IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CMP DEVELOPMENT, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-549 (MN)
	)	
AMNEAL PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

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September 29, 2023
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

Plaintiff CMP Development, LLC ("Plaintiff" or "CMP") brought this Hatch-Waxman action against Defendant Amneal Pharmaceuticals LLC ("Defendant" or "Amneal"). Amneal filed Abbreviated New Drug Application No. 215572 ("Amneal's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version ("ANDA product") of CMP's CaroSpir® product before the expiration of United States Patent Nos. 10,624,906 ("the '906 patent"), 10,660,907 ("the '907 patent") and 10,888,570 ("the '570 patent") (collectively, "the Asserted Patents"). Plaintiff alleges that Amneal will infringe claims 1 and 8 of the '906 patent, claims 1 and 10 of the '907 patent and claims 1 and 7-10 of the '570 patent. Validity of the claims of the Asserted Patents is not contested. (D.I. 99 ¶ 7).

The Court conducted a two-day bench trial on January 13, 2023 and January 18, 2023. (*See* D.I. 110-111 ("Tr.")). The parties completed post-trial briefing on March 13, 2023. (D.I. 112, 114, 117). With their briefing, the parties submitted proposed findings of fact. (D.I. 113, 115).

After considering the entire record and the applicable law, the Court concludes that Plaintiff has failed to show that Defendant's ANDA product will infringe claims 1 and 8 of the '906 patent, claims 1 and 10 of the '907 patent and claims 1 and 7-10 of the '570 patent. Because the Court finds that Plaintiff has not met its burden on infringement, the Court declines to reach Defendant's legal defenses as to infringement.[1] This opinion constitutes the Court's findings of fact and conclusions of law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure.

[1] In its post-trial brief, Defendant argues that CMP is barred from asserting the doctrine of equivalents by prosecution history estoppel, inherently narrow claiming and ensnarement. (D.I. 114 at 17-25). At trial, Defendant also argued that CMP was barred from asserting the doctrine of equivalents by specification disclaimer but appears to have dropped this argument in its post-trial briefing. (*See, e.g.*, Tr. at 46:18-47:2; *see also* D.I. 114).

I. FINDINGS OF FACT ("FF")

A. Introduction

1. CMP is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 8026 U.S. 264A, Farmville, North Carolina 27828. (D.I. 99, Ex. 1 ¶ 2).

2. Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. (*Id*. ¶ 3).

3. CMP owns the Asserted Patents, which are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"), as covering CMP's CaroSpir® product. (D.I. 99 ¶ 5; D.I. 1 ¶ 30).

4. By letters dated March 4, 2021 and March 25, 2021, Amneal advised CMP that it had submitted its ANDA 215572 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale of a generic version of CaroSpir® before the expiration of the Asserted Patents. (D.I. 99, Ex. 1 ¶ 34). Defendant's ANDA No. 215572 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for each of the Asserted Patents. (*Id*. ¶ 35).

5. This action was commenced before the expiration of forty-five days from receipt of Defendant's notice letters, and the thirty-month stay of final FDA approval of Defendant's pending ANDA application expired on September 5, 2023.[2] (*Id*. ¶ 36).

[2] By letter dated August 21, 2023, the parties agree that Amneal will not launch its product until the Court enters final judgment on the case up until September 29, 2023. (D.I. 120).

B. The Witnesses

1. Fact Witnesses

6. Anthony Pipho testified live at trial. Mr. Pipho is the Vice President of Operations at CMP and oversees product development, regulatory, logistics and manufacturing. (Tr. at 50:5-17). Mr. Pipho has worked at CMP for more than eight years. (*Id.*). He was hired by CMP to develop a spironolactone suspension, was responsible for developing CaroSpir® and participated in CMP's efforts to have CaroSpir® approved by the FDA. (Tr. at 50:2-73:9). Mr. Pipho is a named inventor on the Asserted Patents. (D.I. 99, Ex. 1 ¶¶ 6, 14, 21; JTX-001 at 2; JTX-002 at 2; JTX-003 at 2).

7. Hardik Patel testified live at trial. Mr. Patel has worked at Amneal for more than fifteen years and is currently the Senior Director of Research and Development. (Tr. at 194:19-24). Mr. Patel was primarily responsible for Amneal's research and development of the ANDA product. (Tr. at 198:3-16).

2. Plaintiff's Expert Witness

8. Dr. Sriramakamal Jonnalagadda testified live at trial. Dr. Jonnalagadda has been a professor at the Philadelphia College of Pharmacy, St. Joseph's University for twenty years. (Tr. at 110:1-4; JTX-035). He received a Ph.D. from the University of Nebraska Medical Center, focusing on the examination of polymers, polymer characteristics, and the use of polymers to design drugs. (Tr. at 110:4-12). Dr. Jonnalagadda's research focuses on the development of solid and liquid forms, including liquid forms that rely on polymeric materials. (Tr. at 110:13-111:1). The Court recognized Dr. Jonnalagadda as an expert in the field of rheological properties of polymers used in liquid dispersion systems and pharmaceutical dosage forms. (Tr. at 114:9-15).

3. Defendant's Expert Witness

9. Dr. Richard Christian Moreton testified live at trial. Dr. Moreton has a Ph.D. from the University of Wales in Cardiff in the field of pharmaceuticals. (Tr. at 242:21-243:7; DTX-144). Dr. Moreton's work focuses on the performance and function of excipients in pharmaceutical formulations, including suspensions. (Tr. at 242:7-252:6). The Court recognized Dr. Moreton as an expert in the field of pharmaceutical science including pharmaceutical formulation and excipient technology. (Tr. at 252:7-13). The Court found Dr. Moreton to be particularly credible.

