

Aurobindo also requests that the Court disregard statements in Dr. Gonzalez's expert report that contradict his deposition testimony. (*See* D.I. 158 at 8) Although Aurobindo identifies inconsistencies between Dr. Gonzalez's reports and testimony, the Court is not persuaded that Dr. Gonzalez's reports are shams – intended simply to generate a dispute of material fact and defeat summary judgment – such that they should be disregarded. *See Jiminez v. All Am. Rathskeller, Inc.*, 503 F.3d 247, 254 (3d Cir. 2007).

Accordingly, the Court finds no basis on which to limit the evidence to be considered and will decide this motion in view of all record evidence presented by the parties.

C. Aurobindo's Motion for Summary Judgment of Non-Infringement

The summary judgment motion concerns claim limitations that require the claimed drug product to include both an immediate-release (IR) formulation and a sustained-release (SR) formulation. Reckitt asserts that Aurobindo's proposed product literally meets these limitations.[3]

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[2]However, as is clear from the Court's disposition of the summary judgment motion, that evidence (in combination with all of the other evidence of record) is not sufficient to raise a genuine dispute of material fact.

[3]Reckitt initially pursued both literal and equivalency theories of infringement. Following this Court's claim construction opinion, Reckitt elected not to continue to assert infringement under the doctrine of equivalents. (*See* D.I. 151 at 1 n.1, 18)

Aurobindo moves for summary judgment on the basis that Reckitt has failed to present sufficient evidence that Aurobindo's proposed product has two distinct formulations, as required by each asserted claim.

The Court agrees with Aurobindo that summary judgment is warranted here. On the record created by the parties, taking all of the evidence in the light most favorable to Reckitt and drawing all reasonable inferences in Reckitt's favor, no reasonable factfinder could find that Aurobindo's proposed product contains two distinct formulations, which is required by the asserted claims.

1. The Pertinent Claim Constructions

In resolving the parties' claim construction disputes, the Court made clear that the "portion" or "quantity" limitations of the claims require the modified-release drug product of the asserted claims to include two, distinct formulations: an immediate-release formulation and a sustained-release formulation (or release-delaying matrix). *See Reckitt Benckiser LLC v. Aurobindo Pharma Ltd.*, 2016 WL 6542724, at *2-4 (D. Del. Nov. 3, 2016). The Court sets out here the pertinent details of its constructions and reasoning.

Independent claim 1 of the '821 patent reads:

> A ***modified release drug product*** comprising ***a first quantity of guaifenesin in an immediate release formulation*** wherein the guaifenesin becomes bioavailable in a subject's stomach; ***a second quantity of guaifenesin in a release-delaying matrix***; and at least one additional drug,
>
> wherein the release-delaying matrix comprises a hydrophilic polymer and a water-insoluble polymer in a weight ratio of hydrophilic polymer to water-insoluble polymer from about 1:1 to about 9:1,

> wherein the immediate release formulation guaifenesin has a Cmax in a human subject equivalent to the Cmax obtained when a dose of a standard immediate release formulation having one third the amount of guaifenesin is dosed, and immediately after administration the serum concentration of guaifenesin peaks in about an hour, followed by a gradual serum concentration decrease over twenty-four hours but the serum concentration of guaifenesin never decreases below the minimum concentration of said standard immediate release formulation over twelve hours, and
>
> wherein the drug product releases a therapeutically effective bioavailable guaifenesin dose for at least twelve hours after a single dose in the human subject according to serum analysis.

'821 patent col. 30 ll. 12-35 (emphasis added).

Independent claim 29 similarly recites "[a] ***modified release drug product*** comprising a ***first quantity of guaifenesin in an immediate release formulation*** wherein the guaifenesin becomes bioavailable in a subject's stomach; [and] a ***second quantity of guaifenesin in a sustained release form***." Col. 32 ll. 23-27 (emphasis added).

With respect to the '821 patent, the Court construed "modified release drug product" to mean "a dosage form comprising a sustained release quantity and an immediate release quantity, and having both immediate release and sustained release properties." *Reckitt*, 2016 WL 6542724, at *3. In explaining its reasoning for adopting this construction – which was proposed by Reckitt – the Court stated:

> 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. . . .***
>
> 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."

