IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

RECKITT BENCKISER LLC, Plaintiff, v. AMNEAL PHARMACEUTICALS LLC, et al., Defendants.	Civil No. 15-2155 (RMB/JS)
RECKITT BENCKISER LLC, Plaintiff, v. DR. REDDYS LABORATORIES, LTD., et al., Defendants.	Civil No. 15-4524 (RMB/JS) **OPINION** **(PUBLIC)**

Plaintiff Reckitt Benckiser LLC ("Reckitt" or "Plaintiff") brings this Hatch-Waxman action for patent infringement against Defendants Amneal Pharmaceuticals LLC ("Amneal") and Dr. Reddy's Laboratories, Inc. ("DRL") (collectively, "Defendants") pursuant to 35 U.S.C. § 271(e)(2)(A) and §§ 271(a), (b), and (c).

I. Reckitt's Guaifenesin Drug Mucinex® and the Patents-in-Suit

This case involves Reckitt's Mucinex® product, an extended-release guaifenesin tablet used as an expectorant that thins and loosens mucus and relieves chest congestion. Reckitt initially alleged that Amneal's generic 600 mg and 1200 mg guaifenesin sustained-release tablets ("Amneal's ANDA products") will

infringe U.S. Patent Nos. 6,372,252 (the "'252 Patent"), 6,955,821 (the "'821 Patent"), and 7,838,032 (the "'032 Patent"). Similarly, Reckitt initially alleged that DRL's generic 600 mg and 1200 mg guaifenesin and pseudoephedrine hydrochloride sustained-release tablets ("DRL's ANDA Products") will infringe the '252, '821, and '032 Patents. After the filing of the Complaints, Reckitt dismissed its claims under the '252 Patent as to both Defendants [Docket Nos. 64, 65] and its claims under the '821 Patent against Defendant DRL [Docket No. 64].[1]

At the heart of the dispute is whether Defendants' ANDA Products have two distinct formulations, an immediate release formulation ("IR formulation") and a sustained release formulation ("SR formulation"). Reckitt contends that they do. Defendants counter that their ANDA products are single formulation matrix tablets and therefore do not infringe the Patents-in-Suit.

A. The '821 Patent

The '821 Patent is entitled "Sustained Release Formulations of Guaifenesin and Additional Drug Ingredients" and is a continuation-in-part of the '252 Patent. Stipulated Facts ("SF") [Docket No. 157] ¶ 8-9. The named inventors are Robert

[1] The Defendants also dismissed their respective Counterclaims and Affirmative Defenses.

D. Davis, Ralph W. Blume, and Donald Jeffery Keyser. SF ¶ 10. The ’821 Patent was filed on April 15, 2002, as Application No. 10/121,706. The ’821 Patent expires on April 28, 2020. SF ¶ 11. Reckitt is the owner and current assignee of the ’821 Patent. SF ¶ 12.

Claims 30, 35, 36, 41, and 70 of the ’821 Patent are asserted against Defendant Amneal only. SF ¶ 20. Amneal has stipulated that its ANDA products satisfy every limitation of the asserted claims of the ’821 Patent except for the elements: “modified release drug product;” “first quantity of guaifenesin in an immediate release formulation;” and “second quantity of guaifenesin in a sustained release form/release-delaying matrix.” SF ¶ 24.

B. The ’032 Patent

The ’032 Patent is entitled “Sustained Release of Guaifenesin” and is a continuation-in-part of the ’821 Patent, which is a continuation-in-part of the ’252 Patent. SF ¶ 14-15. The named inventors are Robert D. Davis, Ralph W. Blume, and Donald Jeffery Keyser. SF ¶ 16. The ’032 Patent was filed on April 4, 2003 as Application No. 10/406,557. The ’032 Patent expires on April 28, 2020. SF ¶ 17. Reckitt is the owner and current assignee of the ’032 Patent. SF ¶ 18.

Claims 1, 2, 5, and 6 of the ’032 Patent are asserted against both DRL and Amneal. SF ¶ 25. DRL and Amneal have

stipulated that their respective 1200 mg ANDA products satisfy every limitation of claims 1 and 2 except for the following claim elements directed to the drug product "having two portions" of guaifenesin: "a first portion comprises guaifenesin in an immediate release form;" and "a second portion comprises guaifenesin in a sustained release form." SF ¶ 27. DRL and Amneal have also stipulated that their respective 600 mg ANDA products satisfy every limitation of claims 5 and 6 except for the following claim elements directed to the drug product "having two portions" of guaifenesin: "a first portion comprises guaifenesin in an immediate release form;" and "a second portion comprises guaifenesin in a sustained release form." SF ¶ 28.

C. Mucinex®

The FDA approved NDA No. 21-282 in July 2002 for 1200 mg guaifenesin extended-release tablets and in December 2002 for 600 mg guaifenesin extended-release tablets, both of which are marketed by Reckitt under the trademark Mucinex®. SF ¶ 29-30. Mucinex® is approved for use as an expectorant. SF ¶ 30. The FDA approved NDA No. 21-585 in June 2004 for 600 mg/60 mg and 1200 mg/120 mg guaifenesin and pseudoephedrine hydrochloride extended-release tablets, which are marketed by Reckitt under the trademark Mucinex® D. SF ¶ 31-32. Mucinex® D is approved for use as an expectorant and nasal decongestant. SF ¶ 32.

The claims asserted by Reckitt cover both Mucinex® SE and Mucinex® D. Mucinex® SE products contain guaifenesin as the only active pharmaceutical ingredient ("API") and Mucinex® D products contain both guaifenesin and pseudoephedrine as the two APIs. SF ¶ 33, 35.

Both of Reckitt's Mucinex® products are bi-layer tablets, one layer containing guaifenesin in an IR form that provides fast-acting relief, and the other layer containing guaifenesin in a SR form that continues to release guaifenesin for 12 hours. SF ¶ 37. Mucinex® is a preferred example of and is disclosed as Formulation IV in the Patents-it-Suit.[2] Tr. 101:14-102:2; 652:1-6; Tr. 829:22-23.

D. Amneal's ANDA and ANDA Product

Amneal filed an Abbreviated New Drug Application ("ANDA") No. 207342 with the FDA seeking regulatory approval to market guaifenesin extended-release tablets in 1200 mg and 600 mg dosages. SF ¶ 38-39. Amneal's ANDA identifies the listed drug product that is the basis for the submission as Mucinex®. SF ¶ 45. Amneal's ANDA included a paragraph IV certification asserting that the '252, '821, and '032 Patents are invalid, unenforceable, or will not be infringed by the manufacture or

[2] "Tr." refers to the transcript of the trial conducted by the Court on May 15-18.

sale of its generic extended-release guaifenesin tablets. SF ¶ 44. Amneal's ANDA is currently pending.

There is no dispute that Amneal intended to develop generic products that are therapeutically equivalent to Mucinex® SE, nor any dispute that Amneal has concluded that its products have comparable dissolution profiles to, and are bioequivalent with, Mucinex® SE products. SF ¶ 53, 60-61. Moreover, the parties have stipulated that the Amneal's ANDA products have the following composition:

5.1 Formulation Composition of ANDA Exhibit Batches

Components	Guaifenesin Granules (Intermediate) Batch # BA09514, BM08013 & BM09513			
	mg/unit	mg/gm	% w/w	Weight, kg
Guaifenesin, USP	[redacted]			
Povidone USP K-30				
Purified Water, USP				
Total weight of Ingredients				

Components	600 mg Batch # BA12174			1200 mg Batch # BA05614		
	mg/unit	% w/w	Weight, kg	mg/unit	% w/w	Weight, kg
Guaifenesin Granules (intermediate)*	[redacted]					
Hypromellose, USP [redacted]						
Hypromellose, USP [redacted]						
Carbomer 934P, USP/NF [redacted]						
Lactose Monohydrate, USP [redacted]						
Microcrystalline Cellulose, NF [redacted]						
Talc, USP/NF [redacted]						
Colloidal Silicon Dioxide, NF [redacted]						
FD&C Blue # 1Aluminum Lake						
Magnesium Stearate, NF						
Total Weight in kg						
	ANDA Submission Batch , 600 mg			ANDA Submission Batch ,1200 mg		
Batch Size	[redacted]					
Finished Product Tablet Weight, mg						
Finished Product Weight, Kg						
Product Description	600 mg : Light blue colored, oval tablets with "AN036" one side and plain on other side					
	1200 mg: Light blue colored, oval tablets with "AN037" one side and plain on other side					

@ Purified Water Evaporated during process

Note: * Each 1290.00 mg of Guaifenesin Granules (intermediate) contains 1200 mg of Guaifenesin, USP.
Each 645.00 mg of Guaifenesin Granules (Intermediate) contains 600 mg of Guaifenesin, USP

E. DRL's ANDA and ANDA Product

DRL filed ANDA No. 208369 with the FDA seeking regulatory approval to market guaifenesin extended-release tablets. SF ¶ 46-47. DRL's ANDA identifies the listed drug product that is the basis for the submission as Mucinex®. SF ¶ 52. DRL's ANDA included a paragraph IV certification asserting that the '252, '821, and '032 Patents are invalid, unenforceable, or will not be infringed by the manufacture or sale of its generic extended-release guaifenesin tablets. SF ¶ 51. DRL's ANDA is currently pending.

As with Amneal, there is no dispute that DRL intended to develop generic products that are therapeutically equivalent to Mucinex® D, nor any dispute that DRL has concluded that its products have comparable dissolution profiles to, and are bioequivalent with, Mucinex® SE products. SF ¶ 66-68. The parties have also stipulated that DRL's ANDA products have the following composition:

II. Procedural History Before This Court

On August 14, 2015, and September 25, 2015, Amneal and DRL each filed motions for judgment on the pleadings under Rule 12(c) arguing that their ANDA products do not infringe the Patents-in-Suit because their products are single-formulation matrix tablets that were disclaimed during the prosecution of the '252 Patent. On January 15, 2016, the Court denied the motions on the ground that Reckitt should be afforded limited discovery regarding the actual structure of the Defendants' ANDA products.[3]

On May 11, 2016, Defendants, contending their products were single formulation release tablets, filed a summary judgment motion of non-infringement. They argued that the disclaimer of single formulation sustained release tablets that Reckitt had made during the prosecution of the '252 Patent should also apply to the '821 and '032 Patents. On December 22, 2016, the Court denied the motions, without opinion, and thereafter scheduled a trial on the merits.[4]

On March 28, 2017, the Court issued an Order adopting the claim constructions of Judge Stark set forth in Reckitt

[3] The Court also consolidated the cases under Case No. 15-2155. [Docket No. 47].

[4] As discussed infra, the parties dispute that the Defendants' ANDA products are single-formulation release tablets.

Benckiser LLC v. Aurobindo Pharma Ltd., C.A. No. 14-1203-LPS, 2016 U.S. Dist. LEXIS 152337 (D. Del. Nov. 3, 2016) ("Aurobindo I") and Reckitt Benckiser LLC v. Aurobindo Pharma Ltd., C.A. No. 14-1203-LPS, 2017 U.S. Dist. LEXIS 31985 (D. Del. Mar. 6, 2017) ("Aurobindo II"), appeal docketed, No. 17-1895 (3d Cir. Apr. 12, 2017). [Docket No. 127]. The Court set the matter down for trial, limiting the trial to the issue of infringement only.