C. The Asserted Patents

1. The '906 Patent

10. The '906 patent is titled, "Spironolactone Aqueous Compositions" and issued on April 21, 2020, from U.S. Application No. 16/682,477 filed on November 13, 2019. (JTX-001 at 2). The named inventors of the '906 patent are Anthony Pipho and Michael Paul DeHart. (*Id.*). The '906 patent expires on October 28, 2036. (D.I. 99, Ex. 1 ¶ 12).

11. CMP asserts that the ANDA Product will infringe claims 1 and 8 of the '906 patent. Claims 1 and 8 claim:

> 1. A ready-to-use liquid formulation, comprising:
>
> (a) about 0.20% w/v to about 1.0% w/v of spironolactone;
> (b) from about 0.18% w/v to about 0.36% w/v of a xanthan gum;
> (c) a pharmaceutically acceptable excipient; and
> (d) a sufficient amount of a water vehicle;
> wherein the formulation has a spironolactone content of 100±10% labeled content when stored for about 24-months at 25±2ºC. and 40±5% relative humidity.
>
> 8. The ready-to-use liquid formulation of claim 1, which comprises about 0.5% w/v of spironolactone.

(JTX-001).

2. The ’907 Patent

12. The ’907 patent is titled, “Spironolactone Aqueous Compositions” and issued on May 26, 2020, from U.S. Application No. 16/823,604 filed on March 19, 2020. (JTX-002 at 2). The named inventors of the ’907 patent are also Anthony Pipho and Michael Paul DeHart. (*Id*.). The ’907 patent expires on October 28, 2036. (D.I. 99, Ex. 1 ¶ 19).

13. CMP asserts that the ANDA Product will infringe claims 1 and 10 of the ’907 patent. Claims 1 and 10 claim:

> 1. A ready-to-use liquid formulation, comprising:
>
> (a) about 0.20% w/v to about 1.0% w/v of spironolactone;
> (b) from about 0.18% w/v to about 0.36% w/v of a xanthan gum;
> (c) a pharmaceutically acceptable excipient; and
> (d) a sufficient amount of a water vehicle;
> wherein the formulation has a spironolactone content of 100±10% labeled content when stored for about 12-months at 25±2ºC. and 40±5% relative humidity.
>
> 10. The ready-to-use liquid formulation of claim 1, which comprises about 0.5% w/v of spironolactone.

(JTX-002).

3. The ’570 Patent

14. The ’570 patent is titled, “Spironolactone Aqueous Compositions” and issued on January 12, 2021, from U.S. Application No. 16/878,092 filed on May 19, 2020. (JTX-003 at 2). The named inventors of the ’570 patent are Anthony Pipho and Michael Paul DeHart. (*Id.*). The ’570 patent expires on October 28, 2036. (D.I. 99, Ex. 1 ¶ 27).

15. CMP asserts that the ANDA Product will infringe claims 1 and 7-10 of the ’570 patent. Claims 1 and 7-10 claim:

> 1. A ready-to-use liquid formulation, comprising:
>
> (a) about 0.20% w/v to about 1.0% w/v of spironolactone;
> (b) from about 0.18% w/v to about 0.36% w/v of a xanthan gum;

(c) a pharmaceutically acceptable excipient; and
(d) a sufficient amount of a water vehicle;
wherein the formulation exhibits a content uniformity of about 100% labeled content after shaking the formulation for about 10 seconds.

7. A dosage container comprising the ready-to-use liquid formulation of claim 1.

8. The container of claim 7 comprised of an enclosed bottle, wherein the bottle comprises a polyethylene terephthalate and an amber colorant.

9. The bottle of claim 8 having a volume of said bottle of 4 oz. or 16 oz.

10. The ready-to-use liquid formulation of claim 1, which comprises about 0.5% w/v of spironolactone.

(JTX-003).

D. The Products at Issue: CaroSpir® and the ANDA Product

16. CMP holds approved New Drug Application ("NDA") No. 209478,[3] filed on January 11, 2016, which sought approval to sell CaroSpir®. (D.I. 99, Ex. 1 ¶ 32).

17. FDA approved NDA No. 209478 for CaroSpir® on August 4, 2017. (*Id*. ¶ 33).

18. CaroSpir® is a ready-to-use liquid oral suspension with spironolactone as the active pharmaceutical ingredient. (Tr. at 67:7-16; PTX-020 at 1).

19. CaroSpir® is indicated for the treatment of heart failure, hypertension and edema caused by cirrhosis. (PTX-020 at 1; Tr. at 54:5-9).

20. CaroSpir® is commercially available in 118 mL or 473 mL amber polyethylene terephthalate bottles. (PTX-020). CaroSpir® is approved with a dosage strength of 25 mg/5ml of the suspension. (*Id.*)

[3] There is a typo in the Pretrial Order (D.I. 99, Ex. 1 ¶ 32) with respect to the NDA number. (*See* Tr. at 376:15-18). The parties corrected the typo at trial. (Tr. at 378:11-14, 407:11-12). The correction is reflected above.

21. All Asserted Patents are listed in the Orange Book as covering CaroSpir®. (D.I. 99 ¶ 5).

22. Amneal's ANDA seeks approval to market its ANDA product, a generic version of CaroSpir®, prior to the expiration of the patents listed in the Orange Book. (*Id.* ¶ 2-3).

23. The ANDA product has been established as bioequivalent to CaroSpir®. (Tr. at 200:3-203:9, 215:8-17; JTX-048).

24. CaroSpir® and the ANDA Product are both pharmaceutical suspensions. A pharmaceutical suspension is a liquid oral dosage form in which the active ingredient is often undissolved. (Tr. at 51:23-52:2).

25. Suspensions provide an option for patients who have difficulty swallowing tablets, such as pediatric and geriatric patients, and thus need a liquid form of the active ingredient (here, spironolactone). (Tr. at 51:7-18, 67:17-20).