Id. at *4 (all emphasis added except to "must be," which is emphasized in the original).

Claim 1 of the '032 patent includes a limitation comparable to that found in the '821 patent. Specifically, claim 1 of the '032 patent recites "[a] drug product comprising guaifenesin and having two portions, wherein a first ***portion*** comprises guaifenesin in an immediate release form, which releases guaifenesin in a human's stomach, and a second ***portion*** comprises guaifenesin in a sustained release form." '032 patent col. 59 l. 64 - col. 60 l. 2 (emphasis added). The remaining asserted claims depend from these independent claims and, therefore, also contain the two-formulation limitations.

In connection with the '032 patent, the Court construed "portion" as "a distinct formulation." *Reckitt*, 2016 WL 6542724, at *2. In doing so, the Court made reference to a Federal Circuit decision that construed the same term in the context of the related (but here unasserted) '252 patent. *See Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App'x 871 (Fed. Cir. 2011). The Court stated:

> [A]s the Federal Circuit explained in its discussion of the term ["portion"], the two-portion limitation distinguishes the claimed products, which contain distinct IR and SR formulations, from products that contain a single formulation. 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***.

Id. at *3 (emphasis added; internal citation omitted).

2. Reckitt's Theory of Infringement

Reckitt's theory of infringement is based on the assertion that the ANDA product behaves as if it contains two distinct formulations, and so the ANDA product must have two formulations. (*See* D.I. 151 at 4-5) According to Reckitt, the dissolution profile of the ANDA product demonstrates that the product releases guaifenesin at two different rates. (*See id.*) Reckitt contends that any product with two release rates must have two formulations – pointing to Mucinex DM, which has a two-rate dissolution profile and undisputedly contains two formulations. (*See id.* at 5) Thus, Reckitt argues that the two release rates of Aurobindo's product prove that the product contains two distinct formulations.

Aurobindo moves for summary judgment on the basis that Reckitt has provided no evidence that Aurobindo's ANDA product contains two distinct formulations.

3. Reckitt Has Produced No Direct Evidence of Infringement

As a preliminary matter, it is notable what Reckitt does ***not*** produce in support of its claims of infringement. Reckitt does not analyze the ingredient list laid out in the ANDA. Reckitt does not offer any evidence about the excipients that make up the alleged two formulations and it does not discuss the composition of the ANDA product. Nor does Reckitt provide evidence regarding the physical structure of Aurobindo's product to demonstrate that it includes more than a single formulation. Reckitt does not provide any evidence about the physical structure of Aurobindo's tablets. Yet there is no indication in the record that the art lacks testing methods or techniques that would allow a person of skill in the art – or even a litigant asserting infringement – to determine whether a tablet contains two formulations. Nor

did Reckitt take any fact or expert depositions. (*See* D.I. 140 at 6) Instead, Reckitt's entire theory comes down to its expert, Dr. Gonzalez's, circumstantial analysis of the dissolution and pharmacokinetic behavior of Aurobindo's ANDA product and his opinions as to what that data indicates about the product's formulation (which are discussed in the next section).

Reckitt is also unable to point to anywhere in Aurobindo's ANDA that indicates that Aurobindo's ANDA product is going to contain two distinct formulations, one IR and one SR. To the contrary, as Aurobindo explains, a reasonable factfinder could only conclude that Aurobindo seeks FDA approval of a single-formulation, extended-release product. (*See* D.I. 141 Ex. A at 2, 85-86, 97-99) Aurobindo's ANDA acknowledges that Reckitt's Mucinex DM product is a bi-layer tablet with an immediate-release layer and an extended-release layer. (*See id.* at 85) The ANDA also recognizes that Reckitt's '032 patent claims a drug product comprising guaifenesin in an immediate-release portion and an extended-release portion. (*See id.*) The ANDA explains that Aurobindo's proposed product avoids the claims of Reckitt's patents because it contains a "single layer." (*Id.* at 85-86) Hence, the ANDA distinguishes the proposed product from Reckitt's product and Reckitt's patent claims based on the number of formulations. (*See id.*) The ANDA contrasts Mucinex DM's two-formulation bi-layer tablet with Aurobindo's single-layer approach, and does not describe the ANDA product as having two distinct formulations. Although Reckitt takes issue with the fact that the ANDA does not use the term "single formulation," Reckitt does not explain how the ANDA describes two formulations.