III. Prior Related Litigation

The case that comes before this Court is not Reckitt's first challenge against a manufacturer of a generic Mucinex®. Three other courts have found no infringement by three other manufacturers of generic single formulation matrix tablets. Reckitt contends that Defendants' reliance on prior litigation is misplaced because the prior cases involve a different patent (the '252 Patent), different claim construction, and different products. The Court disagrees, in part. While it is true that the '252 Patent is no longer part of this case, Defendants' products must have a discrete IR formulation and SR formulation to infringe. Reckitt has rehashed some of its earlier arguments and the prior courts' discussions of those arguments are instructive. Moreover, whether or not Reckitt adequately addressed the deficiency of proof identified by the Aurobindo court (infra) requires analysis of that court's decision whose claim construction this Court has adopted.

A. Watson Litigation

On April 24, 2009, Reckitt filed an infringement lawsuit against Watson Laboratories, Inc. – Florida and Watson Pharmaceuticals, Inc. ("Watson") for infringement of the '252 and '821 Patents, subsequently dismissing the '821 Patent claim. Plaintiff's Responses to Defendants' Proposed Findings of Fact ("PRDFF"), ¶ 12 (citing Reckitt Benckiser, Inc. v. Watson Laboratories, Inc. Florida, Case No. 09-60609 (S.D. Fla. 2009)).[5] The District Court held that Watson did not infringe the '252 Patent, either literally or under the doctrine of equivalents. Reckitt Benckiser, Inc. v. Watson Laboratories, Inc. Florida, Case No. 09-60609, 2011 U.S. Dist. LEXIS 83090, ¶ 238 (S.D. Fla. Feb. 18, 2011). In relevant part, that Court found that Watson's products were prepared from a single uniform blend. Id. at ¶ 143. Moreover, the Court found that the "guaifenesin granules that touch the surface are not part of a separate structure from the balance of the guaifenesin and the other ingredients; all are part of a single structure. Watson's ANDA products do not have two structural portions." Id. at ¶ 204. On July 7, 2011, the Court of Appeals for the Federal Circuit affirmed the

[5] As will be discussed below, the "portion" containing limitation language in the '252 Patent at issue in Watson and Perrigo, infra, is nearly identical to the language in the Patents-in-Suit.

District Court's judgment of non-infringement, holding that "[t]he district court correctly concluded that Watson's products do not have two structural portions and that guaifenesin granules on the surface of Watson's tablets do not constitute the claimed first portion of guaifenesin in an IR form." Reckitt Benckiser Inc. v. Watson Laboratories, Inc., Florida, 430 Fed. Appx. 871, 877 (Fed. Cir. 2011).

B. Perrigo Litigation

In 2007, Adams Respiratory Therapeutics, Inc., Reckitt's predecessor-in-interest, and related entities filed an infringement lawsuit against Perrigo Company ("Perrigo") and related entities for infringement of the '252 Patent. Adams Respiratory Therapeutics, Inc. et al v. Perrigo Co., Case No. 1:07-CV-993 (W.D. Mich. 2007). The Perrigo District Court granted summary judgment of non-infringement. In relevant part the Court held that "[i]n spite of its attempts to distinguish Watson, [Reckitt] made substantially the same argument to the Federal Circuit in Watson (including that the Guaifenesin on the surface of Watson's tablets was uninhibited by polymer) that it now makes in this case with regard to Perrigo's tablet." Perrigo, Case No. 1:07-CV-993, 2012 U.S. Dist. LEXIS 3288, at *16 (W.D. Mich. Jan. 11, 2012). In short, the Court held that Perrigo, like Watson, made a single formulation tablet which was disclaimed in the '252 Patent.

C. Aurobindo Litigation

On September 14, 2014, Reckitt filed an infringement suit against Aurobindo Pharma Ltd. ("Aurobindo") for infringement of the '821, '032 and '252 Patents, later dismissing the '252 Patent from its suit. See generally Aurobindo I, 2016 U.S. Dist. LEXIS 152337 and Aurobindo II, 2017 U.S. Dist. LEXIS 31985. The Court found that the asserted claims of the '821 and '032 Patents require "two distinct formulations." See Aurobindo I, 2016 U.S. Dist. LEXIS 152337, at *6-8. The Court then granted summary judgment of non-infringement concluding that "a reasonable factfinder could only conclude that Aurobindo seeks FDA approval of a single-formulation, extended-release product." Aurobindo II, 2017 U.S. Dist. LEXIS 31985, at *15. (The Aurobindo decisions will be discussed in greater detail infra.)

IV. Trial Before This Court

Trial on the issue of infringement commenced on May 15, 2017, and lasted four days. Closing arguments were heard on June 29, 2017. Defendants' invalidity claims were stayed pending the outcome of the infringement trial. Reckitt presented the testimony of Dr. Martyn C. Davies, a professor of biomedical surface chemistry at the University of Nottingham School of Pharmacy.[6] In general, relying on his Raman analyses,

[6] Without objection, Dr. Davies was offered by Reckitt as an expert in "the fields of formulation, structural analysis and

Dr. Davies opined that Defendants' ANDA Products have two distinct formulations of guaifenesin, an IR formulation without rate-controlling polymers on the surface and a SR formulation including rate-controlling polymers in the interior.

Defendants presented five experts at trial. Dr. Harry Brittain and Dr. Richard Gemeinhart, two experts in pharmaceutical formulation, generally testified that Defendants' ANDA products are matrix tablets made from a single uniformly distributed blend of ingredients.[7] Two experts, Dr. Robin Rogers and Dr. Neil Spingarn, generally testified about the flaws and weaknesses of Dr. Davies's Raman analyses.[8] Finally, Dr. Jeffrey Rodriguez, a computer imaging expert called by DRL testified

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characterization and performance of controlled release pharmaceutical dosage forms." Tr. 97:25-98:6.

[7] Without objection, Dr. Brittain was offered by DRL as an expert in "pharmaceutical formulations and characterization, including with respect to sustained-release formulations." Tr. 537:1-4. Without objection, Dr. Gemeinhart was offered by Amneal as an expert in "controlled drug delivery systems and dosage forms and the materials used in those systems and dosage forms." Tr. 698:17-23.

[8] Without objection, Dr. Rogers was offered by Amneal as an expert in "solid state chemistry and the characterization of solid state materials and pharmaceutical formulations." Tr. 895:4-8. Without objection, Dr. Spingarn was offered by DRL as an expert in "Raman spectroscopy and its use in analysis of pharmaceutical formulations." Tr. 981:17-21.

about his count of the guaifenesin and [redacted] pixels in Dr. Davies's Raman maps.[9]

After considering all the evidence, and the parties' submissions, for the reasons set forth herein, the Court finds that Amneal and DRL will not infringe the '032 and '821 Patents. The Court declines to exercise jurisdiction over the counterclaims asserting invalidity. This Opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

V. Literal Infringement

To prove infringement, the patentee must show that it is more likely than not that the proposed ANDA product would, if commercially marketed, meet all of the claim limitations of the Patents-in-Suit. See Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1289 (Fed. Cir. 2010); Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002) (infringement analysis turns on whether accused product satisfies every limitation of the claim in question); Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991) ("To establish infringement, every limitation set forth in a patent claim must be found in an accused product . . . ."). In other words, the patentee "has the burden of proving

[9] Without objection, Dr. Rodriguez was called as an expert in "image processing and analysis." Tr. 1080:17-20.

infringement by a preponderance of the evidence." Kegel Co., Inc. v. AMF Bowling, Inc., 127 F.3d 1420, 1425 (Fed. Cir. 1997); SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988). Determining whether an accused product infringes the patent involves a two-step analysis. Kegel, 127 F.3d at 1425. The Court must first construe the scope and meaning of the asserted patent claims and then compare the accused product to the properly construed claims. Id.

A. The Asserted Claims and Claim Construction

Reckitt asserts claims 30, 35, 36 and 41 of the '821 Patent against Amneal, and claims 1 and 5 of the '032 Patent against Amneal and DRL.[10] The claims are as follows:

> 29. 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 sustained release form, . . .
>
> 30. The modified release drug product according to claim 29, wherein a total quantity of guaifenesin is from about 600 mg to about 1200 mg.
>
> 35. The modified release drug product according to claim 30, wherein the guaifenesin has a C_{max} of about

[10] No testimony was presented at trial with respect to claims 2 and 6 of the '032 Patent as asserted in the SF, ¶ 25. Reckitt does not dispute Defendants' presumption that these claims have been abandoned, and thus, this Court will consider them to have been withdrawn by Plaintiff. Nor does it appear, despite the assertions in the SF, ¶ 20, that any testimony was presented at trial with respect to claim 70 of the '821 Patent.

800 to 1250 ng/ml and an AUC_{inf} of about 2800 to 4375 hr*ng/ml.

36. The modified release drug product according to claim 30, wherein the guaifenesin has a C_{max} of least 1000 ng/ml and an AUC_{inf} of at least 3500 hr*ng/ml.

41. The modified release drug product according to claim 29, wherein the drug product is approximately equally effective when administered to the human subject with an empty or full stomach.

'821 Patent (emphasis added).

1. 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.

5. 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 subject's stomach, and a second portion comprises guaifenesin in a sustained release form, . . .

'032 Patent (emphasis added).

As noted, this Court adopted Judge Stark's claim construction from Aurobindo I as follows:

Disputed Word	**Meaning**
"Portion"	"a distinct formulation" ('032 Patent)
"Modified release drug product"	"a dosage form comprising a sustained release quantity and an immediate release quantity, and having both immediate release and sustained release properties" ('821 Patent)
"Immediate release formulation wherein the guaifenesin becomes bioavailable in a subject's stomach"	"a form intended to rapidly release in the stomach guaifenesin for absorption" ('821 Patent)

"Release-delaying matrix"	"a combination of hydrophilic and water insoluble polymers of the sustained release formulation which gels in the stomach" ('821 patent)

Although the two formulations need not be physically separate – except where there is a limitation regarding the spatial orientation of them, like a bi-layered tablet – they must be "inherently physically 'separate'" because they are distinct formulations.[11] This construction is in line with the Federal Circuit's decision that construed the same term in the context of the related (not asserted here) '252 Patent. See Watson, 430 Fed. Appx. at 875-77.

The Aurobindo court, much like the Perrigo court, turned to the Federal Circuit's construction of the "portion" limitation in the '252 Patent. See Aurobindo I, 2016 U.S. Dist. LEXIS 152337, at *6-8. The Federal Circuit construed "portion" as a discrete part of the product. Watson, 430 Fed. Appx. at 875-77. Based on the nearly-identical language of the '032 Patent, the Aurobindo court construed "portion" to mean "distinct formulation." Aurobindo I, 2016 U.S. Dist. LEXIS 152337, at *6,

[11] See Aurobindo I, 2016 U.S. Dist. LEXIS 152337, at *13. As Judge Stark noted, the rejection of any particular spatial relationship means that the two distinct formulations can be put together in any tablet in any physical combination. Id.; see, e.g., '821 Patent, Col. 4:8-16. (describing beads or granules).

*8 n.5 ("[I]n order to avoid confusion . . . the Court has (non-substantively) modified the Federal Circuit's construction of "portion" by substituting "distinct formulation" for "discrete part of the product.") Similarly, regarding the '821 Patent, as Judge Stark found and this Court adopted, the plain language of the claim – a "modified release drug product" comprising a "first quantity"[12] and "second quantity" of guaifenesin – imposes a requirement that the product comprises two distinct formulations. Id. at *12-13.

The parties squabble over whether "discrete" means "distinct." Reckitt contends that the words have different meanings and, thus, the Federal Circuit's construction of "portion" in Claim 1 as a "discrete part of the product" cannot be squared under the doctrine of claim differentiation with Claim 3 which provides "the drug product according to claim 1, wherein the first and second portions are discrete." See Watson, 430 Fed. Appx. at 876 (construing '252 Patent). The Watson case involved a bi-layered tablet. As the Watson court explained, the two-portion limitation distinguished the product from the defendant's non-layered tablet.[13] The Aurobindo case,

[12] The Court construed "quantity" to mean "amount." [Docket No. 127].