26. Suspensions are inherently unstable, both chemically and physically. (Tr. at 124:15-125:2). A suspending agent works to help maintain the uniformity of the particles in a suspension (i.e., the active ingredient) by increasing the viscosity of a suspension to slow the rate of sedimentation. (Tr. at 52:11-53:16, 255:16-256:14). Particles in a suspension will eventually settle at the bottom of a bottle over time even if a suspending agent is used in a suspension. (Tr. at 53:14-18, 255:13-256:14).

27. A viable ready-to-use suspension allows sedimented particles to be resuspended easily but is (at the same time) not so thick that it becomes difficult to resuspend settled particles or dispense the dose. (Tr. at 62:19-22, 312:13-25).

28. CaroSpir® uses xanthan gum as a suspending agent. (Tr. at 217:22-218:5).

29. Defendant's ANDA product does not use xanthan gum as a suspending agent. (D.I. 99, Ex. 1 ¶ 37). Defendant's ANDA product uses tragacanth powder as a suspending agent. (*Id.* ¶ 38).

30. Defendant engaged in independent experimentation to select tragacanth powder as its suspending agent and to optimize the amount of tragacanth powder in its ANDA product. (Tr. at 199:18-202:15, 310:8-22). The experimentation lasted at least six months, involved multiple working groups within Amneal, required making and testing about 150 formulations, and involved testing more than a dozen different potential suspending agents or combinations of suspending agents. (Tr. at 199:18-200:20, 201:11-202:15, 203:10-206:17, 206:24-208:8, 210:8-16).

E. Claim Construction

By letter dated January 25, 2022, the parties agreed that no terms in the Asserted Patents needed construction (D.I. 32) and, as a result, "the plain and ordinary meaning of each term in the claims of the Asserted Patents as understood by a [person of ordinary skill in the art] should apply." (D.I. 99, Ex. 1 ¶ 28).

F. Facts Related to Infringement

1. Person of Ordinary Skill in the Art

31. The definition of a person of ordinary skill in the art applied by CMP's expert for the purposes of the Asserted Patents is as follows:

> A hypothetical person of ordinary skill in the art would have been someone with a degree in pharmaceutical chemistry, analytical chemistry, or pharmacy (or a similar subject related to formulations) with 4-6 years of work experience in the development of, or research related to, drug formulations.

(D.I. 99, Ex. 1 ¶ 29).

32. The definition of a person of ordinary skill in the art applied by Defendant's expert for the purposes of the Asserted Patents is as follows:

> A hypothetical person of ordinary skill in the art would have an advanced degree in pharmaceutical science, analytical chemistry, or a similar subject related to formulations, and at least 2 years' experience in research and/or development relating to drug formulations; or a person with a bachelor's degree in pharmaceutical science, analytical chemistry, or a similar subject related to formulations, and at least 5 years' experience in research and/or development relating to drug formulations.

(*Id*. ¶ 30).

33. The opinions offered by each sides' expert as to the infringement of the Asserted Patents do not change based on which of the above-stated definitions of person of ordinary skill in the art is applied. (*Id*. ¶ 31).

34. At the time of invention, both Dr. Jonnalagadda and Dr. Moreton met the definitions of a person of ordinary skill in the art offered by each side. (*See* Tr. at 109:18-114:15; JTX-035; Tr. at 242:5-246:7, 255:4-9; DTX-144).

2. <u>Doctrine of Equivalents</u>

35. The parties agree that Amneal's ANDA product will literally infringe all elements of the asserted independent claims except for one: the presence of "from about 0.18% w/v to about 0.36% w/v of a xanthan gum," which is a limitation in all asserted claims in this case. (*See* D.I. 99, Ex. 1 ¶¶ 10-11, 17-18, 25-26).

36. Plaintiff argues that this limitation is met under the doctrine of equivalents by the suspending agent in Defendant's ANDA product – i.e., tragacanth powder. (D.I. 112 at 3).

37. In their briefs, the parties address whether (a) tragacanth powder is the equivalent of xanthan gum and (b) the specified amount of tragacanth powder in the ANDA product is the equivalent of the recited amount of xanthan gum in the claims.

a. Equivalence of Xanthan Gum and Tragacanth Powder

38. Plaintiff argues that tragacanth powder is the equivalent of xanthan gum under both the function-way-result test and the insubstantial differences test.[4] (D.I. 112 at 4).

i. The Way Xanthan Gum and Tragacanth Powder Increase Viscosity

39. With respect to the function-way-result test, Defendant does not dispute that tragacanth powder performs substantially the same function to obtain substantially the same result as the recited xanthan gum. (*See* D.I. 112 at 3; Tr. at 20:25-21:6). The function of the claimed xanthan gum is to act as a suspending agent, and the result achieved is a ready-to-use liquid oral spironolactone suspension that results in 100% ± 10% labeled content after 24 months or after about 10 seconds of shaking.

40. The dispute centers on whether tragacanth powder works in substantially the same way as xanthan gum. That is, whether tragacanth powder and xanthan gum increase viscosity in their respective suspensions in substantially the same way. (*See* D.I. 112 at 3; Tr. at 20:25-21:6).

41. Xanthan gum increases the viscosity of a suspension through the random entanglement of its polymer chains. (Tr. at 140:18-141:14, 296:8-25, 297:13-24).

42. Plaintiff argues that tragacanth powder increases viscosity in substantially the same way. (D.I. 112 at 3). At trial, Plaintiff attempted to support this assertion primarily through the testimony of its expert, Dr. Jonnalagadda.