That Aurobindo's product contains a single formulation is supported by the manufacturing conditions presented in the ANDA. (*See id.* at 97-99) During manufacturing, all guaifenesin is added during the same step, and the process generates a single amount of drug

product that is pressed into tablets. (*See id.*) Reckitt does not describe how the manufacturing process, despite all guaifenesin being added in the same step, might give rise to anything other than a single formulation. Reckitt does not attempt to identify any step in the manufacturing process that could result in the formation of two distinct formulations containing guaifenesin. Rather, the fact that all guaifenesin is added at the same time – and, for example, no portion is thereafter removed, processed separately, and then reintroduced – supports Aurobindo's contention that the manufacturing steps produce a single formulation. The record is devoid of evidence that would support a contrary finding.

At bottom, then, Reckitt has failed to provide any direct evidence that Aurobindo's ANDA product will meet the modified release drug product, quantity, and portion limitations of the asserted claims. Thus, Reckitt has failed to produce any direct evidence from which a reasonable factfinder could find literal infringement.

4. Reckitt's Circumstantial Evidence is Insufficient to Create a Genuine Dispute of Material Fact

As discussed above, Reckitt presents no evidence that contradicts Aurobindo's ANDA specification, which describes a single-formulation product that is bioequivalent to Mucinex DM. (*See id.* at 85-86) Instead, Reckitt's infringement position is based entirely on how Aurobindo's proposed product performs. Based on similarities between the dissolution profile of Mucinex DM and the dissolution profile of Aurobindo's ANDA product, Reckitt contends that a reasonable factfinder could infer that the ANDA product, like Mucinex DM, must have two distinct formulations. Having reviewed the record in the light most favorable to Reckitt, and drawing all reasonable inferences in Reckitt's favor, the Court concludes that this circumstantial

evidence does not provide an adequate basis on which a reasonable factfinder could find infringement.

It is undisputed that Aurobindo's ANDA product has dissolution profiles and release rates that are substantially similar to those of Mucinex DM. This is unsurprising, as bioequivalence to an already-approved product is a requirement for ANDA approval, *see* 21 U.S.C. § 355(j)(2)(A)(iv), and Aurobindo's ANDA includes in vitro dissolution studies and in vivo tests to support its claim that the proposed product is bioequivalent to Mucinex DM. (*See, e.g.*, D.I. 141 Ex. A at 47) Reckitt supplements Aurobindo's ANDA studies with an additional in vitro dissolution study. (*See* D.I. 141 Ex. F at ¶¶ 54-74, 94-100) These studies demonstrate that about one third of the amount of guaifenesin is released in the first hour and the remaining amount is released over the next 13 hours. (*See id.* at ¶ 73)

Reckitt contends that this dissolution behavior indicates that Aurobindo's product does not dissolve at a constant rate (*id.* at ¶¶ 67-69), which, according to Reckitt, means that Aurobindo's product necessarily contains two distinct formulations (*id.* at ¶ 72). But Reckitt's expert, Dr. Gonzalez, does not support this contention. Instead, Dr. Gonzalez admits that two tablets with the same dissolution profile nevertheless could have different formulations, indicating that the ANDA product's similarities to Mucinex DM do not mean that their formulations, or the number of formulations, must be the same. (*See* D.I. 141 Ex. D at 45-46) Further, Dr. Gonzalez testified that to determine whether there are formulation differences between two products exhibiting the same dissolution and pharmacokinetic properties, one can look to the "listing of the materials that were used to make those tablets" and "manufacturing conditions." (*Id.* at 46-47) But Reckitt does not analyze either the ingredient list or the

manufacturing process described in the ANDA. As Dr. Gonzalez explained, "I would say that ***a dissolution test isn't going to tell you anything about where the components are or how they interact with each other***, but they will tell you about how the drug is released from the formulation." (D.I. 141 Ex. E at 179) (emphasis added) Accordingly, the fact that the ANDA product and Mucinex DM – a product with two distinct formulations – behave similarly is little evidence that Aurobindo's product has two distinct formulations.