[13] "The [Federal Circuit] also noted that the 'discrete part' construction 'accurately encompass[ed] the three embodiments of two-portion tablets and capsules disclosed in the specification'

like this case, however, did not involve a bilayer tablet. The Aurobindo court modified the construction by substituting "distinct formulation" for "discrete part of the product." Aurobindo I, 2016 U.S. Dist. LEXIS 152337, at *8 n.5. Notably, the Aurobindo court declined to impose a construction that required any particular spatial relationship. Id. at *13. The Court ruled

> 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 . . . 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. (emphasis in original) (citation omitted).

As the court explained in its second opinion

> 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

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of the '252 [P]atent, but did not suggest that the construction was meant to limit the claims to those embodiments or others like them." Aurobindo I, 2016 U.S. Dist. LEXIS 152337, at *8 n.4 (quoting Watson, 430 Fed. Appx. at 877); see also '252 Patent 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).

> tablet in any physical combination. See, e.g., '821 [P]atent 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 [P]atent col. 20 l. 54-col. 21 l. 37 (defining IR and SR formulations by listing components).

Aurobindo II, 2017 U.S. Dist. LEXIS 31985, at *24 (emphasis in original).

In this Court's view, the Aurobindo court recognized that Claims 1 and 3 used the terms "distinct" and "discrete" with somewhat different meanings. Although the words are often used interchangeably, the Court finds that "discrete" in Claim 3 means "separate and distinct." See WEBSTER'S NEW WORLD COLLEGE DICTIONARY 411 (Michael Agnes et al. eds., 4th ed. 2010). Thus, Claim 3 added a particular spatial relationship, see '821 Patent col. 4:10-12 ("beads or granules of both immediate release formulation and beads or granules of sustained release formulation"), not present in Claim 1.[14] Cf. Claim 4 ("The drug

[14] Claim terms should generally be given their ordinary meaning to a person of skill in the art at the time of invention. Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. (2005)(en banc). To determine the ordinary meaning, the Court looks first to the intrinsic evidence, which includes the claims, the specification, and the prosecution history. Id. at 1312-17.

product according to claim 3, which is in a form of a bi-layer tablet"). [15]

[15] Defendants moved, in limine, to exclude Dr. Davies's testimony on literal infringement because he applied the wrong claim construction. [Docket No. 137]. Because this Court finds, for the reasons infra that Dr. Davies's testimony was not persuasive, the motion is moot. The Court notes, however, that Dr. Davies's testimony as to the claim construction he used was confusing. Dr. Davies testified that he did not believe "distinct formulation" was the same as "a discrete part of the product." Tr. 286-290.

> Q: Okay. When you read this definition that you put in your report, the proposed construction, a discrete part of the product or distinct formulation, did you distinguish between a discrete part of the product and distinct formulation in your mind?
>
> A: I did. Well, I thought Amneal and DRL were because it's either/or. It's either a discrete part of the product or a distinct formulation, and I used the distinct formulation as part of my opinions.
>
> Q: Okay. So, you're saying that you understood the proposed construction to be either/or; is that what you're saying?
>
> A: Well, I understood that they were saying it's a discrete part of the product or a distinct formulation, and I knew what discrete part of the product meant in the context of the '252 [P]atent.
>
> Q: Okay. I'm a little confused, sir. Are you saying that you understood a discrete part of the product in defendants' claim construction to mean something different than distinct formulation in defendants' claim construction?
>
> A: I saw that as either/or, a discrete part of the product or a distinct formulation, and I went on to use the distinct formulation in my analysis.

B. Infringement Analysis

The Court must next determine whether the accused product contains every limitation of the properly construed claims. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1467 (Fed. Cir. 1998), abrogated on other grounds by Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015).[16] Thus, the relevant question is whether the Defendants' ANDA Products contain two distinct formulations, an IR Formulation and a SR Formulation. Because Reckitt believed that the Aurobindo court had granted summary judgment against it due to Reckitt's failure to present

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> Q: And when you say it's either/or, you thought that those were alternative definitions?
>
> A: Again, I did not think distinct formulation was the same as discrete part of the product in that context.

Tr. 288-89. He did admit, however, that if the Court finds that there is no substantive difference between distinct and discrete, there would be no infringement. Tr. 412-13 ("If the Court finds . . . that the discrete and distinct portions are the same as were the '252 [P]atent, then I would agree.")

[16] The parties appear to agree on the definition of a person of ordinary skill in the art ("POSA"). See Plaintiff's Contested Facts [Docket No. 157], at ¶ 6-7, which does not appear to be contested by Defendants. "A person of ordinary skill in the art for the '821 and '032 Patents would be, for example, a scientist with a graduate degree in pharmacology, pharmacy, or pharmaceutical chemistry, or a scientist with lesser formal training complemented with suitable professional experience." Id. at ¶ 7.

any evidence of structural or spatial limitations,[17] the trial before this Court primarily involved testimonial evidence focused on that issue.

1. Dr. Davies's Raman Imaging

Reckitt introduced the testimony of Dr. Davies who relied on Raman chemical imaging maps of Defendants' Products to attempt to show that the accused products have a distinct IR formulation on the surface and a distinct SR formulation below the surface. Tr. 98:24 – 99:7. In general, Dr. Davies identified a region where there was guaifenesin and other excipients, without [redacted] (a rate-changing polymer), on and near the surface of the tablets from which guaifenesin would rapidly release, i.e., an IR portion. He then identified another region beneath the surface of the tablets where the rate of guaifenesin would be slower, i.e., an SR portion, because [redacted] is present, which effects the release of guaifenesin. Dr. Davies then testified how the IR and SR portions were, in his opinion, distinct in location, composition, and in release properties.

Defendants argue that the analyses done by Dr. Davies are flawed for numerous reasons. Principally, Defendants aver that

[17] As Judge Stark noted, "the intrinsic record does not support additional structural or spatial limitations being imposed by the word portion." 2016 U.S. Dist. LEXIS 156337, at *13.

Dr. Davies's images merely portray what is well known, that in a non-coated tablet there is always guaifenesin on the surface that rapidly dissolves in the stomach before the rate-controlling polymers have swelled to exert a rate-controlling effect. Defendants also contend that Dr. Davies equated two distinct formulations with dissolution behavior, a theory rejected by the Aurobindo court. See Aurobindo II, 2017 U.S. Dist. LEXIS 31985, at *18, 19-23 ("[That the drugs have similar dissolution profiles] is unsurprising, as bioequivalence to an already-approved product is a requirement for ANDA approval"). The Court now turns to the parties' analyses of the evidence.

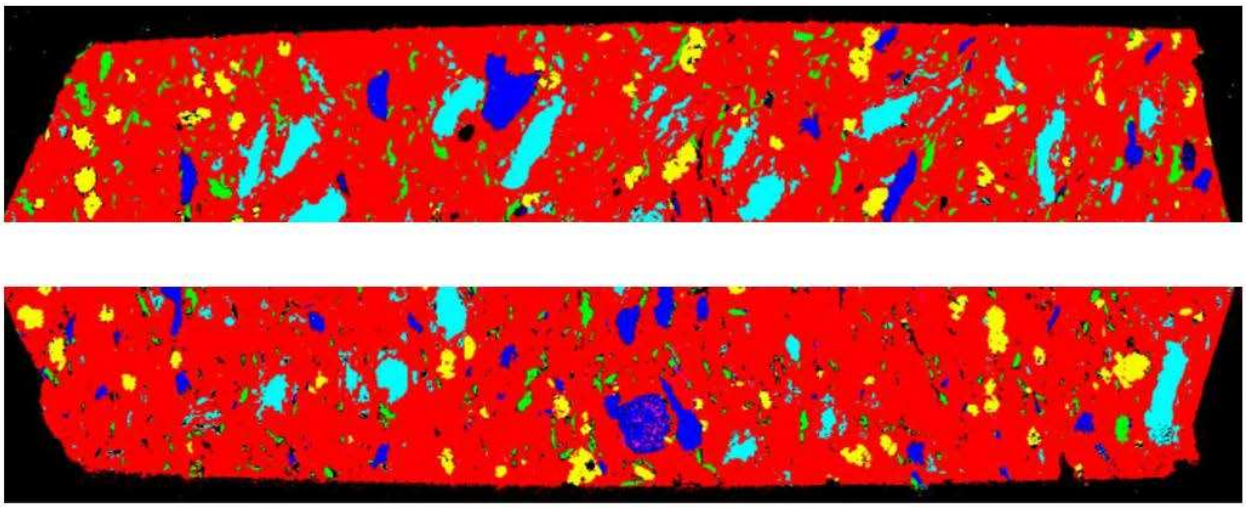
As an initial matter, the parties do not dispute that Raman microscopy testing is used in the pharmaceutical industry as a means to characterize the structure of solid oral dosage forms. Tr. 134:17-20. Raman spectroscopy and microscopy produces unique chemical fingerprints which may enable a person skilled in the art to identify the molecules at any given position. Id. at 134:21-23.

As part of his Raman analysis, Dr. Davies cut a single tablet of each of the Defendants' products in half and then used a microtome to obtain an extremely thin and flat substrate for imaging. Id. at 135:6-12. The spot size of the laser used for imaging was two microns. Id. at 139:9. After a spectrum was obtained the laser moved to a new spot five microns away to

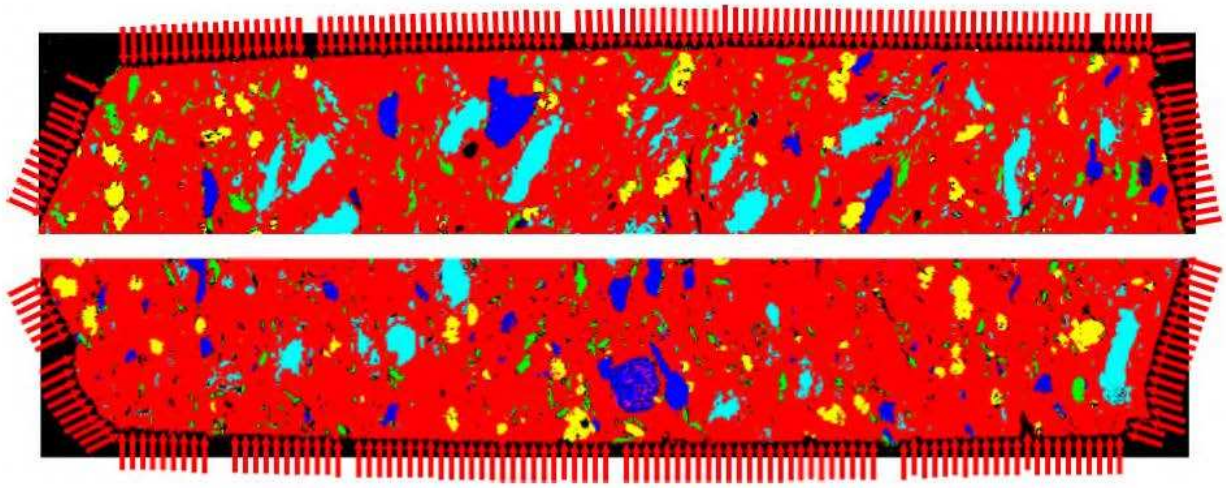
repeat the process. Id. at 139:14-16. For each spectrum, the acquisition time was 400 milliseconds. Id. at 139:21-22. This process was repeated 230,000 times and each spectrum was matched to a compound, using K-means cluster analysis, and a corresponding location in order to create a colored Raman map. Id. at 145:21; 176:17-177:10.

a. Imaging of DRL Tablet

Dr. Davies generated the following two maps which he testified are representative of the structure of DRL's tablets (PTX 35). [redacted] In the third demonstrative map (PDX 237), the red arrows illustrate where, allegedly, guaifenesin is present on the surface.