43. First, Dr. Jonnalagadda testified that he believes tragacanth powder and xanthan gum work in substantially the same way because, in an experiment conducted by Amneal during

[4] At trial, Plaintiff's counsel and expert focused on the function-way-result test. In its post-trial briefing, Plaintiff argues under both tests but does not distinguish between which evidence and arguments it relies on for which test. (*See* D.I. 112). The Court thus addresses the record as a whole in assessing whether Plaintiff has met its burden under either test.

development of its ANDA product, out of the four suspending agents tested, only tragacanth powder and xanthan gum prevented visually observable sedimentation after seven days. (Tr. at 128:3-131:25).

44. Apart from his say-so and expertise as a polymer scientist, Dr. Jonnalagadda did not offer any scientific support for the connection he made between the results of this experiment and his conclusion that the two components work in substantially the same way. (*See, e.g.*, Tr. at 140:22-25 (explaining that he "truly believe[s] the mechanism by which they are increasing the viscosity and the formulation on the particles to prevent them from coming together, the mechanism by which that is happening is precisely the same")).

45. Dr. Jonnalagadda also opined that Defendant's ANDA product matches certain release specifications of CaroSpir® (e.g., visual and physical appearance, viscosity, density, pH, re-suspendability and dissolution) and that these similar physicochemical properties of the finished products indicate that their respective suspending agents both increase viscosity in substantially the same way. (Tr. at 144:9-146:24; JTX-048 at 127-32).

46. Again, apart from his say-so and expertise as a polymer scientist, Dr. Jonnalagadda offered little in the way of scientific support for the connection he made between the similarity in physicochemical properties of the two finished products and the way in which their respective suspending agents increase viscosity.

47. In its reply brief, Plaintiff asserts that Dr, Jonnalagadda's opinion is supported by reliable experimental data – that is, Amneal's Product Development Report and the supporting lab notebook. (*See* D.I. 117 at 1-2). Although these documents may show that the physicochemical properties of both products overall are similar, Dr. Jonnalagadda failed to

adequately explain how the documents support his opinion that similarities in the final products evidence the way their respective suspending agents work.

48. When asked whether it was possible for Amneal's product to meet these specifications with a suspending agent that does not work the same as xanthan gum, the explanation Dr. Jonnalagadda gave was the following: "If the mechanism was different, you would not get that match. So the answer I guess would be no." (Tr. at 146:19-24). In contrast to Dr. Jonnalagadda's testimony, Dr. Moreton testified that the tests made on the final product "explain nothing about how the viscosity develops or how the individual components work." (Tr. at 309:18-310:6).

49. Dr. Jonnalagadda based his product-to-product comparison and opinion on the premise that the ANDA product and CaroSpir® differ solely with respect to their suspending agents and are otherwise the same. (Tr. at 174:21-25).

50. As Dr. Jonnalagadda acknowledged at trial, however, this premise is incorrect because the two formulations also have different buffer systems. (Tr. at 175:20-176:14; *see also* Tr. at 203:10-204:1). Dr. Jonnalagadda further recognized that having different buffers as well as suspending agents may have required an analysis to determine which of the similar physicochemical properties might ultimately be attributable to the buffer rather than the suspending agent. (Tr. at 175:7-19). Although Dr. Jonnalagadda then purported to have conducted such an analysis, he stated that this was "a while ago," so his "knowledge of the buffer is not exactly precise." (Tr. at 176:5-25). Dr. Jonnalagadda did not present or discuss the results of his analysis of the buffers any further.

51. In addition, Plaintiff contends that the fact that both suspending agents are natural gums shows that they both work substantially through polymer entanglement. (D.I. 112 at 7).

The closest Dr. Jonnalagadda's testimony comes to supporting this assertion is when, upon being asked why he believed both suspending agents kept sedimentation from occurring in the Amneal experiments, Dr. Jonnalagadda replied, "They're very similar. They're both natural gums," and then proceeded to list other similarities. (Tr. at 131:12-17). This explanation, however, fails to show why both suspending agents being natural gums holds any relevance with respect to the specific way they increase viscosity.

52. Dr. Jonnalagadda also testified that xanthan gum and tragacanth powder have similar molecular weights and similar chemical structures (*i.e.*, they are both anionic polysaccharides). (Tr. at 131:10-133:13, 147:2-150:6). Dr. Jonnalagadda opined that these similarities indicate that the two suspending agents increase viscosity in substantially the same way.[5] (*Id.*).

53. Apart from his say-so and expertise as a polymer scientist, Dr. Jonnalagadda offered no scientific support for the connection he made between these properties and the way in which the two suspending agents work.

54. Plaintiff has failed to establish that the characteristics and qualities that its expert cites (*i.e.*, that both suspending agents prevented visually observable sedimentation, that the finished products exhibit similar characteristics, that both are natural gums, and that they have a similar molecular weight and chemical structure) in fact indicate that xanthan gum and tragacanth powder increase viscosity in substantially the same way.

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[5] In its post-trial briefing, Plaintiff also contends that these qualities indicate that both suspending agents work through "film formation." (D.I. 112 at 7). It is unclear what Plaintiff is referring to given that, at trial, Dr. Jonnalagadda only briefly noted that he would "expect the film formation mechanisms . . . to be the same as well" without explaining what film formation is. (Tr. at 141:15-142:14; *see also* Tr. at 301:10-15).

a. Bassorin

55. Defendant contends that the two suspending agents do not increase viscosity in substantially the same way due to the presence of bassorin in tragacanth powder. (*See* D.I. 114 at 10-12).

56. There is no dispute as to the following facts: (1) xanthan gum is a water-soluble hydrocolloid; (2) tragacanth powder is made up of two components – bassorin and tragacanthin; (3) tragacanthin is water soluble. (Tr. at 118:17-18, 148:18-149:8, 291:5-16; JTX-066 at 1; JTX-070 at 480; *see also* D.I. 112 at 7-8; D.I. 113 ¶¶ 89-91; D.I. 114 at 4-5).