Although Reckitt asserted at oral argument that it is not possible for a tablet to display two release rates unless that tablet contains two distinct formulations (*see, e.g.*, Tr. at 6), its expert, Dr. Gonzalez, does not directly express this opinion. Throughout his expert report, Dr. Gonzalez suggests that the ANDA product's dissolution profile "is only possible" if it "contain[s] an immediate release as well as a sustained release ***quantity***," but he does not assert that the composition of those quantities must necessarily be different. (*See, e.g.*, D.I. 141 Ex. F at ¶ 86) (emphasis added) At most, Dr. Gonzalez states that "the only way that the Aurobindo drug product could exhibit such a dissolution profile is to have one quantity of guaifenesin in an immediate release form and another quantity of guaifenesin in a release-delaying matrix (sustained release form)." (D.I. 141 Ex. F at ¶ 72) Dr. Gonzalez's reference to a release-delaying matrix may suggest two different formulations – an immediate-release portion without a release-delaying matrix and a sustained-release portion with the matrix. But this is, at best, a mere scintilla of evidence in support of Reckitt's position, and is insufficient to raise a genuine dispute of material fact.[4] Moreover, although the Court has decided not to exclude his expert reports, Dr.

[4]The Court's conclusion on this point is supported by the fact that Reckitt does not appear to place great weight on paragraph 72 itself, even though, in the Court's view, it is the paragraph that comes closest to being actual evidence of what Reckitt insists must be true. Reckitt points to

Gonzalez's deposition testimony does call into question whether he can credibly form an opinion about the formulation of the ANDA product based on the experiments he analyzed. (*See, e.g.*, D.I. 141 Ex. D at 45-47) Again, Dr. Gonzalez himself explained, "I would say that ***a dissolution test isn't going to tell you anything about where the components are or how they interact with each other***, but they will tell you about how the drug is released from the formulation." (D.I. 141 Ex. E at 179) (emphasis added)

More important than all this is the fact that Reckitt's contention that only a two-formulation product can give rise to the ANDA product's observed dissolution profile is directly contradicted by the patents in suit. Both the '821 and '032 patents describe single-formulation products. *See* '821 patent col. 6 l. 64 - col. 11 l. 55; '032 patent col. 11 l. 9 - col. 16 l. 56. These ***single***-formulation products display dissolution profiles that are qualitatively similar to that of the ANDA product. For instance, Example 1 of the '821 patent provides the composition for two batches of tablets, each with a single listing of ingredients and containing a single quantity of guaifenesin. *See* col. 17 ll. 20-45. The dissolution profiles show rapid release of some guaifenesin (approximately one-quarter in these examples) followed by slower release over twelve hours. *Compare* col. 18 ll. 4-30, Fig. 4 *with* D.I. 141 Ex. F at ¶¶ 46-47, Table 1. The reported in vivo behavior of the patent's single-formulation examples is similarly comparable to that of the ANDA product, with both showing a sharp increase in guaifenesin concentration within an hour or so of ingestion followed by a gradual decrease in concentration over twelve hours. *Compare* col. 19 l. 9 - col. 20 l. 15, Fig. 6 *with* D.I. 141 Ex. F at ¶¶ 49-50, Fig. 1.

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paragraph 72 only once in its briefing to the Court (*see* D.I. 151 at 7) (citing D.I. 141 Ex. F at ¶¶ 54-74), and when asked to provide specific record citations during the oral argument, Reckitt did not identify this paragraph (*see* Tr. at 33).

Quantitatively, the pharmacokinetic parameters measured from these in vivo experiments are also similar. *Compare* col. 19 ll. 35-53 *with* D.I. 141 Ex. F at ¶¶ 51-52, Table 2. The '032 patent presents the same data. *See* '032 patent col. 26 l. 33 - col. 29 l. 35; Fig. 4-6. Accordingly, the patents' single-formulation examples directly contradict Reckitt's claim that a product must have two formulations to result in the observed dissolution and pharmacokinetic behavior. Dr. Gonzalez's opinions do not provide any explanation or basis for contradicting the patents' teachings and, therefore, do not create a genuine dispute of material fact on this point. *See Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1080 (Fed. Cir. 2005) ("A party does not manufacture more than a merely colorable dispute simply by submitting an expert declaration asserting that something is black when the moving party's expert says it is white; there must be some foundation or basis for the opinion."); *see also K-TEC, Inc. v. Vita-Mix Corp.*, 696 F.3d 1364, 1374 (Fed. Cir. 2012).