(PTX 35)



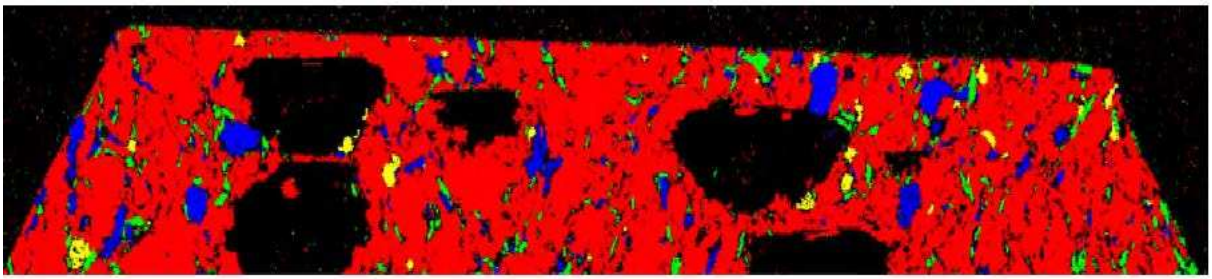
(PDX 237)

According to Dr. Davies, the surface of DRL's tablet was "dominated" by guaifenesin. Tr. 147:25-148:15. He explained that regions on and near the surface of DRL's tablet dominated by guaifenesin and other excipients, but without the rate-controlling [redacted] polymers, constitute the first portion of guaifenesin in IR form. Id. at 148:15-20. Because the guaifenesin present in the IR region is uninhibited by [redacted] (which is rate-controlling), it rapidly releases in the gastric fluid upon contact. Id. at 148:21-23. The consistent release rate in the first hour is about 23%. Id. at 118:20-24. In his opinion, this is a distinct immediate release formulation within the meaning of the asserted claims. Id. at 118:22-25; 191-198. Dr. Davies further testified that DRL's products contain a second portion of guaifenesin in SR form, which is guaifenesin in the interior of the tablet in the presence of the rate-

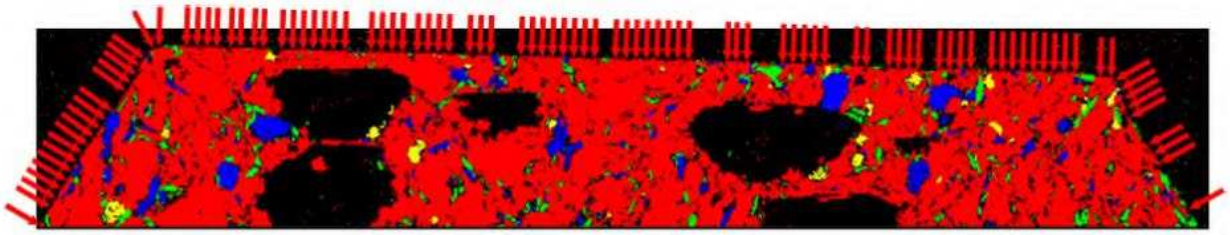
controlling polymers, a second formulation within the asserted claims. Id. at 118:25-119:4; 191-198.

b. Imaging of Amneal Tablet

Dr. Davies also generated the following map (PTX 36), which he testified is representative of the structure of Amneal's tablets:



(PTX 36)



(PDX 241)

Similar to the DRL tablet, the red arrows in the demonstrative map above, (PDX 241), illustrate where guaifenesin is present on the surface of the Amneal tablet. According to Dr. Davies, the surface is dominated by guaifenesin and other excipients without Methocel, which constitutes the IR formulation. Id. at 160:6-10. Dr. Davies testified that Amneal's tablets provide a consistent release in the first hour,

about 20% and 24% for the 1200 mg and 600 mg products, respectively. Id. 422:6-10. In his opinion, this is a distinct immediate release formulation. Id. at 160:7-9. He further provided that, similar to the DRL tablet, the guaifenesin below the surface is inhibited by the rate-controlling polymers and is the SR distinct formulation.

2. Dr. Davies's Analysis is Flawed and Unreliable

Because the parties spent a considerable amount of time either defending or attacking Dr. Davies's Raman analyses, the Court first turns to some of the parties' specific arguments. In the Court's final analysis, however, it is not so much that Dr. Davies's images were flawed — as they were for the reasons set forth herein — but that his interpretation of those images was fundamentally flawed. Defendants argue as a general principle that Dr. Davies's Raman maps should be given no evidentiary weight because they are nothing more than "window dressing." They essentially rely on an exchange between Dr. Davies and the Court:

> The Court: But it seems to me, correct me if I'm wrong, that if you have to do content blending, uniformity blending, you are going to get this mixture. You know the significant percentages of guaifenesin going into it. It seems to me that that picture could have been painted without the imaging.
>
> The Witness: **Your Honor, to me it could because . . . I think looking at the dissolution and the PK data, somebody of ordinary skill in the art would know that**

> **such formulations would be able to achieve that because they have the first portion and an immediate-release portion and they have a sustained-release portion that can give you that long term effect. It's – I guess we're here because Judge Stark said that they had – you had to show it physically.**

Tr. 365:7-366:1 (emphasis added).

Dr. Davies's answer to the Court's question does hint that he conducted a structural analysis to "mask [his improper] reliance on the dissolution rate of guaifenesin" as Defendants argue, Def. Resp. Post-Trial Br. at 1 [Docket No. 180], a theory the Aurobindo court had rejected. Def. Resp. Post-Trial Br. at 28. Indeed, as set forth below, it was this Court's overall impression that Dr. Davies believed that the dissolution behavior alone was evidence enough that the Defendants' products have two infringing distinct formulations. Given that firmly held opinion, Dr. Davies labored to convince not only this Court, but himself, it seemed, that his analyses showed two distinct formulations. This may help explain why Dr. Davies's opinions at times came off as either creative or conclusory, as the Court explains below. Setting these general criticisms aside for the moment, the Court now turns to the specific arguments the Defendants have made against his structural analyses, before addressing his flawed interpretation of such analyses.

Dr. Davies explained that the black, unidentified pixels on his map of Amneal's tablet (see PTX 35 supra) were the result of fluorescence between the dye and the Raman laser. Tr. 433:23-434:1. Dr. Rogers, however, explained that what Dr. Davies described as fluorescence interfering with the Raman signal essentially means that the data is "botched" and he should have performed the Raman testing more times to obtain better data. Tr. 907:9; see also Tr. 911:2-5 ("Fluorescence from the blue dye could cause the entire background to be so high that nothing would be identifiable, so the large black voids appear throughout the interior of this map.") Additionally, he testified that the Raman map was littered with far more black areas than just the large black voids in the center; he enlarged the map to illustrate this problem. Id. at 915-917, 916:1-11 ("I just want to draw your attention to all of the black, all of these black areas, which in Dr. Davies's map are indicated as unidentified areas . . . . But if you go past the black voids and if you pay attention to both what's called the surface and what's called the interior, this entire map is filled with unidentified regions").

In the Court's view, Dr. Rogers persuasively testified the image was neither complete nor an accurate representation of the structure of the ingredients within Amneal's tablet. Id. at 911:23 – 912:4. Dr. Davies's assertion that the majority of the

unidentified pixels were in the interior of the tablet, the supposed SR portion, and therefore the fluorescence did not interfere with his ability to distinguish an IR portion was not convincing. Additionally, Dr. Davies's testimony that he was unable to eliminate the fluorescence with the dye makes the Defendants' point.

Dr. Rogers also criticized Dr. Davies's images because half of the ingredients in the tablet were not detected.[18] Tr. 921:13-23. Although Dr. Davies agreed that the map he created for Amneal was "incomplete," Tr. 428:11-15, he disagreed that his analysis was affected by the non-appearance of this group of compounds because they are not involved in the release of guaifenesin. Tr. 166:16-24. Dr. Rogers agreed that four of the ingredients, talc, colloidal silicon dioxide, magnesium stearate, and povidone, were not added to control the rate of release of guaifenesin,[19] Tr. 965:24–966:3, but disagreed that carbomer did not exert a rate-controlling effect.

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[18] Five ingredients, carbomer 934P, povidone, colloidal silicon dioxide, talc, and magnesium stearate, making up about 8% by weight of the ingredients were not detected in Dr. Davies's Raman map.

[19] First, Dr. Rogers agreed that talc is used as a glidant and that its weight percentage in the formulation is 0.44%. Tr. 964:8-17. Second, Dr. Rogers agreed that colloidal silicon dioxide is also used as a glidant and that its weight percentage in the formulation is 0.44%. Id. at 964:20–965:5. Third, Dr. Rogers agreed that magnesium stearate is used as a lubricant and that its weight percentage in the formulation is 0.95%. Id. at

More specifically, according to Dr. Davies, carbomer only begins to swell and exert a rate-limiting effect once the pill reaches the basic conditions of the small intestine. Id. at 155. In support of this testimony, Dr. Davies cited an excerpt from the Handbook of Pharmaceutical Excipients (PTX 106) that showed carbomer was a weak acid. Id. at 167-168.[20] Therefore, Dr. Davies testified, because the tablet takes about two hours to reach the small intestine, and because the IR portion is released within the first hour, carbomer does not affect the IR portion of the tablet. Id. at 156:6-7.

In contrast, Dr. Gemeinhart, a pharmaceutical scientist who conducts research on polymers and studies carbomer and other polyacrylic acids, testified that carbomer will gel during the timeframe of any potential IR formulation. Tr. 748:3-16. Dr. Gemeinhart testified that in the low pH of the stomach, the

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965:8-13. Finally, Dr. Rogers agreed that povidone is used as a binder and that its weight percentage in the formulation is 5.70%. Tr. 965:17-23.

[20] According to the Handbook "when neutralized, carbomers produce highly viscous gels." Tr. 961:8-11; PTX 106, at 5. Dr. Rogers agreed that the more viscous the gel, the more likely it is it will act as an inhibitor. Tr. 961:8-19. Additionally, the book stated that the "viscosity [of carbomers] is considerably reduced at pH values less than three" and Dr. Rogers agreed that pH levels in the stomach are normally less than three. Id. at 962:1-6. In further support of Reckitt's position, Dr. Davies cited an excerpt from Amneal's ANDA indicating that the compound won't start to ionize until about pH 4.5, at which time it will swell much more readily. Tr. 169-170.

polymer forms a less swollen network than in the higher pH of the small intestine; however, in the stomach there is still a swollen network. Id. at 710:4-10. This means that carbomer will exert a rate-controlling effect on drug release while the tablet is in the stomach. In support of his position, Dr. Gemeinhart cited a research article titled "A Novel Method to Study the Effect of pH and Excipients on Water Uptake and Swelling Behavior of Carbopol Polymers" (DTX 82 (the "Sharmin article")).[21] Id. at 711:1-104; 712:4-7 ("[I]t clearly says the extent of swelling is less when it is in that lower pH in the stomach. But, it clearly doesn't say that it doesn't exist, it just says less.") (emphasis added). Dr. Gemeinhart highlighted a graph (DTX 82-5) that demonstrates a difference between the swelling of carbopol in distilled water and in acid comparable to gastric fluid, but still shows that for a 200 mg tablet in acid, there is an increase of two times the amount of mass of water within one hour.[22] Id. at 712:11-713:15. According to Dr. Gemeinhart this clearly shows carbopol will be taking up a

[21] It is not in dispute that carbomer and carbopol are used interchangeably at times.