57. Bassorin is the majority component, making up around 60-70% of tragacanth powder. (Tr. at 291:5-16; JTX-066 at 1; JTX-070 at 480). Tragacanthin is the minority component, making up around 30-40% of tragacanth powder. (Tr. at 291:5-16; JTX-066 at 1; JTX-070 at 480; *see also* D.I. 112 at 7).

58. The parties' experts disagree as to whether the majority component bassorin is, according to Dr. Moreton, "insoluble" in water or, according to Dr. Jonnalagadda, "less soluble" in water.[6] (Tr. at 148:18-149:21, 291:5-11, 294:6-296:2).

59. Regardless of whether bassorin is categorized as insoluble or less soluble, the parties agree that bassorin – the majority component of tragacanth powder – increases viscosity through a different mechanism than tragacanthin. That is, in Plaintiff's words, "tragacanthin (the

[6] The Court found Dr. Moreton's opinion on the solubility of bassorin more credible than that of Dr. Jonnalagadda's given that it was backed by more scientific support and explanation. (*See* Tr. at 291:5-11, 294:6-296:3; JTX-066 at 1; JTX-072 at 2). The Court, however, declines to reach the factual issue of whether bassorin is technically "less soluble" or "insoluble." As noted above, regardless of the way bassorin is characterized, the parties do not dispute that tragacanth powder is made up of two components rather than one and that the way in which bassorin increases viscosity is through swelling in water and forming a gel rather than through polymer entanglement. Based on the record before the Court, whether bassorin is characterized as either "insoluble" or "less soluble" in water compared with tragacanthin would not impact the Court's determination regarding infringement.

soluble portion) increases viscosity through random entanglement . . . while bassorin (the less soluble portion), swells and forms a gel." (D.I. 112 at 8; *see also* D.I. 114 at 11; Tr. at 297:1-298:6; 319:14-16).

60. Thus, as explained by Dr. Moreton at trial, tragacanth powder increases viscosity by a combination of swelling and polymer chain entanglement. (Tr. at 297:1-298:6, 307:9-14).

61. In addition, as Dr. Moreton testified, scientific literature reflects that the presence of bassorin interacting with tragacanthin in tragacanth powder has a different effect on viscosity than that of either compound interacting alone with water. (Tr. at 298:7-300:16, 302:9-303:1; JTX-072 at 4-5). Accordingly, as Dr. Moreton explained, tragacanth powder increases viscosity by a combination of three interactions: (1) the majority component of water-insoluble (or less soluble) bassorin swelling with water; (2) the minority component tragacanthin dissolving in water, leading to polymer chain entanglement; and (3) the interaction between bassorin and tragacanthin. (Tr. at 297:1-12, 307:9-14).

62. It is undisputed that xanthan gum increases viscosity in a single way – by the entanglement of dissolved polymer chains. (Tr. at 296:8-22, 297:13-24, 140:18-141:14).

63. Plaintiff contends, however, that "the presence of bassorin simply does not matter." (D.I. 112 at 9).

64. In support of this argument, Plaintiff first points to Amneal's experiments that showed tragacanth powder prevented sedimentation. Plaintiff contends that because bassorin takes up to twenty-four hours to fully hydrate without heat and the Amneal scientists did not heat the tragacanth powder batches during their experiments, the experiments show that tragacanthin alone is responsible for the suspension of spironolactone. (D.I. 112 at 10). The testimony that comes closest to supporting this theory is the following from Dr. Jonnalagadda:

> Q: Assuming [Amneal] heat[ed] the batches, does that change your opinion in any way about the manner in which these two suspending agents are achieving the increased viscosity of the suspension?
>
> A: No, the mechanism of action of viscosity increase is the same between tragacanth and xanthan.
>
> Q: Regardless of whether it's heated?
>
> A: Regardless of whether it's heated.

(Tr. at 143:21-144:3). Dr. Jonnalagadda offered no further explanation as to why heating would not impact the mechanism by which both suspending agents increase viscosity and did not testify that these experiments show that tragacanthin alone is responsible for the suspension of spironolactone. The record is insufficient to support this theory.

65. In support of its contention that the presence of bassorin "simply does not matter," Plaintiff further argues that the asserted claims are all "comprising" claims; that is, they are open-ended and thus the presence of additional material, such as bassorin, does not negate infringement. (D.I. 112 at 9). Plaintiff presented no testimony in support of this argument.

66. Furthermore, Plaintiff has waived this argument as it was not properly disclosed in the Pretrial Order. (*See* D.I. 99).

67. When asked whether the difference in solubility between the two portions of tragacanth powder makes a difference as to his opinion that tragacanth powder and xanthan gum increase viscosity in the same way, Dr. Jonnalagadda did not respond with either of Plaintiff's attorneys' arguments noted above. Rather, Dr. Jonnalagadda testified that the difference in solubility "does not" make a difference in his opinion because "[t]he less soluble portion is also a [water-soluble] hydrocolloid, that's what I would call it. There are some references that call it insoluble, but that is why I give the explanation if it wasn't soluble, probably that would have settled, too." (Tr. at 149:15-19).

68. Apart from his say-so and expertise, Dr. Jonnalagadda offered no scientific support for his opinion as to the solubility of bassorin. Furthermore, he failed to identify, let alone meaningfully address, the undisputed difference between the two suspending agents; that is, the fact that the majority component, bassorin, increases viscosity via a different mechanism than xanthan gum. (*See* Tr. at 148:18-149:21).

69. As Dr. Moreton testified, however, the swelling of bassorin (which does not cause polymer entanglement) is recognized in the scientific literature to be largely responsible for the viscosity-increasing property of tragacanth powder. (Tr. at 293:1-294:5; JTX-070 at 481).

* * *

70. Given the utter lack of scientific support and substantive explanation provided, the Court does not credit Dr. Jonnalagadda's opinion that the two suspending agents work in substantially the same way or that their differences are insubstantial.