5. Reckitt's Position is Inconsistent with the Court's Claim Construction

In addition to being unsupported by evidence, Reckitt's infringement position is also inconsistent with the Court's claim construction. Reckitt contends that two formulations are distinct so long as the release rate is different. (*See* D.I. 151 at 2) That is, Reckitt argues that the release rate alone can be the feature that distinguishes one formulation from another. Reckitt claims to find support for this conclusion in the Court's claim construction opinion, in which the Court made clear that no particular spatial relationship of the two formulations is required by the claims. *See Reckitt*, 2016 WL 6542724, at *2-4. But the Court's discussion on this point does not support Reckitt. In discussing spatial relationships, the Court considered, and rejected, Aurobindo's suggestion that the claims require the two distinct formulations to exist in a

particular relationship, such as being layered. But the Court's rejection of any particular spatial relationship simply means that the two distinct formulations can be put together into a tablet in any physical combination. *See, e.g.*, '821 patent col. 4 ll. 8-16 (describing tablet embodiments composed of two types of beads or granules mixed together; a sustained-release core with immediate-release outer coating; or two layers). It does not eliminate the requirement for two distinct ***formulations***, which are defined in the patents by their ingredients. *See, e.g.*, '821 patent col. 20 l. 54 - col. 21 l. 37 (defining IR and SR formulations by listing components).[5]

Reckitt's view of the claims – that different release rates satisfies the distinct formulations limitation – fails to give meaning to the requirement for two distinct formulations beyond what is separately required by the claim limitations involving the release properties of the claimed drug product. That is, as the patents explain, a product that meets the functional limitations by, among other things, delivering a dose such that "immediately after administration the serum concentration of guaifenesin peaks in about an hour" and also releases a "dose for at least twelve hours," necessarily will have two release rates: a fast rate resulting in the early peak and a slow rate allowing the dose to persist for twelve hours. '821 patent col. 30 ll. 25-27, 33-34. If, as Reckitt argues, these two release rates are sufficient to satisfy the formulation limitations, the separate requirement for two formulations would become redundant. The Court rejects Reckitt's view that the claims can be satisfied simply by showing two different release rates. *See generally Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950-51 (Fed. Cir. 2006) ("[C]laims are interpreted

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[5]This is not to say, however, that Reckitt must provide listings of ingredients to prove infringement. There may be proxies for an ingredient list that could serve as circumstantial evidence that the ANDA product contains two compositionally-distinct formulations, but, as already discussed, Reckitt does not present circumstantial evidence sufficient for a reasonable factfinder to find infringement.

with an eye toward giving effect to all terms in the claim.").

6. The Record Does Not Support a Finding of Infringement

To prove literal infringement, Reckitt must show that the accused product contains each and every limitation of the asserted claims. *See Convolve, Inc. v. Compaq Comput. Corp.*, 812 F.3d 1313, 1317 (Fed. Cir. 2016). The asserted claims recite structural limitations about two distinct formulations as well as functional limitations regarding the release properties of the claimed drug product. The studies Reckitt relies on are relevant to determining whether Aurobindo's proposed product meets the functional limitations. But those are not the limitations in dispute here, and – for the reasons described above – the studies do not speak to the formulation of the product. (*See* D.I. 141 Ex. E at 179)

Reckitt's infringement position essentially comes down to bioequivalence. Aurobindo's ANDA seeks to demonstrate that its proposed product is bioequivalent to Mucinex DM. But bioequivalence is not the test for infringement. *See Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009) (discussing doctrine of equivalents). "Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes." *Id.* Infringement, in contrast, "requires an element-by-element comparison of the patent claim and the accused product." *Id.* Thus, without identifying how Aurobindo's product contains two formulations – which Reckitt has failed to do – bioequivalence does not establish that it contains two distinct formulations. *See also Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App'x 871, 877-78 (Fed. Cir. 2011).

Accordingly, the Court will grant Aurobindo's motion for summary judgment of non-infringement.

IV. CONCLUSION

For the foregoing reasons, the Court will grant Aurobindo's motion for summary judgment of non-infringement and deny its motion to exclude expert testimony. An appropriate Order follows.