[22] On cross examination, Dr. Gemeinhart admitted that this experiment was performed with tablets that were 100% polymer and lacked any active ingredient. Tr. 835:9-11.

significant amount of water in acid solutions. Id. at 713:17-18.

Reckitt takes issue with Amneal's reliance on the Sharmin article, contending that it dealt with experimental tablets that were 100% carbomer, unlike Amneal's tablets which are less than 1% carbomer. Dr. Davies accuses Dr. Gemeinhart of comparing "apples and oranges." Tr. 171:7. Nonetheless, the parties appear to be in agreement that carbomer does not have the same level of rate-controlling effect in the low pH environment of the stomach as it does in the higher pH environment of the small intestine. The Court, however, is persuaded by Defendant's evidence that carbomer nonetheless exerts some rate-controlling effect in the stomach. At best, Dr. Davies's testimony served to support the finding that carbomer has less of a rate-controlling effect in the stomach, but it did not contradict Dr. Gemeinhart's testimony that carbomer has some rate-controlling effect. Hence, that carbomer does play some role in the dissolution of Amneal's tablets should have been accounted for by Dr. Davies in his Raman analysis. The failure to do so weakens his analysis. In short, the Court agrees with Defendants that Dr. Davies's disregard of carbomer in his Raman testing makes his Raman images less reliable.[23]

[23] Because the Court need not rely on Dr. Rogers' testimony regarding Dr. Davies's reliance on reference spectra from a

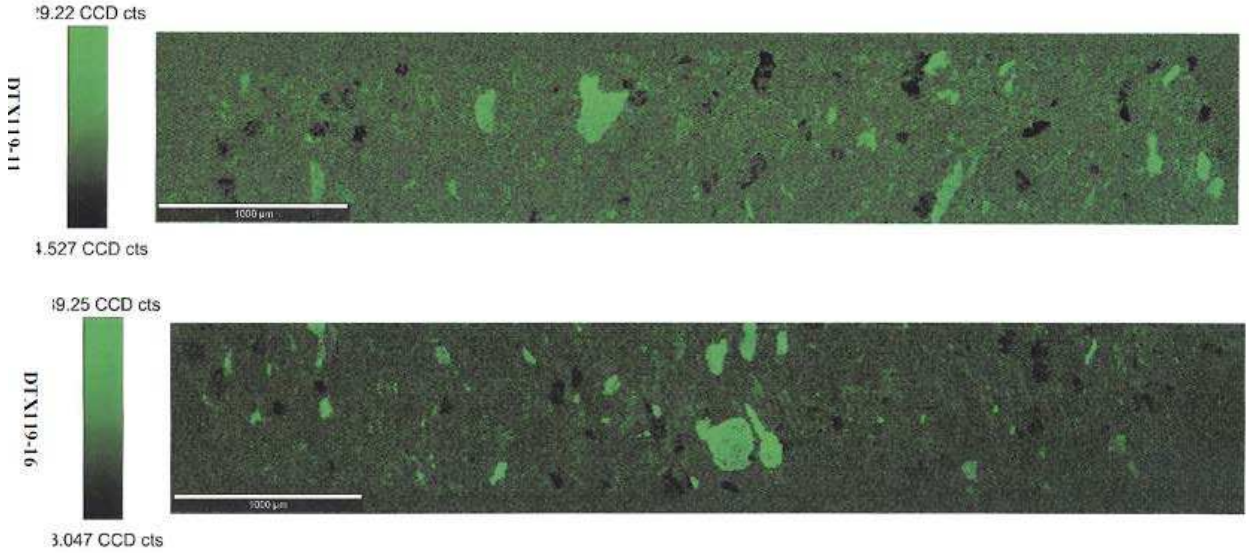
DRL argues that, like Amneal's map, Dr. Davies's maps of its tablet did not include [redacted] Tr. 312-315. This criticism carries little weight as it is undisputed that these [redacted] ingredients do not affect the rate of release of guaifenesin, and [redacted]

More importantly, however, DRL argues that because Dr. Davies was not able to accurately image all of the [redacted] in the tablet, his Raman maps were fundamentally flawed. DRL presented the testimony of Dr. Spingarn who testified that with Raman spectroscopy it is easy to identify a strong emitting compound that is in a high concentration, but difficult to identify a weak emitting compound in a low concentration. Tr. 984:12-21. Because [redacted] is present in a relatively low concentration [redacted] and because [redacted] is less than a tenth as strong of a Raman emitter as guaifenesin, he testified that it is likely it would be difficult to identify [redacted] but easy to identify the distributions of guaifenesin. Id. at 985-86 (referencing DDX-301).

To prove the point, Dr. Spingarn produced a univariate (single frequency) map of the [redacted]

textbook, Reckitt's objection to such testimony is dismissed as moot. See Tr. 919-921.

[redacted] using Dr. Davies's data. Dr. Spingarn explained that a univariate map extracts spectra at a single frequency. Id. at 994:20-21. Because [redacted] have similar spectra, the map contains the distribution of both compounds and does not differentiate between them. Id. at 998-999. Unlike Dr. Davies's Raman maps, Dr. Spingarn's univariate maps, two of which are shown below, included the intensity data for each corresponding spectrum, with higher intensity corresponding to brighter colors. Tr. 991:20-21.



Dr. Spingarn explained that a significant number of green pixels could be seen outside the known area of the tablet because of noise in the data. Id. at 1000:1-11. Dr. Spingarn testified that there is a level of green pixel intensity throughout the tablet that is very similar to the noise level; therefore, it will be difficult to identify [redacted] within that area. Id. at 1001-1002. Dr. Spingarn testified:

> And the obvious question you might ask is, why are there all those green pixels outside the area of the map. The important thing to remember is, I'm not processing anything, I'm not generating this. This is the data that exists within Dr. Davies's maps. That is to say, this area outside the tablet is undoubtedly noise. We have no reason to suspect that there is an abundance of [redacted] outside the tablet off the area [redacted] but what we have out there is noise, and we will have to understand noise to understand why we have a lot of problems or why Dr. Davies has a lot of problems with his imaging of [redacted]
>
> Now, we do see some nice bright spots and those are crystals of either [redacted] We don't know from this map which [redacted]ut if we compare them to Dr. Davies's map, all of those bright spots correspond to the dark blue areas that he painted on his map, which he identifies as [redacted]
>
> So if we know that all the bright spots are [redacted] then the question is, where are the bright s [redacted] and that's the question that we ultimately [redacted]nswer, where is the [redacted]

Tr. 1000:1-21.

Reckitt disputes DRL's contention that Dr. Davies's map reflected only the largest, most intense particles of [redacted] Specifically, Dr. Davies testified that he could resolve [redacted] particles unless they were smaller than 2 microns (Tr. 182:11-15) and according to the manufacturer of [redacted] Moreover, focusing on a single peak as a univariate analysis does is a less valuable tool. Dr. Spingarn appeared to have agreed with some of Dr. Davies's criticisms. Tr. 996:9-10 ("When you're doing a data analysis, you always want to start

with the simple way of looking at [the data]."); Tr. 1070:11-17 ("Q: But you agree with me if there is more information available to you about a particular material you are examining it might help to look at all that information and consider that in making an identification of the material that's being examined right? A: Correct. And that's why people do multicomponent resolution, they are K-mean cluster.")

Dr. Spingarn responded to Dr. Davies's criticism of his univariate analysis by analyzing Dr. Davies's K-means cluster analysis, which is a multivariate ("looking at more than one thing at a time") analysis. Tr. 995:11-12. As Dr. Spingarn explained, K-means cluster analysis divides the data into "clusters" based on similarities between spectra. Dr. Spingarn concluded:

> A: Sure. When we look at the cluster averages that Dr. Davies presented in his data production, those data cluster averages, the cluster average for [redacted] has a bigger peak for guaifenesin in it than i[redacted]or [redacted] What that means is, if you take all of the [redacted]els, his map, all of them together, average them, the green pixels, which he characterizes as being [redacted] peaks, have a larger guaifenesin peak in it [redacted] peak.
>
> That means that all of those things that he has green dots on are combinations of guaifenesin and [redacted] they are not pure [redacted] peaks the way Dr. [redacted]s characterizing the[redacted]s map would mislead you to believe, and that is a critical point in understanding the problems with this map.

Tr. 1026:9-21.

The Court finds Dr. Spingarn's testimony persuasive. Although Dr. Davies attempted to explain the guaifenesin peaks in his spectra by stating that they are the result of "edge effects," Tr. 350:7-15; 358:12-20, 359:13-18, Dr. Spingarn credibly explained this could not be true.[24] Edge effects occur when the Raman laser hits between a [redacted] particle and a guaifenesin particle, and some guaifenesin signal is introduced into the [redacted] spectrum. Id. at 1026. Dr. Spingarn used a cross section of one of Dr. Davies's own Raman images, (DDX 321), specifically focusing on one [redacted] pixel, to illustrate that Dr. Davies's "edge effects" theory cannot explain every situation in which guaifenesin peaks appear in a [redacted] labeled spectrum.[25] Dr. Spingarn explained that guaifenesin peaks in a [redacted] pixel at least "five . . . [to] seven pixels away [from any guaifenesin pixel]," could not be the result of edge

[24] Reckitt objects to any of Dr. Spingarn's testimony regarding "edge effects" because he, Dr. Spingarn, never offered such opinion in his expert report. Defendants maintain that Dr. Spingarn's opinion was elicited as a response to Dr. Davies's testimony elicited on cross-examination. Because this Court finds that this topic was well within the scope of Dr. Davies's expert report, but he did not discuss it, and Defendants first learned of it on cross-examination, such testimony is proper. Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div., 60 F.3d 153, 156 (3d Cir. 1995) (discussing courts' "discretion" in determining whether to exclude evidence for violation of Fed. R. Civ. P. 26).

[25] The corresponding spectrum of the pixel identified in (DDX 321) contains guaifenesin peaks.

effects; therefore, in at least one documented case Dr. Davies's Raman laser picked up more than one compound. Tr. 1034:10-17. The Court credits Dr. Spingarn's testimony that the Raman laser often landed on more than one particle, which resulted in the average cluster spectrum for [redacted] containing strong guaifenesin peaks. As guaifenesin is by far the strongest Raman scatterer in the tablet, the Court is not persuaded that the guaifenesin peaks in the [redacted] spectra indicate that Dr. Davies has overrepresented the amount of [redacted] in the tablet; instead, Defendants' experts have persuaded the Court that it is far more likely that guaifenesin obscured [redacted] in the tablet.

Dr. Davies's testimony that the surface of each of the Defendants' tablets was dominated by guaifenesin fares no better. Dr. Spingarn persuasively testified that if one wants to draw quantitative conclusions from Raman mapping, this requires statistical representations and one tablet would not be anywhere near adequate for reaching quantitative conclusions. Id. at 1042:23–1043:5. He further clarified that quantitative conclusions include conclusions about the concentration of ingredients in particular areas of the tablet. Id. at 1043:6-9.

Similarly, Dr. Rodriguez, a computer imaging expert, was asked by DRL to analyze two of Dr. Davies's images by calculating the percentage of pixels colored red and green

respectively in each of the two images, and also to perform that calculation pixel layer by pixel layer. Tr. 1081-82. In order to achieve this, Dr. Rodriguez first wrote a computer program and then took the electronic file representing Dr. Davies's opening report and extracted the images in order to obtain the pixel data without the superimposed white and black circles.[26] Id. Finally, Dr. Rodriguez utilized the computer program to count the red and green pixels layer by layer and additionally calculated the percentage of each colored pixel in each layer. Id. at 1084-85.