71. Plaintiff has failed to show that tragacanth powder increases viscosity in substantially the same way as xanthan gum or that their differences are insubstantial.

ii. Other Alleged Evidence of Equivalence

72. Plaintiff also argues that tragacanth powder is "known to be interchangeable with xanthan" gum. (D.I. 112 at 8). Neither of Plaintiff's witnesses – Dr. Jonnalagadda nor Mr. Pipho – testified that tragacanth powder and xanthan gum were known to be interchangeable.

73. The only testimony regarding known interchangeability in the context of pharmaceutical suspensions is Dr. Moreton's unrebutted testimony that tragacanth powder and xanthan gum were not considered interchangeable. (Tr. at 311:2-9).

74. In support of its assertion that the two were known to be interchangeable suspending agents for use in pharmaceutical products in 2015, Plaintiff cites to the following

portion of Dr. Moreton's testimony discussing a passage in a book on tragacanth powder and xanthan gum in the food industry: "Q: So, xanthan gum nowadays, is the more common substitute[] for tragacanth, would you agree? A: I think I would agree with you, yes." (Tr. at 327:6-13; JTX-070 at 482). Dr. Moreton later clarified, however, that the passage did *not* indicate that the two suspending agents are interchangeable substitutes in pharmaceutical suspensions. (Tr. at 357:11-18). This statement is consistent with the initial opinion Dr. Moreton gave, *i.e.*, that the two were not known to be interchangeable suspending agents for use in pharmaceutical products in 2015. (*See* Tr. at 311:2-9).

75. Plaintiff cites to certain exhibits in support of its contention that the two suspending agents were known to be interchangeable. (*See* D.I. 113 ¶ 85 (citing JTX-070 at 482; JTX-066 at 3)). Neither exhibit was accompanied by any testimony explaining that the documents indicate tragacanth powder and xanthan gum were known to be interchangeable in the context of pharmaceutical formulations. Rather, with respect to the book entitled *Food Polysaccharides and Their Applications* (JTX-070), Dr. Moreton testified to the contrary. (*See* Tr. at 357:11-18).

76. Plaintiff has not established that tragacanth powder was known to be interchangeable with xanthan gum.

77. Plaintiff also argues that the Amneal scientists understood tragacanth powder to be an equivalent of xanthan gum because when developing its product, Amneal "started with 0.70% w/v of tragacanth, which is about twice the amount of xanthan claimed in the Asserted Patents" and, given that tragacanthin comprises 30-40% of tragacanth powder, a "reasonable inference can be drawn that Amneal increased the amount of tragacanth used so that approximately the same amount of tragacanthin is present as the amount of xanthan used in

CaroSpir®, and this ensures enough tragacanthin was present to create an ANDA product that had the same properties as CaroSpir®." (D.I. 112 at 7). In addition, Plaintiff argues that the fact that the Amneal scientists did not use heat to dissolve the tragacanth powder during their experiments shows that they viewed the two to be equivalent. (*Id.* at 6).

78. Plaintiff cites to no testimony that Amneal chose to start with 0.7% w/v of tragacanth powder because it would double the concentration of tragacanthin. Rather, Plaintiff cites to Dr. Moreton's testimony that, in general, doubling the amount of tragacanth powder would also double the amount of tragacanthin in a suspension. (Tr. at 330:14-23). Nor does Plaintiff cite to any testimony that these actions taken by the Amneal scientists shows that they viewed the two suspending agents as equivalents. There is little, if any, foundation in the record for this argument.

79. Plaintiff next cites the fact that Amneal tested CaroSpir® in developing its ANDA product as evidence of copying and thus indicative that the two suspending agents are equivalent.

80. Defendant's ANDA specifications require that multiple physicochemical properties of its suspension, including its visual and physical appearance, viscosity, density, pH, re-suspendability, sedimentation rate and re-dispersibility match the corresponding physicochemical properties of CaroSpir®. (Tr. at 202:17-203:9, 225:12-230:3; JTX-048 at 127-32; JTX-031 at 3-17). Amneal conducted reverse-engineering studies on CaroSpir® that, in Plaintiff's words, were "necessary to identify and match the desired properties and attributes necessary for the FDA approval of the ANDA product." (D.I. 113 ¶ 101 (citing Tr. at 71:15-72:6; JTX-048; Tr. at 202:17-203:9)). Given the ANDA context, the Court does not give significant weight to the purported evidence of copying.

81. Dr. Jonnalagadda testified that xanthan gum and tragacanth powder also have "physical and structural differences." (Tr. at 147:2-5). Dr. Jonnalagadda then briefly opined that he "believe[s] the difference between them are [not] substantial with respect to the mechanism and how they act as suspending agents." (Tr. at 147:6-11). The only difference between the two suspending agents that Dr. Jonnalagadda specifically identified was the fact that tragacanth powder has two components, one being (in his view) less soluble than the other. (Tr. at 148:18-149:21). As noted above, his explanation with respect to whether this difference is substantial was lacking in both support and substance. (*See supra* FF ¶¶ 67-68).

82. In contrast, Dr. Moreton testified that a person of ordinary skill in the art would consider xanthan gum and tragacanth powder substantially different. (Tr. at 288:24-289:3). Dr. Moreton testified at length regarding the two suspending agents' differences in their source of procurement, composition, solubility, polymer branching, mechanism by which they increase viscosity and need for the use of heat during the commercial process. (Tr. at 289:4-307:16).

* * *

83. Plaintiff has not shown that xanthan gum and tragacanth powder work in substantially the same way or that the differences between the two suspending agents are insubstantial.