Dr. Rodriguez testified that the average percentage of the red pixels for the first four layers is 95.87% and also that the average percentage of green pixels for the first four layers is 1.625%. Id. at 1099:25–1100:7. More importantly, Dr. Rodriguez testified that his pixel count could not be used to draw conclusions about the amount of guaifenesin on the surface because he did not have either volumetric information about the pixels or quantitative information about how much of each ingredient was present at a given pixel location. Id. at 1090. Although Dr. Davies testified that this information supported his conclusion that there was a distinct IR formulation and that it confirmed an enrichment of guaifenesin on the surface of

[26] DDX 402.

DRL's tablet, Tr. 145-149, the Court does not agree. Dr. Davies conceded on cross examination that Dr. Rodriguez's pixel count could not be equated to concentration and instead his opinion rested on the simple relative proportion of guaifenesin as depicted by the pixels. Tr. 308:15–309:12 ("I'm not converting the 96 percent guaifenesin into weight as in composition.").

In the end, the Court finds that Defendants' criticisms of Dr. Davies's Raman analyses were well-placed and called into question the reliability of Dr. Davies's opinion. However, as alluded to above, Dr. Davies's interpretations the maps created by those analyses present a greater issue. Dr. Davies's testimony leads this Court to the conclusion that, with some creative thinking, one could define any region of a tablet as having a distinct formulation. Dr. Spingarn expressed this very concept:

> "[Y]ou could circle any region of this [map] with a small enough circle or a large enough circle to come up with another mix of ingredients. You could come up with an infinite number of formulations if a formulation is defined as a group of components inside one microscopic volume of a tablet . . . . What this is, is quite clearly a random assortment of or uniform distribution of components throughout the tablet. There is no evidence of any distinct formulations other than that which comprises the entire tablet.

Tr. 1040:5-15.

Most troubling was Dr. Davies's concession that an SR formulation could be transformed into an IR formulation simply

by cutting off the original surface of the tablets. No matter how many times the tablet was cut, the outer layer would transform into the IR formulation even though it had been the SR formulation. During questioning by counsel for DRL, Dr. Davies testified

> Q: . . . [Y]ou've postulated that the immediate release is at the surface, okay? So I'm saying, if I cut that surface off and now I'm in the part that you've defined or at least you originally defined the sustained-release formulation, by your logic, that new surface has become an immediate release formulation, right?
>
> . . .
>
> The Witness: Yes.
>
> The Court: That you have now converted what you said was a sustained-release formulation, now becomes an initial release formulation because it's exposed. Do you agree with that?
>
> The Witness: I do.

Tr. 395:19-396:8. During the same cross-examination by DRL's counsel, Dr. Davies further stated that

> Q: . . . if I took a knife . . . and I cut this tablet in half, right through the center of your black circles . . . This surface here, this newly-exposed surface that you have characterized as a sustained-release formulation, right?
>
> A: Yes.
>
> . . .
>
> Q: Regardless, sir, in this new surface, this – the formerly sustained-release surface, now I have a lot of exposed guaifenesin, right, and there's no

[redacted] at least on parts of it, so that's going to ccording to you, right?

A: I agree that you've changed the formulation . . . **You changed the composition**, you've changed the location, so, therefore, this would be a different formulation.

. . .

Q: . . . So I'm saying, if I cut that surface off and now I'm in the part that you've defined or at least you originally defined as the sustained-release formulation, by your logic, that new surface has become an immediate-release formulation, right?

. . .

THE COURT: Do you agree with that last sentence?

THE WITNESS: Yes.

Tr. 393:16–396:3.

This testimony alone, it seems, should end the inquiry as to whether Defendants' tablets have two distinct formulations necessary for a finding of infringement. If changing the location of an SR formulation can transform it into an IR formulation without changing the composition of that formulation, both formulations necessarily are not distinct. See Id. at 933:19-25 ("If I cut it that way or I cut it this way, this that was clearly identified as sustained release would automatically become immediate release, simply because the tablet was cut in half. That's not indicative of two distinct formulations. That's indicative that there's one formulation and it goes throughout the tablet.") (testimony of Dr. Rogers);

see also Id. at 618:9-16 ("[W]e know what exists from the manufacturing process. We know there is a uniform distribution of ingredients in the tablet. And so therefore, if I cut off any portion of the tablet, let's say in the dry state, and then swallow that, that cut off portion will undergo the exact same wetting process and dissolution as before. Just cutting off the surface of a homogeneous tablet cannot change the mechanism, because everything is the same throughout.") (testimony of Dr. Brittain).

Moreover, in describing the location and shape of the IR formulation, Dr. Davies acknowledged that the location of what he viewed to be the IR portion (which may at one time have been the SR portion, supra) would vary not only from tablet to tablet, but within a single tablet. Dr. Davies agreed with this Court's question that the IR formulation would resemble an "upside down mountain range." Tr. 259:14–260:20 ("[I]n some areas you're going . . . to go way further down in because there's only guaifenesin. In some areas . . . it's right at the surface . . . so . . . you're going to have jagged teeth throughout"). As counsel for DRL aptly noted at closing argument:

> [t]he problem is I don't know what that means, neither does a POSA. Are we talking about the Himalayan mountains, are we talking about the Watchung Hills? There's no shape to it, there's no dimension, there's nothing that a POSA could say, oh, there's the

> immediate release portion . . . . There's no way to define it except if you could go back after the tablet is dissolved and somehow reconstruct what the outline was of this stuff that dissolved in the first hour.

Closing Arguments Tr. 83:1-9 [Docket No. 197]. The Court agrees. A "you'll know it when you see it" approach hardly meets the structural claim limitation.

Moreover, when the Court inquired further as to whether the "upside down mountain range" would vary from tablet to tablet, Dr. Davies indicated it would. Tr. 260:21-25. He went on to explain:

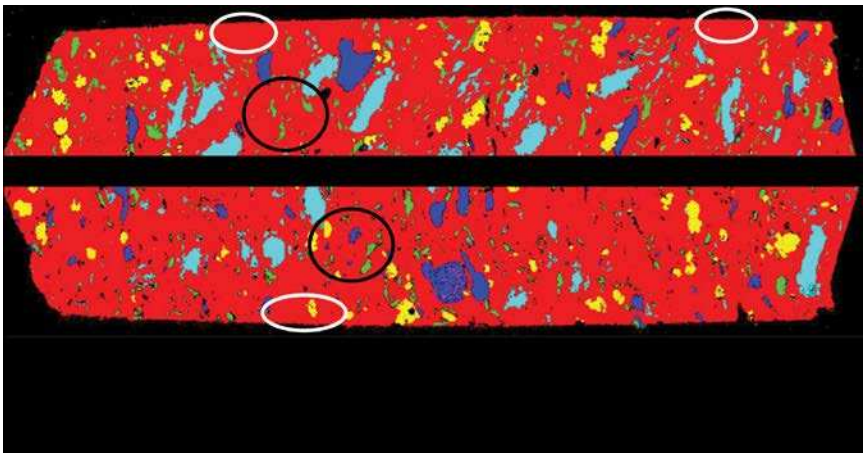
> It could look different, in terms of its shape, but the overall effect from tablet to tablet would be the same because we -- from the dissolution data, the burst effect, we know that occurs with both DRL and Amneal's tablet.

Id. at 260:25-261:4 (emphasis added). Dr. Davies's answer, not surprisingly, reveals that Dr. Davies returned to his misplaced reliance on the dissolution data.

Furthermore, Dr. Davies was unable to adequately describe a consistent method for determining which parts of the tablet would swell and control the rate of release of guaifenesin. As discussed supra, Dr. Davies testified that the IR formulation is the guaifenesin that is present at the surface in the absence of [redacted] and the SR portion is the drug in the presence of excipients with the rate controlling polymer. Yet, Dr. Davies also testified that "[i]f you have [redacted] right on the

outside, because the drug here has been dissolved, it's likely that the [redacted] will be swept away in that initial rapid dissolution, whereas the [redacted] that's in the bulk here will start to hydrate." Tr. 263:6-14; see also id. at 451:16-452:2; 442:16-442:20. In other words, Dr. Davies seems to have acknowledged that the compositions of his two formulations could have the same ingredients. This, however, contradicted his own ingredients-based approach (guaifenesin versus guaifenesin and [redacted] to differentiating the IR and SR formulations.[27]

The above testimony also demonstrated that Dr. Davies's definition of "surface" was less than clear. On DDX 100, Dr. Davies drew white circles (below) to illustrate regions of guaifenesin on the surface of the tablet formulation.



(DDX 100)

[27] The Court notes that Dr. Davies did not provide a measure of when enough [redacted] is present to prevent it from falling away at the surfa

According to Dr. Davies, the guaifenesin on the surface – again, as illustrated by the white circles - will rapidly dissolve, thus constituting the IR formulation. The SR formulation begins acting once the guaifenesin comes into contact with the rate-controlling polymer, which will start to hydrate and form the gel layer. Tr. 258. The problem with Dr. Davies's testimony, however, is that the surface as he defined it, the "area at the surface and just below the surface where there is drug present in an immediate release form," Tr. 257:16-19, included not only [redacted] particles on the surface but [redacted] particles under guaifenesin on the surface. Tr. 261-262.

Dr. Davies was more definitive that the guaifenesin <u>on</u> the surface would rapidly dissolve than he was about the guaifenesin that was <u>near</u> the surface with [redacted] around it.

> THE COURT: Why is the guaifenesin below the [redacted]? Why do you say it's an immediate release?
>
> THE WITNESS: Because, Your Honor, if you look below -- if we're looking at this particular part, you see you've got some [redacted] here. If you have [redacted] right[redacted]tside, because the drug here [redacted]issolved, it's likely that the [redacted] will be swept away in that initial rapid [redacted]n, whereas the [redacted] that's in the bulk here will start to hyd
>
> THE COURT: It sounds like you're not -- you don't really know. You would have to sort of do an analysis to see.

THE WITNESS: Well, it's not so much -- I know how these formulations work, I've studied them for many years, Your Honor. But –-

THE COURT: But how would a POSA know, looking at -- how would a POSA know what it is that it's doing? Whether it's an IR or an SR, how would they know?

THE WITNESS: Oh, a POSA would know looking at this that there is guaifenesin on the surface. The POSA would know straightaway that that's an immediate release form, because it's in the absence of the rate-controlling polymer.

THE COURT: Yeah, but how would a POSA know -– going back to the question that Ms. HUTTNER is asking you, the guaifenesin right below the [redacted], whether it's an IR or an SR.

THE WITNESS: A POSA would know that just the position as described is very close to the surface, which is known, will produce the burst effect.

THE COURT: Even with the rate-controlling polymer ahead of it?

THE WITNESS: Yes, the rate-controlling polymer is likely to fall away at the surface because of the very fact that it's having this burst effect. You're having this rapid dissolution of the drug, it's falling off the surface. But as that solvent ingresses, you then meet more of the rate-controlling polymer, which starts to form the gel structure.

Tr. 263:6-264:23.

The Court pressed Dr. Davies as to whether a non-infringing tablet could be made without a coating containing a rate-controlling polymer

THE COURT: Okay. So, I'm going to box you in here. Tell me the two distinct formulations in your opinion.

THE WITNESS: Two distinct formulations in both of these formulations is the guaifenesin present with

excipients on the outer surface of these tablets in the absence of the rate controlling polymer which provides that burst release, so it's like the core coated -- the immediate-release layer on the core coated tablet. The sustained-release portion is where -- and that provides the burst, provides the C_{max}. The sustained-release portion is that portion where the guaifenesin is present below the surface in the presence of the rate controlling polymers which control the release of the drug.

THE COURT: And so –-

THE WITNESS: And provide that 12 hours.

THE COURT: -- is it your testimony then that the only way that a non-infringing sustained-release tablet could be made is by having a coating of a rate controlling polymer?

THE WITNESS: No, I think -- I thought about that. I think if one was -- one way to do it is to actually increase the level of polymer to drug, and in those cases you will reduce or eliminate the burst effect. But that –-

Tr. 340:8-341:4.

Yet, Dr. Davies could offer little clarity on how he defined a burst effect

Q: Okay. And are you equating -- are you saying that, and I was going to ask you more specifically what do you mean by burst or how big does the burst have to be to matter, but as a foundation question, are you saying that you are equating the immediate release formulation with what we call the burst effect, or what you call the burst effect?

A: I am equating the first portion which is related to the burst effect, because the burst effect is caused by the presence of drug in the immediate release form.

Q: So let's put a finer point on it. How big does the release of guaifenesin have to be and over what time

period does it have to happen for you to consider it to be a burst?

A: It depends. It depends what you mean by that, if you mean –-

Q: Well, it's your term, sir, your term "burst." What I'm asking you is to define what you mean, because you've equated burst and immediate release formulation, I'm asking you to define for us what you mean by a burst, how much guaifenesin has to be released and how quickly does it have to be released to qualify as a burst, in your opinion?

A: Thank you. I believe the immediate release formulation that's present in the formulations that we see here today provide a burst effect in the first hour of the -- and that's clear from the -- both the dissolution data and it's also clear by the PK data, clearly within that first hour of the amount that is released from the first portion will also be -- there will be additional drug released from sustained release portion just as there is in the Mucinex®.

Q: Okay. I'm not sure I heard any words that you said, but I did hear you say, that in terms of time frame, you're putting an hour, you are defining it -- burst as something has to happen within an hour, right?

A: The burst will happen within the first hour, that's correct.

Q: All right. And in terms of the size of the burst, you, made reference to DRL’s ANDA formulation, that releases about -- I think it's somewhere between 22 and 25 percent of guaifenesin in the first hour, right?

A: That's correct.

Q: And I guess the question is, if it's 20 percent, is it still a burst?

A: It would be a burst, yeah.

Q: How about 15?

A: It depends on the -- again, looking at the dissolution profile, it would depend on the profile but it could be a burst, yes.

Q: How about 10 percent?

A: Again, it depends how much of the formulation, if there is just 10 percent released in the first hour, that may indeed be a burst effect, but it could be off a polymer system where there is much more polymer so there is much -- little less burst released.

Q: Well, sir, I guess it begs the question, if you are a manufacturer like DRL and you are trying to respect the patent rights of -- in this case of Reckitt Benckiser and you want to make sure you don't have a burst effect, if we hypothetically accept your opinion that that equates to an immediate release formulation, how do you know?

A: How do you know what?

Q: How do you know if you have a burst effect based on what I've asked you?

A: Oh, of course, DRL and Amneal know they have burst effects, their scientists say they have a burst effect.

THE COURT: The question is, how do you know how to create a tablet that doesn't have the burst effect?

THE WITNESS: Amneal knew what they were doing in making that formulation, how would you make an alternative formulation?

THE COURT: Excuse me, that wasn't the question. The question is, how would you know how to make a tablet that doesn't have that burst effect, not whether or not Amneal knew what they were doing.

THE WITNESS: You would know for the reasons I've described. You could make a formulation which is controlled such that it doesn't have an immediate release burst effect for the reasons I've described. You could use a formulation, say, which has

> controlling membrane, that would overcome the burst effect.

Tr. 383:14-386:16.

Moreover, Dr. Davies could provide little guidance, beyond the dissolution profile,[28] to describe the Defendants' supposed immediate release formulation.

> Q: And so if I'm a manufacturer and I want to make a matrix tablet that doesn't contain an immediate release formulation of guaifenesin, in your opinion, how big can -- how much dissolution can I have of guaifenesin in the first hour without someone like you coming and arguing that I have an immediate release formulation of guaifenesin?
>
> A: I think -- I think it would be that you would not be able to make a matrix tablet to meet this dissolution profile. Given the dissolution profile and the PK data, you'd have to use some kind of coating to stop that burst effect based on the formulations.

[28] Dr. Davies testified that the dissolution and PK data of DRL's tablet support his Raman analysis conclusions. Tr. 118-19. Dissolution testing shows that in the first hour, [redacted] guaifenesin in DRL's tablet is released, and that [redacted]e rate slows significantly such that the guaifenesin continues releasing for 12 hours. Id. Summarizing his findings, Dr. Davies testified that the IR portion of DRL's products contributes to the [redacted] of guaifenesin released within the first hour, while the SR [redacted]tion releases guaifenesin after that time. Id. Dr. Davies ALSO testified that the dissolution and PK data of Amneal's tablet support his analysis conclusions that there are two portions. Id. at 191-93. Dissolution testing shows that in the first hour, [redacted] of the guaifenesin in DRL's tablet is released, and [redacted]he release rate slows significantly such that the guaifenesin continues releasing for 18 hours. Id. at 117:12. Dr. Davies testified that this evidence, in addition to Amneal's own *in vitro* dissolution studies and *in vivo* pharmacokinetic studies, show that Amneal's products have a biphasic release profile. Id. at 116-17.

Tr. 387:9-19.

Essentially, Dr. Davies labeled guaifenesin on the surface (and maybe a little bit below) as an immediate release formulation. He opined that a POSA would know "straightaway" that guaifenesin on the surface is an immediate release formulation. Tr. 263:23-25. In other words, Dr. Davies's opinion boiled down to this simple proposition: if there is any guaifenesin on the outside of the tablet, there is, by definition, an immediate release formulation present. Thus, in any non core-coated tablet, there will seemingly always be at least two formulations. The Court is unconvinced for the reasons the Defendants' experts articulated as set forth above.

3. Defendants' Manufacturing Processes Confirm a Single Formulation

Each Defendant introduced evidence of its manufacturing process to show that its process produces single formulation tablets. Specifically, Drs. Gemeinhart and Brittain testified that Defendants' manufacturing processes start with a single formulation and end with single formulation matrix tablets. As Defendants correctly argue, Reckitt failed to identify any step in the process that could result in the formulation of two distinct formulations.[29]

[29] Reckitt argues that this Court should ignore evidence about Defendants' manufacturing processes because that would impermissibly import process limitations into the claims. This

a. Amneal's Manufacturing Process

Dr. Gemeinhart described Amneal's process as mixing everything together, blending it to uniformity, and then compressing it into a tablet. Tr. 718:2-8. First, guaifenesin granules are produced through a wet-granulation process, in which water is added to a guaifenesin and povidone premix and mixed to create a homogeneous blend of ingredients. Id. at 718:10–720:22. Following wet-granulation, the granules are dried and then re-milled to obtain a uniform granule. Id. at 721:4-13. The next step is to effectively mix the rest of the ingredients[30] together in a particular "V blender" and then blend to obtain a uniform mixture. Id. at 721:19–722:22. Finally, the uniform blend undergoes compression to create a tablet. Id. at 725:20-24. Dr. Gemeinhart testified that this manufacturing process creates a one formulation tablet. Id. at 725:25-726:4.

Dr. Gemeinhart also discussed the blend uniformity and content uniformity testing that Amneal conducts during its manufacturing process. Amneal ensures blend uniformity by taking ten samples from the V-blender and testing for guaifenesin content, which Dr. Gemeinhart persuasively explained

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Court disagrees. Such evidence goes to whether or not the products produced contain two formulations.

[30] The exception is magnesium stearate, which is added after blending because if it is mixed too long its properties can be altered. Tr. 724:11-22.

is representative of the uniformity of all the ingredients in the mixture. Id. at 726:9–730:7. Dr. Gemeinhart testified that Amneal's blend uniformity data shows that its products do not undergo segregation or separation. Id. at 733:2-19. Dr. Gemeinhart testified that this tells a POSA "that you have a uniform – and in this case . . . matrix tablet, that you will have that type of tablet every time, or nearly every time." Id. at 733:24-734:1.

Again, although Reckitt argues that Amneal's blend uniformity testing does not prove the final product is uniform, because the testing occurs before the mixture is compressed into tablets, the Court, nonetheless, finds such testing to be probative. P. Res. Post-Trial Br. 8. Reckitt has put forth no evidence that the compression process will destroy the blend uniformity. Additionally, while Plaintiff has put indirect evidence contesting the adequacy of the blend uniformity testing, the Court finds Dr. Gemeinhart's testimony far more persuasive. Dr. Gemeinhart's testimony regarding the blend uniformity data supports Amneal's position that Amneal's manufacturing process produces a single and uniform formulation in the final product.[31]

[31] As further evidence that Amneal's manufacturing process produces a uniform tablet, Dr. Rogers testified about the optical microscopy that he performed. First, Dr. Rogers used a scalpel to cut the tablets in half and then took pictures at

b. DRL's Manufacturing Process

Defendant DRL put forth evidence regarding its manufacturing process to prove its ANDA products are single-formulation matrix tablets. [redacted] Tr. 556:24–558:3. As Reckitt put forth no evidence to refute this manufacturing process, the Court is persuaded by Dr. Brittain's testimony.

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various magnifications of the outside of the pill as well as a cross-section of the pill. Id. at 902:24–903:8. Dr. Rogers testified that these images do not show the chemical composition of the tablet, but do illustrate a uniform mix of the blue dye and the white ingredients. Id. at 903:12-16. Additionally, he stated that images DTX-044-2 (depicts exterior) and DTX-044-5 (depicts interior) show the same uniform mix of blue and white in the cross section of the tablet as in the exterior, and that no aggregation or segregation is visually detectable. Id. at 903:21–904:3. However, on cross examination Dr. Rogers agreed that the test did not function as a chemical identification and that he could only see color. Id. at 970:7-25. Additionally, the test did not give information on the distribution of the molecular components. Id. at 971:1-4. As such, the Court does not find Dr. Rogers's optical microscopy testing to be particularly useful.

[redacted] The Court credits Dr. Brittain's testimony that "the entire manufacturing process is geared towards yielding dosage forms that are uniform. You can only make uniform dosage forms from uniform blends." Tr. 594:24–595:3. Additionally, Dr. Brittain persuasively testified that it is not possible for the compression step to "somehow transform the guaifenesin into a layer around the surface that doesn't contain the ingredients that were intimately mixed with the guaifenesin in the granules." Id. at 595:8-11. In sum, DRL's evidence, unrebutted

by Reckitt, supports a finding that DRL's manufacturing process produces a single formulation.[32]

C. Conclusion – No Literal Infringement

For the foregoing reasons, this Court finds that Defendants' products are a single formulation matrix and do not contain two distinct formulations. Accordingly, Reckitt has failed to prove by a preponderance of the evidence that every limitation of the asserted claims was literally met by Defendants' ANDA products.