84. Amneal's proposed ANDA product does not meet the claim limitation "from about 0.18% w/v to about 0.36% w/v of a xanthan gum."

b. Equivalence of the Respective Amounts of Xanthan Gum and Tragacanth Powder

85. All asserted claims require xanthan gum to be present in a weight percent amount of "from about 0.18% w/v to about 0.36% w/v." (D.I. 99, Ex. 1 ¶¶ 9, 16, 24; JTX-001; JTX-002; JTX-003).

86. The amount of tragacanth powder in the ANDA product is 0.65% w/v – i.e., almost double the highest claimed amount of xanthan gum. (Tr. at 311:23-312:3; JTX-048 at 65).

87. In its reply brief, Plaintiff argues that "[b]ecause 30-40% of tragacanth will be tragacanthin (the portion of tragacanth that indisputably increases viscosity through random entanglement) it is reasonable to conclude that it was necessary to increase the amount of tragacanth to impart an equivalent viscosity to its suspension. In other words, 0.7% w/v tragacanth is equivalent to the claimed amount of xanthan in the claimed invention." (D.I. 117 at 7).

88. The evidence Plaintiff cites that comes closest to supporting this theory is Dr. Moreton's testimony that doubling the weight/volume of tragacanth powder in a suspension will generally double the amount of tragacanthin in the suspension. (D.I. 117 at 6-7 (citing Tr. at 329:14-330:23)).

89. Neither of Plaintiff's witnesses testified about this theory of infringement. In fact, neither witness testified that the amount of tragacanth powder in the ANDA product is the equivalent to the amount of xanthan gum in the asserted claims.

90. Plaintiff has not met its burden to show that the amount of tragacanth powder in the ANDA product is the equivalent to the claimed amount of xanthan gum in the asserted claims.

91. Amneal's proposed ANDA product does not meet the claim limitation "from about 0.18% w/v to about 0.36% w/v of a xanthan gum."

II. LEGAL STANDARDS

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent[.]" 35 U.S.C.

§ 271(a). Courts employ a two-step analysis in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, a court must construe the asserted claims. *See id.* Next, the trier of fact must compare the properly construed claims to the accused infringing product. *See id.*

The patent owner has the burden of proving infringement by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Lab'ys Corp.,* 859 F.2d 878, 889 (Fed. Cir. 1988). To prove infringement, the patent owner must show that "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). A patent owner may do so under two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs where "every limitation set forth in a claim [is] found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Infringement under the doctrine of equivalents occurs where the accused product embodies every element of a claim either literally or by an equivalent. *See id.* at 1579. This doctrine "allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733 (2002).

Analysis under the doctrine of equivalents follows one of two tests endorsed by the Supreme Court – the function-way-result test or the insubstantial differences test – both of which are performed on an element-by-element basis. The function-way-result test evaluates whether the element in the accused product performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed element. *Warner-Jenkinson,* 520 U.S. at 35-40. Under the insubstantial differences test, "[a]n element in the accused device

is equivalent to a claim limitation if the only differences between the two are insubstantial." *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004).

III. DISCUSSION

CMP argues that Amneal's ANDA product meets the claim limitation "from about 0.18% w/v to about 0.36% w/v of a xanthan gum" under the doctrine of equivalents. Amneal counters that CMP has failed to meet its burden to show (a) tragacanth powder is the equivalent of xanthan gum and (b) the amount of tragacanth powder in the ANDA product is the equivalent of the claimed amount of xanthan gum in the patented invention. The Court agrees.

A. Equivalence of Xanthan Gum and Tragacanth Powder

Plaintiff contends that tragacanth powder is the equivalent of xanthan gum under both the function-way-result test and the insubstantial differences test. The Court finds that Plaintiff has failed to meet its burden to show that tragacanth powder is the equivalent of xanthan gum under either test.

1. The Way Xanthan Gum and Tragacanth Powder Increase Viscosity

At trial, Plaintiff's evidence and argument focused primarily on the function-way-result test. (*See* D.I 112 at 4 ("The test used by the parties to date in this case" is the function-way-result test.)). The parties agree that the two suspending agents perform substantially the same function to achieve substantially the same result. (FF ¶ 39). The dispute centers on whether xanthan gum claimed and tragacanth powder in the ANDA product increase viscosity and suspend spironolactone particles in substantially the same way. (FF ¶ 40). It is undisputed that xanthan gum increases viscosity through random entanglement of its polymer chains. (FF ¶ 41). Plaintiff contends that tragacanth powder increases viscosity through substantially the same mechanism.

Plaintiff's arguments in support of this assertion, however, primarily consist of unsupported attorney argument and the say-so of its expert witness, Dr. Jonnalagadda. (*See* FF ¶¶ 38-68). For example, Plaintiff recites a myriad of indicators that purport to show that the two suspending agents work in substantially the same way: (1) that, in experiments run by Amneal, xanthan gum and tragacanth powder were the only two of four suspending agents tested to prevent visually observable sedimentation after seven days, (2) that the ANDA product matches certain release specifications of CaroSpir®, (3) the similar molecular weights of the two suspending agents, (4) the similar chemical structures of the two suspending agents and (5) that they are both natural gums. (FF ¶¶ 43, 45, 51, 52).