VI. Infringement Under Doctrine of Equivalents

Even if the Defendants' ANDA products do not literally infringe, Reckitt argues that they infringe under the doctrine of equivalents. Under the doctrine of equivalents, a device or product "that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed element of the patented invention." Warner-Jenkinson Co. v. Hilton Davies Chem. Co., 520 U.S. 17, 21 (1997). A patentee must establish "equivalency on a limitation-by-limitation basis" by "particularized testimony and linking argument" as to the insubstantiality of the differences between

[32] The Court need not reach Reckitt's reserved objection on the issue of DRL's content uniformity tests.

the claimed invention and the accused device or process. Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1566 (Fed. Cir. 1996). If a theory of equivalence would vitiate a particular claim element, then non-infringement is warranted. Stated differently, if the alleged equivalent product is so inconsistent with the claimed element that a finding of equivalents would essentially eliminate the element as a meaningful limitation of the invention, then non-infringement is warranted. Akzo Nobel Coatings, Inc. v. Dow Chemical Co., 811 F.3d 1334, 1342 (Fed. Cir. 2016).

Although two different tests have developed for establishing equivalency, the function-way-result and insubstantial differences tests, the Supreme Court has accepted both as probative of the essential inquiry. Warner-Jenkinson, 520 U.S. at 40. The function-way result test often suffices to show the substantiality or insubstantiality of the differences. Akzo, 811 F.3d at 1342. A device or process infringes if it performs "substantially the same function in substantially the same way to obtain the same result." Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 608 (1950). Relatedly, a claim element is deemed to be equivalently present in an accused product if "'insubstantial differences' distinguish the missing claim element from the corresponding aspects of the accused

device." Sage Prod., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed. Cir. 1997).

Relevant to this case, the Federal Circuit has explained that "bioequivalency and equivalent infringement are different inquiries." Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1298 (Fed. Cir. 2009). Therefore, under the doctrine of equivalents bioequivalence does not necessitate infringement by equivalence. Watson, 430 F. App'x 871, 878 (Fed. Cir. 2011).

Reckitt contends that Defendants' products infringe under the doctrine of equivalents because they contain two "portions" or "quantities" that perform substantially the same function, in substantially the same way, with substantially the same results as the IR and SR "portions" or "quantities" of the asserted claims. P. Post-Trial Br. 35. Reckitt states that the pertinent question is:

> Does the surface of Defendants' tablets, which are covered almost entirely with guaifenesin and very small amount of polymer, perform substantially the same function, in substantially the same way, with substantially the same results as the first immediate release portion and/or quantity of the asserted claims?

Id. As there is not much disagreement between the parties over the "function" and "result" analysis, this Court will focus on the "way" the Defendants' products operate.

Dr. Davies testified that the Defendants have a structure that is similar to the core-coated tablet that is a preferred

embodiment in the Patents-in-Suit. Tr. 235:13-15; see also '821 Patent col. 12:46-56; '032 Patent col. 17:45-54.[33] According to Dr. Davies, there is no difference between the coating layer of a core-coated tablet and the regions of the Defendants' products that he identified as the immediate release portions. Dr. Davies acknowledged, however, that unlike the core-coated tablet embodied in the Patents-in-Suit, the so-called immediate release layer in Defendants' is "not 100 percent covering the outside of the tablet." Tr. 237:3-8. Summarized below is Dr. Davies's opinion on equivalents:

> Q: Okay. Dr. Davies, focusing on the immediate release coating layer of a core coated tablet, one in which the core and the outer layer are manufactured separately and separately applied to produce the product, what is the function of that outer coating layer, this one right here?
>
> A: The function is to obtain a burst of the immediate release of the drug.
>
> Q: And what is the way in which this coating layer performs that function?

[33] The Patents provide "The bi-layer tablet may be manufactured according to any method known to those of skill in the art. The resulting tablet comprises the two portions compressed against one another so that the face of each portion is exposed as either the top or bottom of the tablet, or the resulting tablet may comprise the sustained release portion in the center coated by the immediate release portion so that only the immediate release portion is exposed. In a preferred embodiment, a bi-layer tablet comprises the two portions compressed against one another so that the face of each portion is exposed." See '821 Patent col. 12:46-56; '032 Patent col. 17:45-54.

A: The way in which it performs the function is that it -- guaifenesin present in other excipients other than the rate-controlling polymer, such that it will be an immediate release form and be released. It's also the fact that it's configured on the outside of the tablet, such that it's the first part of the tablet that is in contact with the gastric juice allowing immediate release of the drug.

Q: And what is the result obtained through such an immediate release coating layer, separately applied coating layer?

A: The result is the contribution to the C_{max} which will be equivalent to that in Mucinex® or in immediate release formulation.

Q: Is this also a fair recitation of the function, way and result of the first portion, first quantity elements of the asserted claims in the case?

A: I believe so.

. . .

Q: So, now the regions of defendants' products that you identified as the first portion or first quantity, do they perform the same function as that which you identified for an IR coating of a core coated tablet?

A: Yes, they do, as we see from the diagram that they provide an immediate or rapid release of guaifenesin.

Q: And why do you say that they provide a rapid release of guaifenesin?

A: Because we know that they do based on dissolution studies and the like, and they're also, as I've said, they're all in the surface in a form, in immediate release form, that they are present on the surface, on the outer surface so they are the first, that's the first part of the tablet which is exposed to the gastric juice.

Tr. 239:5-241:2

As further support for his testimony, Dr. Davies highlighted a passage from Amneal's ANDA that provides:

> [its] composition is very similar [to Mucinex®], however minor differences between the proposed formulation and the RLD [Mucinex®] are considered irrelevant in the context of having a potential effect with respect to therapeutic equivalence or stability. This is based upon the noted similarities between the two products, both in terms of dosage form and dosage form design.

PTX-63 at 0262. In Dr. Davies's opinion, this statement also applies to DRL's products. Tr. 242:11-13.

Plaintiff next cites to statements made by Defendants' own experts. Dr. Rogers testified that the way an IR portion would rapidly release could be achieved by not inhibiting guaifenesin with polymer. Tr. 973:1-4. Additionally, Plaintiff cites to several statements that it claims show Defendants' experts agreed that guaifenesin on the surface of Defendants' tablets rapidly releases because it is uninhibited by [redacted] polymers. Tr. 640:5-641:4; 660:19-24; 668:10-16; 670:14-20 (Dr. Brittain); Tr. 812:4-25; 875:5-9 (Dr. Gemeinhart). Finally, Plaintiff cites to statements by Defendants' experts that it claims undermine Defendants' argument that their products release guaifenesin via a single mechanism. Dr. Gemeinhart testified that once the gel layer forms, the drug is released by diffusion through the layer; however, "instantaneously upon ingestion," the guaifenesin molecules at the surface are not diffusing through any polymer gel. Tr. 863:1-8. Thus, Reckitt argues

that the IR regions of guaifenesin identified by Dr. Davies in Defendants' products perform substantially the same function, in substantially the same way, to provide substantially the same result as the immediate release layer of the core-coated tablet embodiment of the '032 and '821 Patents.

Defendants counter that "Reckitt's simplistic suggestion that Defendants' matrix tablets operate in the same way as a true immediate release formulation because both permit the release of guaifenesin when wetted with gastric juice ignores the details of this process" which are necessary in an equivalents analysis. Def. Resp. post-Trial Br. at 35. The Court agrees.

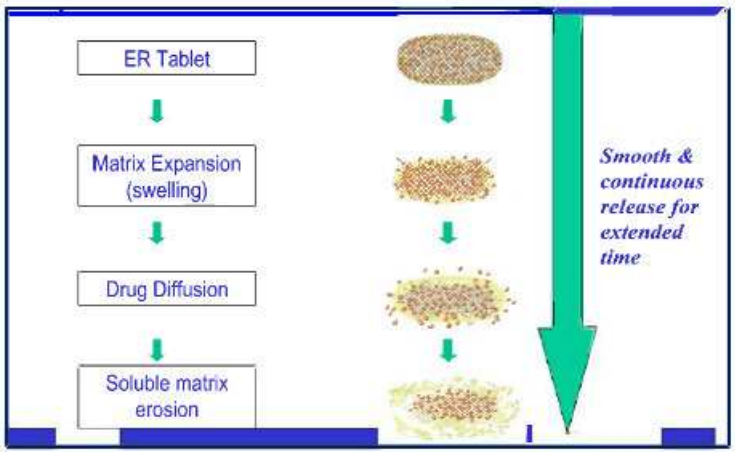
The evidence at trial demonstrated that, in a core-coated tablet, the immediate release formulation on the outside is specifically designed to disintegrate quickly. Tr. 600:15-25; see also Tr. 819:9-10. In contrast, Defendants' matrix tablets do not have a "distinct formulation" that is designed to disintegrate and rapidly release the drug. Both Drs. Gemeinhart and Brittain persuasively explained that the sustained drug release in Defendants' matrix tablets, including the about 20% guaifenesin released during the first hour, is a function of the degree to which the polymer matrix continuously hydrates and gels. As Dr. Brittain credibly testified, the polymer matrix begins to hydrate and gel as soon as the tablet is wetted in the

mouth or the stomach but, initially, the gel layer is simply not fully formed and not very efficient. Tr. 658-659. As the gel layer continues to hydrate over time, it creates a physical barrier through which the drug substance must diffuse, resulting in a slower rate of release. Id.

> This is simply a continuous process, and there are no intermediate stages that you can say correspond to a different type of drug release. The drug is always being released through the same mechanism. It's just that the size of the barrier is changing.

Tr. 594:10-14; see also Tr. 590:4-594:13; 610:10-21.

Using a schematic, DTX 31-37 (below), Dr. Gemeinhart also credibly explained the process:



(DTX 31-37)

> Q: What does this show, Dr. Gemeinhart?
>
> A: So this is the schema for what really is described as a continuous or smooth and continuous release of the guaifenesin, the API from the tablets, that you start with that matrix. It's a single matrix at that point, that as you enter this into the fluid, and you'll begin several processes all at once, and that the rates of each of those are going to be based on the chemistry of those individual pieces.

> So you will have molecules of the API dissolving, based on their dissolution and dissolution rate, and you will have the polymer swelling, interacting and forming that gel. It's those -- at every single time point within here. You will have molecules diffusing and that it goes through a process, that gel network will form and the gelation is really the description of what's happening.
>
> . . .
>
> If you look at this schematic depiction, the description is the molecules are coming off, the gel is forming and then you have the gel eroding.

Tr. 734:7-735:10.[34]

In sum, the Court finds that the initial rapid dissolution of guaifenesin from the surface of Defendants' tablets, as a result of hydration, which is a continuing release, is not equivalent to an immediate release formulation. These are substantially different. A true immediate release formulation releases everything at once. That some guaifenesin molecules are on the surface of Defendants' tablets and release as a result of hydration does not mean that Defendants' products function the same way. At best, Dr. Davies testified that the guaifenesin on the surface rapidly releases because it is uninhibited by [redacted] polymers. This, however, is not the

[34] For the reasons articulated by Defendants, Def. Supp. Post-Trial Br. at 13-14 [Docket No. 203], the Court does not agree with Reckitt's argument that Dr. Gemeinhart admitted that any product that perform an immediate function does so in the same way.

"particularized testimony" that is needed to show that the incidental release of guaifenesin is the same as an immediate release layer. A finding of equivalents under this theory would vitiate the claims' requirement that there be two distinct formulations. Accordingly, Reckitt has not met its burden of proving infringement under the doctrine of equivalents.

VII. Conclusion

For the foregoing reasons, the Court finds that Defendants' ANDA products will not infringe the '032 and '821 Patents. Accordingly, the Court enters judgment of non-infringement.[35] An appropriate Order will issue herewith.

s/Renée Marie Bumb
RENÉE MARIE BUMB
UNITED STATES DISTRICT JUDGE

[35] The Court declines to exercise jurisdiction over the counter claims alleging invalidity of the Patents-in-Suit. AstraZeneca LP v. Breath Ltd., 542 Fed. Appx. 971, 981 (Fed. Cir. 2013).