With respect to each of these alleged indicators, however, Plaintiff's expert failed to provide any meaningful scientific support for his conclusion that these facts, if true, indicate that the two suspending agents work in substantially the same way. (FF ¶¶ 43-54). Indeed, many of Dr. Jonnalagadda's explanations of his opinions regarding these supposed indicators consist of nothing more than brief, conclusory statements devoid of any substantive reasoning. (*See, id.*). Such "[g]eneralized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice" to prove infringement under the doctrine of equivalents. *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996); *see also Warner-Jenkinson*, 520 U.S. at 29 ("[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."). Given the utter lack of scientific support and substantive explanation, the Court does not credit

Dr. Jonnalagadda's opinions that the two suspending agents work in substantially the same way or that their differences are insubstantial.[7]

Moreover, although it is not Defendant's burden to prove noninfringement, Defendant offered compelling evidence at trial that tragacanth powder does not increase viscosity in substantially the same way as xanthan gum due to the presence of its majority component bassorin, which increases viscosity through swelling rather than polymer entanglement. (FF ¶¶ 55-57, 59-61). Plaintiff does not dispute the substantial presence of bassorin or the fact that it increases viscosity through this different mechanism. (FF ¶¶ 59, 61-62). Rather, Plaintiff asserts that the presence of bassorin "does not matter." (FF ¶ 63). The record, however, demonstrates the contrary. (*See* FF ¶¶ 55-69). Indeed, in contrast to xanthan gum, as explained by Dr. Moreton and reflected in the scientific literature, tragacanth powder increases viscosity by a combination of interactions including each of the components of the powder interacting with water (bassorin swelling and tragacanthin dissolving and leading to polymer chain entanglement) as well as the two components interacting with each other. (FF ¶¶ 60-61).

Plaintiff's response to this evidence relies mainly on arguments that were never endorsed by either of its witnesses at trial. First, Plaintiff argues that an experiment conducted by Amneal shows that tragacanthin alone is responsible for suspension of spironolactone because bassorin takes up to twenty-four hours to fully hydrate if not heated. And second, Plaintiff argues that the asserted claims are "comprising" claims and thus the presence of additional material such as

[7] In its opening brief, Plaintiff argues that Defendant has waived its right to assert a *Daubert* challenge against its expert. (D.I. 112 at 11-12). To be clear, the Court is not ruling that Dr. Jonnalagadda's testimony is inadmissible. Rather, the Court is considering his testimony and determining the degree of weight the testimony merits in light of the dearth of factual support provided beyond the expert's say-so.

bassorin does not negate infringement. Neither of these attorney arguments finds any support in the record. (FFFF ¶ 64, ¶ 65). And are thus, not compelling.

2. Other Asserted Evidence of Equivalence

In addition to the way in which the two suspending agents increase viscosity, Plaintiff asserts the following to support a finding of equivalence between xanthan gum and tragacanth powder: (1) tragacanth powder is known to be interchangeable with xanthan gum in suspensions, (2) Amneal understood the two suspending agents to be interchangeable, and (3) Amneal copied CaroSpir® during its development of its ANDA product. None of these arguments is supported by the record.

First, with respect to the alleged known interchangeability, there is no evidence on the record to support this contention. (FF ¶¶ 72-76). Second, Plaintiff argues that the way in which Amneal developed its ANDA product, *i.e.*, they did not use heat and doubled the concentration of tragacanth powder, indicates that Amneal understood tragacanth powder to be an equivalent of xanthan gum. Again, Plaintiff cites to no evidence that supports that either action on the part of the Amneal scientists indicates that they understood tragacanth powder to be an equivalent of xanthan gum. (FF ¶ 78). Finally, with respect to alleged copying, this evidence does not carry much weight in the ANDA context given that a showing of bioequivalence is required for FDA approval. (*See* FF ¶ 80); *Cf. Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013) ("[E]vidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval."); *see also Purdue Pharma Prods. L.P. v. Par Pharma., Inc.*, 377 F. App'x 978, 983 (Fed. Cir. 2010). Regardless, even giving the evidence of copying due weight, the record as a whole fails to establish that tragacanth powder is the equivalent of xanthan gum.

* * *

Plaintiff has failed to prove that tragacanth powder is the equivalent of xanthan gum by a preponderance of the evidence under both the function-way-result test and the insubstantial differences test. (FF ¶¶ 35-83). Thus, Plaintiff has not shown that Defendant's ANDA product meets the claim limitation "from about 0.18% w/v to about 0.36% w/v of a xanthan gum." Plaintiff has not met its burden to show that Defendant will infringe the claims of the Asserted Patents.

B. Equivalence of the Respective Amounts of Xanthan Gum and Tragacanth Powder

In addition, Plaintiff has failed to show that the amount of tragacanth powder in the ANDA product is the equivalent of the claimed amount of xanthan gum in the invention. The limitations at issue claim "from about 0.18% w/v to about 0.36% w/v" of xanthan gum. (FF ¶ 85). It is undisputed that the amount of tragacanth powder in the ANDA product is 0.65% w/v. (FF ¶ 86). Plaintiff failed to present any evidence that a person of ordinary skill in the art would consider the amount of tragacanth powder in the ANDA product equivalent to the amount of xanthan gum required by the asserted claims. (FF ¶¶ 87-90). Thus, Plaintiff has failed to show by a preponderance of the evidence that Defendant's ANDA product meets the limitation at issue. (FF ¶¶ 85-91). For this independent reason as well, Plaintiff has not met its burden to show that Defendant will infringe the Asserted Patents.

IV. CONCLUSION

For the foregoing reasons, Plaintiff has failed to show that Defendant's ANDA product will infringe claims 1 and 8 of the '906 patent, claims 1 and 10 of the '907 patent and claims 1 and 7-10 of the '570 patent.

An appropriate order will be entered.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CMP DEVELOPMENT, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-549 (MN)
	)	
AMNEAL PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

ORDER

At Wilmington, this 29th day of September 2023, for the reasons set forth in the Memorandum Opinion issued on this date,

IT IS HEREBY ORDERED that Plaintiff has failed to show that Defendant's ANDA product will infringe claims 1 and 8 of the '906 patent, claims 1 and 10 of the '907 patent and claims 1 and 7-10 of the '570 patent.

IT IS FURTHER ORDERED that the parties shall meet and confer and submit, no later than October 11, 2023, a proposed form of judgment consistent with the Memorandum Opinion that will result in final judgment upon entry in favor of Defendant and against Plaintiff.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge