VIVA HEALTHCARE PACKAGING USA INC., Viva Healthcare Packaging HK Ltd, and Viva Healthcare Packaging Ltd, Plaintiffs,

v.

CTL PACKAGING USA INC., and Tuboplast Hispania, Defendants.

DOCKET NO. 3:13-cv-00569-MOC-DSC

United States District Court, W.D. North Carolina, Charlotte Division.

> Signed 07/11/2016 Filed 07/12/2016

Background: Manufacturer of plastic tubes and flexible tubular containers used in cosmetics industry brought action against competitor, alleging infringement of patents pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers. Parties cross-moved for summary judgment, and to exclude proposed expert testimony.

Holdings: The District Court, Max O. Cogburn Jr., J., held that:

- (1) manufacturer's expert witnesses' testimony was admissible;
- (2) expert testimony as to meaning of "compatible polymer" would be excluded to the extent it conflicted with District Court's construction of such term;
- (3) expert witness's proposed testimony that patents were invalid as anticipated by prior art was admissible;
- (4) genuine issues of material fact existed as to whether patent claims informed those skilled in the art about the scope of the inventions with reasonable certainty:
- (5) genuine issues of material fact existed as to whether patents taught those skilled in the art how to make and use the full scope of the claimed inventions without undue experimentation;

- (6) patent was not invalid as anticipated by academic study; and
- (7) genuine issue of material fact existed as to whether prior art anticipated patent claim teaching the injection molding process for making thin-walled tubes.

Plaintiffs' motions granted in part and denied in part, and defendants' motions denied.

1. Evidence €=555.2

In assessing the reliability of expert testimony, a court should consider: (1) whether the particular scientific theory can be, and has been, tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community. Fed. R. Evid. 702.

2. Evidence ⋘508

The test for relevance, or "fit," of proposed expert testimony considers whether the testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute; scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. Fed. R. Evid. 702.

3. Evidence ⋘536

While the proponent of expert testimony must establish its admissibility by a preponderance of proof, the test for exclusion of an expert is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered. Fed. R. Evid. 702.

4. Evidence €=536

One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an expert opinion. Fed. R. Evid. 702.

5. Evidence €=555.2

Daubert requires that a trial court give broad consideration to all of the various factors that may illuminate the reliability of proffered expert testimony. Fed. R. Evid. 702.

6. Evidence \$\sim 555.2\$

A district court may exclude evidence that is based upon unreliable principles or methods, legally insufficient facts and data, or where the reasoning or methodology is not sufficiently tied to the facts of the case, but the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court.

7. Evidence \$\sim 555.2\$

Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.

8. Federal Civil Procedure €=1278

To determine whether a failure to disclose information required by civil procedure rule governing expert witnesses is substantially justified or harmless, so as not to warrant exclusion of evidence, the District Court examines the following five factors: (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence. Fed. R. Civ. P. 26(a), 37(c)(1).

9. Federal Civil Procedure €=1278, 1451

Litigant need not have acted in bad faith or in callous disregard of discovery rules in failing to supplement its expert's reports and deposition testimony, in order for its conduct to provide basis for court to exclude any new opinion offered by expert. Fed. R. Civ. P. 26(a), 37(c)(1).

10. Evidence \$\sim 555.2\$

Expert witness's proposed testimony that patent for method of manufacturing flexible plastic tubes and other thin-walled tubular containers was infringed with regard to the environmental stress cracking resistance (ESCR) test described and claimed therein, and that patent was not indefinite was admissible, in patent infringement action; expert's opinions were precisely the sort that could be addressed through vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof, and left to the fact-finder to determine credibility. Fed. R. Evid. 702.

11. Evidence ⋘539, 555.2

Expert witness's proposed testimony that patents pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers do not lack enablement with regard to their teaching on the process for the manufacture of injection molded tubes was admissible in patent infringement action; expert was a person of ordinary skill in the art and offered opinions that were both reliable and relevant, and expert's experience, or alleged lack thereof, with injection molding, was ideal subject for exploration on cross-examination. Fed. R. Evid. 702.

12. Patents \$\infty\$1760(2)

Expert report, which disclosed expert's conversations with another of plaintiff's experts, and that other expert's report adequately disclosed expert's reliance upon the other expert's opinions in form-

ing opinion that patents pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers do not lack enablement with regard to their teaching on the process for the manufacture of injection molded tubes. Fed. R. Civ. P. 26; Fed. R. Evid. 703.

13. Evidence €=555.2

Expert witness's proposed testimony that competitor infringed upon patent for method of manufacturing flexible plastic tubes and other thin-walled tubular containers because the polymers used in competitor's tube manufacturing process were "compatible polymers," as described in the patent, was admissible in patent infringement action; expert's opinions were precisely the sort that could be addressed through vigorous cross-examination. Fed. R. Evid. 702.

14. Evidence \$\sim 555.2\$

Expert witness's proposed testimony that patent for method of manufacturing flexible plastic tubes and other thin-walled tubular containers was not indefinite because one of ordinary skill in the art would know that a "compatible polymer," as referred to in the patent, was homogeneous and one that remarkably improved clarity when blended with the other polymers in the blend, was admissible in patent infringement action; fact that expert called inventor after he submitted his expert reports in no way affected the reliability of those opinions. Fed. R. Evid. 702.

15. Patents €=1848

Once a district court has construed the relevant patent claim terms, and unless altered by the district court, then that legal determination governs for purposes of trial; no party may contradict the court's construction to a jury.

16. Evidence €=146

Expert testimony as to meaning of "compatible polymer," a claim term in patents for methods of manufacturing flexible

plastic tubes and other thin-walled tubular containers, would be excluded from patent infringement action to the extent it conflicted with District Court's construction of such term; such testimony could only serve to complicate the issue in an already complicated case.

17. Patents \$\sim 1760(2)\$

Competitor's expert witness's proposed testimony that patents pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers were invalid as anticipated by prior art was admissible in patent infringement action, where competitor disclosed each item of prior art that allegedly anticipated or rendered obvious the asserted patent claims of the patents-in-suit, and specific polymers referenced by experts were examples of polymers disclosed in those prior art references. Fed. R. Evid. 702.

18. Patents \$\sim 1119\$

Overcoming the presumption of validity requires the party seeking to invalidate a patent to prove invalidity by clear and convincing evidence. 35 U.S.C.A. § 282.

19. Patents €=1934

In order to prevail at the summary judgment stage, the party seeking summary judgment on the issue of patent invalidity must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. 35 U.S.C.A. § 282; Fed. R. Civ. P. 56(a).

20. Patents ≈1934

If the decisive determination of patent invalidity depends on resolution of material factual differences, then summary judgment is inappropriate. 35 U.S.C.A. § 282; Fed. R. Civ. P. 56(a).

21. Patents \$\sim 816\$

A patent is invalid for indefiniteness if its language, read in light of the specification and prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. 35 U.S.C.A. § 112.

22. Patents \$\sim 816\$

A patent does not satisfy the statutory definiteness requirement merely because a court can ascribe some meaning to a patent's claims; rather, the claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art. 35 U.S.C.A. § 112.

23. Patents \$\infty 816

In ruling on a claim of patent indefiniteness, a court must determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. 35 U.S.C.A. § 282.

24. Patents ≈1934

Where expert evidence addressing what one skilled in the art would have understood by looking at a patent is in conflict, summary judgment on issue of definiteness is inappropriate. 35 U.S.C.A. § 282; Fed. R. Civ. P. 56(a).

25. Patents €=1936

A moving party may provide support for motion for summary judgment in patent infringement action by submitting affidavits from fact and expert witnesses, so long as such evidence is necessary to support summary judgment in patent cases where the technology is not "easily understandable without" expert's explanatory testimony. Fed. R. Civ. P. 56(a).

26. Patents \$\infty\$1936

In a patent infringement action, nonmoving party may oppose summary judgment based on expert testimony by pointing to an evidentiary conflict created on the record at least by a counter statement of fact or facts set forth in detail in an affidavit by a knowledgeable affiant; mere denials or conclusory statements are insufficient. Fed. R. Civ. P. 56(a).

27. Patents \$\infty\$1935(5)

Genuine issues of material fact as to whether claims in patents pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers informed those skilled in the art about the scope of the inventions with reasonable certainty precluded summary judgment on competitor's claim that patents were invalid for indefiniteness. 35 U.S.C.A. §§ 112, 282; Fed. R. Civ. P. 56(a).

28. Patents \$\sim 908(2)\$

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation; undue experimentation is required when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out. 35 U.S.C.A. § 112.

29. Patents \$\sim 908(1)\$

While every aspect of a generic patent claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. 35 U.S.C.A. § 112.

30. Patents \$\sim 908(1)\$

A determination of enablement in action challenging patent validity is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. 35 U.S.C.A. § 112.

31. Patents \$\sim 908(6)\$

The determination of a patent's enablement is a question of law based on underlying factual inquiries. 35 U.S.C.A. § 112.

32. Patents \$\infty\$1935(5)

Genuine issues of material fact as to whether patents pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers taught those skilled in the art how to make and use the full scope of the claimed inventions without undue experimentation precluded summary judgment on competitor's claim that patent was invalid for non-enablement. 35 U.S.C.A. §§ 112, 282; Fed. R. Civ. P. 56(a).

33. Patents \$\infty\$1918

Subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless. 35 U.S.C.A. § 284.

34. Patents \$\sim 1824\$

Appropriate burden of proof in proving recklessness, for purpose of establishing entitlement to enhanced damages award for willful patent infringement, is a preponderance of the evidence, not clear and convincing evidence. 35 U.S.C.A. § 284.

35. Patents €=1918

Determining the issue of willful patent infringement is more appropriate once the court has received findings of fact from the jury as to infringement and validity arguments. 35 U.S.C.A. § 284.

36. Patents €=488

Invalidity based on lack of novelty, often called "anticipation," requires that the same invention, including each element and limitation of patent claims, was known or used by others before it was invented by the patentee. 35 U.S.C.A. § 102.

37. Patents €=1119

A party who would establish a patent's invalidity by anticipation shoulders an especially heavy burden; to overcome this presumption of validity, the patent's challenger must prove facts supporting a determination of invalidity by clear and convincing evidence. 35 U.S.C.A. §§ 102, 282.

38. Patents \$\infty\$582, 1848

Anticipation analysis is a two-step process: the first step patent is claim construction, a question of law for the court, while the second step of the process involves a comparison of the asserted claims with the prior art, a fact-finding endeavor for the jury. 35 U.S.C.A. § 102.

39. Patents ⇐=489(2)

To establish patent invalidity based on anticipation, every limitation of a claim must identically appear in a single prior art reference. 35 U.S.C.A. § 102.

40. Patents \$\sim 489(1)\$

When more than one prior art reference is required to establish unpatentability of a claimed invention, anticipation cannot be found. 35 U.S.C.A. § 102.

41. Patents \$\sim 488\$

To establish anticipation, a party must show that there is no difference between the patented claim and that which is disclosed by the prior art, as viewed by a person of ordinary skill in the field of invention. 35 U.S.C.A. § 102.

42. Patents \$\sim 489(1)\$

If a prior art reference lacks any claimed element of a patent, then as a matter of law the court cannot find anticipation; further, the prior art must disclose all of the claim elements arranged or combined in the same way as recited in the challenged patent, clearly and unequivocally disclosing the claimed invention, without any need for picking, choosing, or combining various disclosures not directly related to each other by the teachings of the cited reference. 35 U.S.C.A. § 102.

43. Patents \$\sim 487(2)\$

To anticipate a patent, a prior art reference must enable one of skill in the art to make and use the claimed invention. 35 U.S.C.A. § 102.

44. Patents \$\infty 489(2), 490

A prior art reference may anticipate a patent by disclosing claim limitations either expressly or inherently. 35 U.S.C.A. § 102.

45. Patents \$\sim 485\$

Express anticipation is determined by reading patent claims in the context of the patent specification in which they arise and in which the invention is described. 35 U.S.C.A. § 102.

46. Patents €=485

In determining whether a prior art reference anticipates a patent, trier of fact must identify the elements of patent claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. 35 U.S.C.A. § 102.

47. Patents \$\sim 490\$

A prior art reference may be found to inherently disclose a patent claim limitation if the limitation is necessarily present in the reference and a person of ordinary skill in the art would recognize its presence; it is not sufficient that a person following the prior art disclosure sometimes obtain the result set forth in the claim, it must invariably happen. 35 U.S.C.A. § 102.

48. Patents \$\infty 490, 574

When a prior art reference is silent about an asserted inherent characteristic, such a gap in the reference may be filled with recourse to extrinsic evidence that makes clear that the missing descriptive matter is necessarily present in the thing described; this modest flexibility in the rule that anticipation requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference. 35 U.S.C.A. § 102.

49. Patents €=574

In considering the anticipatory teaching of a prior art reference, in determining patent validity, extrinsic evidence may only be considered when it is used to explain, not expand, the meaning of a reference. 35 U.S.C.A. § 102.

50. Patents \$\sim 580

Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each patent claim element, state the witness's interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference; the testimony is insufficient if it is merely conclusory. 35 U.S.C.A. § 102.

51. Patents \$\sim 1933\$

It is not the task of the district court to attempt to interpret confusing or general testimony to determine whether a case of patent invalidity has been made out, particularly at the summary judgment stage; indeed, to accept confusing or generalized testimony as evidence of invalidity is improper. 35 U.S.C.A. § 282; Fed. R. Civ. P. 56(a).

52. Patents €=1934

Regarding the standards for summary judgment as to anticipation in the context of a patent case, although anticipation is a question of fact, it still may be decided on summary judgment if the record reveals no genuine dispute of material fact. 35 U.S.C.A. §§ 102, 282; Fed. R. Civ. P. 56(a).

53. Patents \$\infty\$1119, 1934

Because a patent enjoys a presumption of validity which can be overcome only by clear and convincing evidence, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. 35 U.S.C.A. § 282; Fed. R. Civ. P. 56(a).

54. Patents \$\sim 1934\$

When a party moving for summary judgment based on no anticipation of patent points to the absence of evidence to support the non-moving party's case, and the non-moving party produces no evidence, the court should grant summary judgment to the moving party. 35 U.S.C.A. § 102; Fed. R. Civ. P. 56(a).

55. Patents \$\infty\$1936

For a non-moving party to establish a genuine dispute of material fact as to "no anticipation" of patent, the non-moving party is required to do more than establish that the experts disagree; rather, an accused infringer must point to sufficient evidence for a reasonable jury to conclude by clear and convincing evidence that the asserted claims are anticipated. 35 U.S.C.A. § 102; Fed. R. Civ. P. 56(a).

56. Patents \$\sim 1934\$

Where the party alleging a patent's invalidity due to anticipation presents expert testimony which cites to prior art by setting forth some but not all claim elements, or which makes conclusory statements regarding anticipation, no triable issue of fact thereby arises. 35 U.S.C.A. § 102.

57. Patents \$\sim 485\$

If a prior art does not anticipate an independent patent claim, it cannot, as a matter of law, anticipate associated dependent claims. 35 U.S.C.A. § 102; 37 C.F.R. § 1.75(c).

58. Patents €=558

Academic study that did not teach high shear, long flow length conditions for the manufacture of test strips did not anticipate environmental stress cracking resistance (ESCR) test described by patent for method of manufacturing flexible plastic tubes and other thin-walled tubular containers, which taught such conditions. 35 U.S.C.A. § 102.

59. Patents \$\sim 558\$

Clear and convincing evidence did not establish that metallocene limitation in claim for patent pertaining to methods of manufacturing flexible plastic tubes and other thin-walled tubular containers was anticipated by "general teaching" in prior art, which stated that polymers made using metallocene catalysts, among a variety of other suitable polymers, could be used in the claimed injection molding process. 35 U.S.C.A. § 102.

60. Patents \$\infty\$1935(6)

Genuine issue of material fact as to whether the language in academic study taught that the injection molding process disclosed in that prior art should be practiced specifically for the manufacture of tubes precluded summary judgment on issue of whether patent claim teaching the injection molding process for making thinwalled tube was invalid as anticipated by prior art. 35 U.S.C.A. § 102; Fed. R. Civ. P. 56(a).

61. Patents \$\infty\$1935(6)

Genuine issue of material fact as to whether prior art patent taught the manufacture of tubes using the injection molding process described in patent pertaining to method of manufacturing flexible plastic tubes and other thin-walled tubular containers precluded summary judgment on issue of whether patent claim was invalid as anticipated by prior art. 35 U.S.C.A. § 102; Fed. R. Civ. P. 56(a).

Patents \$\infty\$2091

8,518,318. Valid in Part.

Patents \$\sim 2091\$

6,143,818, 6,547,094. Cited.

Patents €=2091

6,159,566. Cited as Prior Art.

Anthony T. Lathrop, Moore & Van Allen, Charlotte, NC, Kripa Raman, Michael Francis Milea, Sana Chaudhry, Catherine Nyarady, Michael Wu, Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, NY, Damon C. Andrews, Paul, Weiss, Rifkind, Wharton & Garrison LLP, Washington, DC, for Plaintiffs.

Barry J. Herman, Kara Lacy Boyle, Womble Carlyle Sandridge & Rice, LLP, Baltimore, MD, Carl Bruce Massey, Jr., Womble Carlyle Sandridge & Rice, LLP, Winston-Salem, NC, Christine Holleman Dupriest, Womble Carlyle Sandridge & Rice, LLP, Washington, DC, Kurt E. Lindquist, II, Russ Ferguson, Womble Carlyle Sandridge & Rice, LLP, Charlotte, NC, David R. Boaz, Womble Carlyle Sandridge & Rice LLP, Raleigh, NC, for Defendants.

ORDER

Max O. Cogburn Jr., United States District Judge

THIS MATTER is before the court on several Motions of the parties. This patent infringement action relates to two patents—U.S. Patent Nos. 8,518,318 ("the '318 Patent"") and 6,547,094 ("the '094 Patent""), which both pertain to methods of manufacturing flexible plastic tubes and other thinwalled tubular containers. Plaintiffs Viva Healthcare Packaging, Ltd., Viva Healthcare Packaging (HK) Ltd., and Viva Healthcare Packaging (USA) Inc., (collectively, "Viva" or "Plaintiffs") have alleged that Defendants CTL Packaging USA,

Inc., and Tuboplast Hispania (collectively, "CTL" or "Defendants") infringed these two patents; Defendants have asserted several defenses to the infringement allegations. The court issued a Claim Construction Order on March 23, 2015. After discovery was complete, the parties filed the following Motions, which have been fully briefed and are ripe for review:

- 1. Defendants' Motion for Summary Judgment as to Indefiniteness (#178);
- 2. Defendants' Motion for Summary Judgment as to Lack of Enablement (#180);
- Defendants' Motion for Summary Judgment of No Willful Infringement (#182);
- Plaintiffs' Motion for Partial Summary Judgment of No Anticipation of United States Patent No. 6,547,094 (#196);
- Plaintiffs' Motion for Partial Summary Judgment of No Anticipation Of United States Patent No. 8,518,-318 (#198);
- Defendants' Motion to Exclude Certain Opinions by Expert Witness Stephen Driscoll (#184);
- 7. Defendants' Motion to Exclude Certain Testimony of Expert Dr. Michael Rubinstein (#186);
- 8. Plaintiffs' Motion to Exclude Certain Purported Expert Testimony of Tim Osswald and Mukerrem Cakmak (#190);
- 9. Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith (#203); and
- Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith and Tim Osswald (#208).

The court heard oral arguments on these motions on May 4, 2016. Having consid-

ered the Motions, the applicable law, and the arguments of counsel, the court enters the following findings, conclusions, and Order.

I. BACKGROUND

This is an action for patent infringement relating to U.S. Patent Nos. 8,518,318 ("the '318 Patent'") and 6,547,094 ("the '094 Patent'") (collectively, the "patents in-suit"). Plaintiffs have alleged that Defendants (infringed these two patents, which both pertain to methods of manufacturing flexible plastic tubes and other thinwalled tubular containers used in the cosmetics industry. The manufacture of these tubes is done through a process called "injection molding," which involves heating up plastic and injecting it into a mold to cool and harden. Injection molding is a common method used in plastics manufacturing for three-dimensional objects. Injection-molded tubes are typically more durable and flexible in shape, nozzle, cap, and label than predecessor technologies.

Viva contends that injection molding was not a viable option for the manufacture of thin-walled tubes before the technology covered by the patents-in-suit was developed because it was difficult to find polymers with the appropriate properties. The patents-in-suit purportedly identify physical blends of polymers that can be used in injection molding to make flexible, thinwalled plastic objects with the requisite properties to protect the cosmetics that they encase, such as crack-resistance and an ability to withstand handling. The '094 Patent teaches that blends of polymers with certain environmental stress cracking resistance ("ESCR") values, particularly those with at least one polymer with certain melt flow properties, can be effectively and feasibly used in injection moldingbased manufacturing processes to make these flexible, thin-walled plastic objects. The '318 Patent claims to improve on these findings by adding that the polymer blends benefit from containing "compatible" polymers, with at least one of such polymers having a high melt flow index. According to Viva, the patented methodology made it easier and cheaper to develop flexible, thin-walled plastic tubes through injection molding, which has allowed for more variety in tube shape, texture, and embossment.

After the issue had been fully briefed and argued in court at a hearing, the court entered a Claim Construction Order (#109) construing the disputed terms in this case. Now that discovery has been completed, the parties have filed an array of Motions for Summary Judgment and Motions to Exclude proffered expert testimony, largely as such opinions have bearing on the parties' arguments on summary judgment. The court will address each motion in turn.

II. MOTIONS TO EXCLUDE EXPERT TESTIMONY

The parties have both filed Motions seeking to exclude testimony from experts in this case. Plaintiffs seek to exclude certain expert testimony offered by Tim Osswald, Mukerrem Cakmak, and Cynthia Smith. See (##190, 203, 208). Defendants seek to exclude certain opinions of Professor Stephen Driscoll and Dr. Michael Rubinstein. See (##184, 186). The court will address each Motion seriatim.

A. Legal Standards

[1,2] The legal standards governing the parties' Motions to exclude expert testimony are as follows. Fed. R. Evid. 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue:

- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Id. The Supreme Court's decision in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) clarified "that it is the duty of the trial court to perform the gatekeeping function with respect to expert testimony: 'the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" United States v. Prince-Oyibo, 320 F.3d 494, 498 (4th Cir.2003) (quoting Daubert, 509 U.S. at 589, 113 S.Ct. 2786). In assessing the reliability of expert testimony, a court should consider:

(1) whether the particular scientific theory can be (and has been) tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; and (5) whether the technique has achieved general acceptance in the relevant scientific or expert community.

United States v. Crisp, 324 F.3d 261, 266 (4th Cir.2003) (quoting Daubert, 509 U.S. at 593–94, 113 S.Ct. 2786) (quotation marks omitted). This list of factors is not exhaustive. Id. The test for relevance, or "fit," considers "whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert, 509 U.S. at 591, 113 S.Ct. 2786. Similarly, "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Id.

[3-5] While the proponent of expert testimony must establish its admissibility by a preponderance of proof, see Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir.2001), "the test for exclusion [of an expert] is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered." (Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799 (4th Cir. 1989)). Of particular relevance in this patent case, "[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion." Id. (citing Martin v. Fleissner GMBH, 741 F.2d 61, 64 (4th Cir.1984)). "In short, Daubert requires that a trial court give broad consideration to all of the various factors that may illuminate the reliability of proffered expert testimony." United States v. Prince-Oyibo, 320 F.3d 494, 498 (4th Cir. 2003).

[6, 7] Fed. R. Evid. 703 provides:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

<u>Id.</u> As the Federal Circuit recently summarized,

Under these rules, a district court may exclude evidence that is based upon unreliable principles or methods, legally insufficient facts and data, or where the reasoning or methodology is not sufficiently tied to the facts of the case. But the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court. Indeed, [v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.

Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1295–96 (Fed.Cir.2015) (internal citations and quotation marks omitted) (alteration in original).

Regarding written expert reports, the Federal Rules of Civil Procedure require that a party who intends to offer expert testimony provide an expert report containing "a complete statement of all opinions the witness will express." Fed. R. Civ. P. 26(a)(2)(B)(i). A party must also disclose the "basis and reasons" for all of those opinions, id. as well as "the facts or data considered by the witness in forming them," Fed. R. Civ. P. 26(a)(2)(B)(ii). The Rules also require supplementation of disclosures, including the reports of an expert, if such disclosures are materially incomplete or incorrect or it is later discovered the disclosures are incomplete or incorrect. Fed. R. Civ. P. 26(e).

[8, 9] Rule 37(c)(1) provides that if "a party fails to provide information . . . as required by Rule 26(a) . . . the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). To determine whether a failure to disclose is "substantially justified or harmless," the Fourth Circuit examines the following five factors:

(1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

S. States Rack & Fixture, Inc. v. Sherwin—Williams Co., 318 F.3d 592, 597 (4th Cir. 2003) (citation and quotation marks omitted). A party need not have acted in bad faith or "callous disregard of the discovery rules" for the sanction to apply. Id. at 596.

B. Discussion

1. Defendants' Motion to Exclude Certain Opinions by Expert Witness Professor Stephen Driscoll (#184)

Defendants challenge two of Professor Driscoll's opinions in his expert report (#193-9) as they relate to the '094 Patent. Professor Driscoll opines in his report that the '094 Patent (1) is infringed with regard to the "ESCR as herein defined" test described and claimed therein, and (2) is not indefinite because one of ordinary skill in the art could determine infringement based on such ECSR test. See, e.g., (#193-9) at ¶¶28, 115-39. Defendants do not challenge the remainder of Professor Driscoll's opinions.

In support of their argument, Defendants contend that prior to this litigation, Professor Driscoll had no experience in ESCR testing or any similar testing on thin-walled articles. They also argue that he had no practical or supervisory experience in injection molding, so any analysis regarding the subject is likewise suspect. They note that he has never authored any peer-reviewed books or articles specific to ESCR testing. Generally, they argue that Professor Driscoll opining on the reasonable certainty of the "ESCR as herein defined" of the '094 Patent as performed on injection molded articles is no different than any layperson opining on the subject and that his opinions as to invalidity and indefiniteness should be excluded because they are unreliable.

Plaintiffs respond that Professor Driscoll does have experience with ESCR testing and injection molding, and that his qualifications ¹ show that his opinions are reliable. They also note that Defendants fail to point out how exactly he fails to qualify as an expert under the standards articulated in Fed. R. Ev. 702. Plaintiffs also note that Defendants only challenge certain aspects of Professor Driscoll's report even though all of the opinions therein are based on the same expertise and experience.

[10] The court has considered Professor Driscoll's qualifications as they relate to the offered opinions and finds no reason to exclude the challenged expert opinions based on the standards articulated in Daubert and Fed. R. Evid. 702. As noted at the hearing, however, the court finds that Professor Driscoll's experience in ESCR testing remains excellent fodder for cross examination at trial. The court believes that the opinions challenged here are precisely the sort that can be addressed through "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof," Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1295–96 (Fed.Cir.2015), and left to the fact-finder to determine credibility.

1. Professor Driscoll set forth his qualifications in his expert report and curriculum vitae, explaining his experience and familiarity with the scientific issues relevant in this case as follows. See (#193-9 at ¶¶4-8; #243-10). Professor Driscoll holds both a B.S. and M.S. degree in plastics engineering, has forty-eight years of teaching experience in the Department of Plastics Engineering at the University of Massachusetts Lowell. While at the University of Massachusetts Lowell, he served as a thesis advisor for over 130 M.S. and doctoral thesis candidates, performed research related to polymer blends and alloys, dynamic mechanical behavior, and economic considerations in the commercial development of plastics. Professor Driscoll also teaches undergraduate and graduate courses in polymeric materials engineering, polymer modifiThe court will therefore **DENY** Defendants' Motion to Exclude Certain Expert Testimony of Professor Driscoll (#184).

2. Defendant's Motion to Exclude Expert Testimony of Dr. Michael Rubinstein

Plaintiffs have proffered Dr. Michael Rubinstein as an expert in polymer physics. Defendants do not challenge him as an expert in that field, but challenge some of his opinions as beyond the scope of his expertise and for other reasons described herein. Citing Daubert, Fed. R. Evid. 702, and Fed. R. Civ. P. 26(a)(2), Defendants move to exclude the opinions expressed by Dr. Rubinstein that: (1) both Patents-in-Suit do not lack enablement with regard to their teaching on the process for the manufacture of injection molded tubes, (2) CTL infringes the '318 Patent with regard to the "compatible polymer" element, and (3) that the '318 Patent is not indefinite based on the term "compatible polymer." Defendants argue that Dr. Rubinstein is not an expert in injection molding.

a. Enablement

Defendants move to exclude any testimony from Dr. Rubinstein that the Patents-in-Suit were enabled when they were

ers and additives, and polymer characterization with emphasis on dynamic mechanical properties, and has decades of extensive instructional and supervisory laboratory work in testing of materials according to various American Society for Testing and Materials ("ASTM") standards, and injection molding of various plastic articles. Regarding polymers and plastic articles made from polymers, he specializes broadly in materials testing and commercial development. He has also held leadership positions on ASTM committees, including vice-chair of the ASTM committee related to ESCR testing of plastics, and including ESCR testing standards. Defendants do not appear to contest the existence of these qualifications, but contend that they do not render him qualified to opine about ESCR testing.

filed because one skilled in the art would know how to select the appropriate molding conditions and parameters to manufacture injection molded tubes. See Rubinstein Reb. Rep. (#193-14) at ¶¶79-95, 162-66. Defendants contend that Dr. Rubinstein is not an expert when it comes to injection molding and that he is not qualified to offer any opinions as to how injection molded tubes are made. They contend that he simply relied on Professor Driscoll-Viva's other expert-for injection molding expertise and then failed to disclose such reliance in his expert report. Defendants also take issue with the fact that Dr. Rubinstein's opinion on use of antiblock agents makes no mention of Professor Driscoll or any information provided by him. Dr. Rubinstein then stated at his deposition that the information was provided by Professor Driscoll. Defendants argue that the alleged failure to disclose the basis and reasons for an opinion, as well as the facts and data considered to arrive at it, amounts to a violation of Fed. R. Civ. P. 26 that merits exclusion under Rule 37.

Plaintiffs respond that Dr. Rubenstein properly relied on factual information about injection molding from Professor Driscoll, and that it was routine and in conformance with Fed. R. Evid. 703 because "[e]xperts routinely rely upon other experts hired by the party they represent for expertise outside their field." Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., 807 F.3d 1283, 1303 (Fed.Cir.), reh'g en banc denied in part, 805 F.3d 1382 (Fed. Cir.2015) (quoting Apple Inc. v. Motorola, Inc., 757 F.3d 1286, 1321 (Fed.Cir.2014)). Plaintiffs maintain that Professor Driscoll is an expert in injection molding and to the extent that Defendants challenge Dr. Rubinstein's reliance on his work, that is fodder for cross-examination. Plaintiffs also argue Dr. Rubinstein did, in fact, disclose his reliance on Professor Driscoll in his report, and note that Dr. Rubinstein listed "conversation with Driscoll" in an exhibit attached to his report listing the documents and things considered in preparing his own expert report. See (#193-14) at p. 98.

[11, 12] As to Dr. Rubinstein's opinions on enablement, the court finds no reason to exclude them under Daubert or Fed. R. Evid. 702, as he meets both parties' definitions of a "person of ordinary skill in the art," see, e.g., Rubinstein Rep. (#193-11) at ¶23; Osswald Rep. (#157) at ¶37, and has offered opinions that are both reliable and relevant. However, to the extent that Defendants challenge Rubinstein's experience, or alleged lack thereof, with injection molding, the court finds such material to be ideal for exploration on cross-examination. Regarding Defendants' argument that Dr. Rubinstein improperly relied on Professor Driscoll in formulating his opinions, the court has reviewed the paragraphs cited by Defendants and find that they appropriately cite the source of information for his opinions and are otherwise in conformance with Fed. R. Evid. 703. Additionally, the expert report discloses the fact that Dr. Rubinstein relied on "conversations with Stephen Driscoll" and Professor Driscoll's expert report, which the court finds to be sufficient disclosure for the purposes of Fed. R. Civ. P. 26. As such, the court need not consider whether the opinions are subject to exclusion pursuant to Fed. R. Civ. P. 37.

b. Infringement

[13] Defendants also move to exclude any opinion by Dr. Rubinstein that CTL infringes the '318 Patent because the polymers used in CTL's tube manufacturing process are "compatible polymers," as described in the patent. Defendants claim that Dr. Rubinstein failed to disclose in his expert report that to arrive at that opinion he called polymer manufacturers to ask them whether their polymers are "compat-

ible." They argue that not only is that a violation of Rule 26, but that the opinion derived therefrom is not reliable because Dr. Rubinstein has no recollection of how he defined "compatible" in his conversations, which manufacturers he called, who he talked to, what he asked them, or what answers they gave. They contend that he admits to not being able to recall the basic details he learned from those conversations.

Plaintiffs contend that exclusion is inappropriate because Dr. Rubinstein makes clear that he did not base his opinions on those phone calls alone, but to "double check" the opinion he had already come up with based on the business records of the polymer manufacturers cited in his opening report. See Rubinstein Dep. (#244-8) at Tr. 190:6-19. Plaintiffs contend that Defendants were on notice of the fact that Dr. Rubinstein relied on such business records, and that such reliance is common in the field.

The court has considered the arguments and relevant evidence before it. Again, the court finds that the issues at hand present excellent material for cross-examination, but that exclusion of Dr. Rubinstein's infringement opinions is inappropriate despite the arguments provided by Defendants.

c. Indefiniteness

[14] Finally, Defendants move to exclude the opinion of Dr. Rubinstein that the '318 Patent is not indefinite because one of ordinary skill in the art would know that a "compatible polymer," as referred to in the '318 Patent, is homogeneous and one that remarkably improves clarity when blended with the other polymers in the blend. But Defendants claim that the basis for that opinion is a conversation with the inventor, Ian Jacobs, that occurred after opening and rebuttal reports were submitted—thus the basis is not included therein—and select portions of Jacobs

cobs' deposition transcript where he "explained" certain statements in the Patents-in-Suit. Defendants argue that to avoid a finding of indefiniteness under Section 112(2), a patent must allow any individual of skill in the art to know whether a product infringes the patent claims or not—the inquiry is not limited to individuals such as Dr. Rubinstein who had access to the inventor in order to "verify" the statements Jacobs made in his confidential deposition.

Plaintiffs respond that they could not have disclosed the existence of a conversation before it happened, that Dr. Rubinstein's opinion is based on the court's claim construction, and that the theory that he sought a basis for his opinion after forming it is completely unfounded. They also argue that the conversation occurred in response to an untimely opinion by Dr. Osswald (Defendants' expert). Having considered the record, the court finds Defendants' arguments unpersuasive on this issue. The fact that Dr. Rubinstein called Mr. Jacobs after he submitted his expert reports in no way affects the reliability of those opinions. The court will therefore deny Defendants' Motion in that regard.

3. Plaintiffs' Motion to Exclude Certain Purported Expert Testimony of Tim Osswald and Mukerrem Cakmak

Pursuant to <u>Daubert</u> and Fed. R. Evid. 702, Plaintiffs move to preclude Tim Osswald and Mukerrem Cakmak, who have been proffered as expert witnesses by Defendants, from offering invalidity opinions regarding the term "compatible polymer" of the '318 Patent because such opinions disregard the court's claim construction.

The Claim Construction Order in this case construed the disputed terms of the patents-in-suit. Regarding the term "high melt flow compatible polymer" of the '318 patent, the Court ruled that the term means "the high melt flow polymer of the

polymer blend that is compatible with the 'at least one polymer.' "See Claim Construction Order (#109) at p. 26. Defendants did not propose a construction of this term, but merely relied on indefiniteness arguments. Id. Though the court did not adopt a specific claim construction of "compatible" because neither party proposed one, the court noted in the context

of construing the disputed claim term:

extrinsic evidence also indicates that "compatible polymer" is a term of art in the field meaning the "tendency of different polymers or different grades of a given polymer to mix uniformly or homogeneously and not separate into discrete phases." Nothing in the intrinsic record indicates that "compatible" is used in a manner contrary to this plain and ordinary meaning. The court also notes that the patent requires that the "at least one polymer" and the "at least one high melt flow compatible polymer" be compatible with one another. There is no dispute that "compatible" is a relative term used in the field to denote that a specific polymer can be mixed uniformly with some polymers, but not with others. Most polymers are not compatible with one another and testing is typically required to determine compatibility. As such, common sense dictates that the court construe the term to mean that the polymers taught in the blend be compatible with one another. The court will therefore construe the term to mean "the high melt flow polymer of the polymer blend that is compatible with the 'at least one polymer."

Id. at 27 (internal citations omitted).

Plaintiffs argue that Defendants' invalidity contentions submitted after claim construction refused to apply the court's adopted claim construction of "compatible polymer." See, e.g., Invalidity Charts (#141-6) at K-2, L-2, M-3-M-4. They further argue that Defendants' experts Drs. Cakmak and Osswald inappropriately sub-

stitute their own definitions of "compatible polymer" for the one stated by court Order. Dr. Cakmak, who is a professor of Polymer Engineering in the Polymer Engineering Department of the College of Polymer Science and Polymer Engineering at the University of Akron, has offered opinions in his expert report as to whether the patents-in-suit are invalid due to indefiniteness and whether the '318 patent is invalid as anticipated. Dr. Cakmak states several times in his report that he disagrees with the court's claim construction of "compatible polymer," comes up with his own meaning of the term, and then applies that in his report. See, e.g., (#194-Exhibit D) at ¶84 ("As an initial matter, I do not agree that 'compatible polymer' is a term of art in the field meaning the "tendency of different polymers or different grades of a given polymer to mix uniformly or homogeneously and not separate into discrete phases.") (citing Claim Construction Order at 27); id. ("The definition adopted by the Court is also inconsistent with the fact testimony that occurred after the claim construction hearing, including...depositions...and documents produced in this case. It is also inconsistent with the IUPAC definition..."). Notably, Dr. Cakmak states in his report that "'compatible' ... is an industry term used to refer to a polymer that can be blended with others and result in a good saleable product," id. at ¶ 92, and then bases all of his opinions regarding "compatible polymer" in the '318 patent claims on this alternative definition. Id. at ¶¶ 92-100.

Dr. Tim Osswald, another of Defendants' experts, is a Professor in the Department of Mechanical Engineering at the University of Wisconsin-Madison. He also states in his invalidity opinions on the '318 patent that he rejects the court's construction of the term "compatible polymer" of the '318 patent. See, e.g., Osswald Rep. (#193-5) at ¶141 ("I have reviewed

Dr. Cakmak's Report, which concludes that the 'high melt flow compatible polymer' in the '318 Patent is indefinite. I agree with this conclusion that the term 'compatible' as used there is vague, ambiguous, and ill-defined and thus does not permit those skilled in the art to know, with reasonable certainty, whether they are within the scope of the claims."); id. at ¶156 ("I have reviewed the testimony of Ian Jacobs and understand he testified that a polymer is 'compatible' (as used in the '318 Patent) with the at least one polymer if it improves a number of characteristics of the neat polymers as seen in the finished product (the tube). Thus, the '318 Patent requires one of skill in the art to create an enormous number of polymer blends (with a vast range of possible percentages for each polymer), mold them into tubes, and then apparently determine whether that tube shows 'improved properties' as compared to a tube made from the neat 'at least one polymer' (which can be two or more polymers)."); Osswald Rep. (# 156-3, Exs. I, J, K, L, M) ("As stated in [] my report, I have reviewed [Dr. Cakmak's] expert report and agree with his conclusions....For purposes of this analysis, compatibility shall mean similarly compatible to the examples of the '318 patent.").

Defendants argue that Plaintiffs are now attempting to exclude testimony about the very issue that they contended required more discovery—the issue of indefiniteness. They argue that expert discovery provided additional insight into the meaning of "compatible" that should be considered by the court. They also note that neither party proposed a definition of "compatible" at claim construction, and that the court adopted a "plain and ordinary" meaning of compatible.

[15] Regarding the applicability of claim construction to a patent proceeding, the Federal Circuit has held that "[o]nce a

district court has construed the relevant claim terms, and unless altered by the district court, then that legal determination governs for purposes of trial. No party may contradict the court's construction to a jury." Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1321 (Fed.Cir. 2009). District courts routinely exclude expert opinions that are inconsistent with claim construction. See, e.g., Callpod, Inc. v. GN Netcom, Inc., 703 F.Supp.2d 815, 821-22 (N.D.Ill.2010) ("Expert opinions that conflict with a court's established claim construction tend only to create confusion and are thus unhelpful to the jury.") (citing CytoLogix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1173 (Fed.Cir. 2005)); Cook Inc. v. Endologix, Inc., No. 1:09-CV-01248-TWP, 2012 WL 3886204, at *3 (S.D.Ind. Sept. 6, 2012), on reconsideration in part on other grounds, No. 1:09-CV-01248-TWP, 2012 WL4755361 (S.D.Ind. Oct. 4, 2012). Defendants may not use expert testimony as a means to contradict the claim construction set forth by the court.

[16] Here, "compatible polymer" is not one of the six terms existing in the patents-in-suit that the court was asked to construe. See (#84) at p. 2 (setting forth the proposed list of disputed claim terms). While "compatible polymer" is clearly a component of the term "high melt flow compatible polymer," which the court was asked to construe, it was not, in and of itself, a disputed claim term. However, the court considered the meaning of the phrase as it exists in the patent, and made a ruling as to its meaning based on the parties' contentions and the evidence before it. To the extent that Defendants argue that the court's findings on the meaning of "compatible polymer" are dicta, the court disagrees. The court will not allow expert testimony on the meaning of "compatible polymer" that conflicts with the

court's findings, as such testimony can only serve to complicate the issue in an already complicated case. Neither party has asked the court to reconsider the construction of the disputed claim term or proposed any additional terms for construction. The court will not reassess its earlier finding as to the construction of "high melt flow compatible polymer" or any term therein without being moved to do so.

While the court will not allow any expert testimony to be admitted that conflicts with its claim constructions or other findings, it is reluctant to exclude all indefiniteness opinions of Drs. Osswald and Cakmak relevant to the '318 Patent, which is what Plaintiffs seek. Thus, to the extent that Defendants wish to introduce their expert opinions on the matter at trial that conflicts with this court's prior Order, such testimony shall be excluded. However, Defendants are entitled to present expert opinion evidence on indefiniteness to the extent that it does not conflict with the court's previous rulings. The Court will thus GRANT in part and DENY in part Plaintiffs' Motion to Exclude Certain Purported Expert Testimony of Tim Osswald and Mukerrem Cakmak, as explained herein.

4. Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith

Plaintiffs move pursuant to Fed. R. Civ. P. 37(c) to exclude proffered expert opinions of Cynthia Smith regarding the '094 Patent, arguing that such opinions rely on testing that was not timely disclosed to Plaintiffs. They also move to exclude the opinion as unreliable under <u>Daubert</u>. In support of their invalidity contentions, namely that the '094 patent ESCR test renders the asserted claims of that patent invalid because that claim element is purportedly (a) indefinite due to variability of its results, and (b) taught by prior art

references, Defendants rely in part on the expert opinions of Ms. Smith included in her November 2015 report.

Plaintiffs claim that Defendants failed to disclose the details of the sample preparation for the ESCR test despite their considering this information and making repeatedly clear that it is fundamental to understanding and evaluating the probative value of the testing at issue. Plaintiffs also argue that Defendants failed to disclose certain of the test results at all or in a timely manner and blocked legitimate requests for fact discovery regarding such testing details. Plaintiffs maintain that all of this undisclosed information was explicitly considered by Ms. Smith in forming her opinions relating to the '094 patent and is key to evaluating the credibility of her opinions, which plaintiffs were denied the opportunity to do.

Regarding reliability, Plaintiffs contend that Ms. Smith's opinions should be excluded because she failed to provide, and Defendants blocked discovery of, the practiced ESCR Testing. They argue that she did not provide sufficient information to allow other scientists to reproduce the various tubes she tested. Thus, Plaintiffs contend that the testing and results on which she bases all her opinions cannot be independently verified by other scientists. Plaintiffs also complain that Ms. Smith failed to provide any raw data recording her purported contemporaneous observations of the ESCR testing and that she relies on only one test (instead of multiple) in rendering her opinion, which Plaintiffs argue is bad science. They also argue that she did not test enough strips and that she improperly used a microscope in combination with fiber optic lighting to determine cracking, as opposed to just naked eye observation.

As discussed at the hearing, the court believes that it has already fashioned an appropriate remedy to the parties' dispute here by allowing additional discovery, including depositions for Ms. Smith and a 30(b)(6) representative of Tuboplast, on the subject of how the injection-molded articles were made and tested, which would include questions about Tuboplast's sample tube production that arise out of any newly produced documents and/or testimony from Tuboplast's 30(b)(6) representative. See (#309). The court believes that Plaintiff's Motion to exclude the testimony of Ms. Smith is now moot and will therefore be **DENIED** without prejudice.

5. Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith and Tim Osswald

Finally, Plaintiffs move to exclude testimony from Ms. Smith and Mr. Osswald about '094 Patent invalidity that rely on two prior art references which Plaintiffs argue were not timely disclosed—Capilene QT 80A and PPC 9760, which Plaintiffs characterize as polymer data sheets. See (#208). Pursuant to Local Patent Rules, on February 24, 2014, Defendants submitted their invalidity contentions, which were to disclose "each item of prior art that allegedly anticipates" or renders obvious the asserted claims of the patents-in-suit. See Defs.' Initial Invalidity Contentions (#161-3) at 4-6. Plaintiffs argue that Defendants' contentions, however, did not disclose two prior art references—the polymers Capilene QT 80 and PPC 9760—relied on by their experts, and that Defendants again failed to disclose them when they amended their invalidity contentions in May 2015 and for a second time in February 2016.

The opening report of Ms. Smith (who opines on whether the '094 Patent is invalid due to indefiniteness) reveals that in May 2015, and again in October 2015, upon Defendants' instruction, Ms. Smith performed ESCR testing on Capilene QT 80 and PPC 9760 that was intended to support Defendants' invalidity theories based

on these references. See Smith Rep. (#211) at Ex. D, ¶¶ 34, 49, 80-96. Dr. Osswald, who opines on the invalidity of the '094 patent on the grounds of indefiniteness and lack of enablement, advances invalidity theories based on these references and by explicitly relying on Ms. Smith's conclusions based on her testing of the materials discussed in the references. See Osswald Rep. (#193-5) at ¶¶ 106-07, 110-11, 115, 121.

Plaintiffs argue that Defendants withheld this information and only revealed it when they served their opening expert reports on November 9, 2015, long after fact discovery had closed and they sought information under relevant interrogatories. They argue that this is a violation of local patent rules, see P.R. 3.3-3.4 (requiring that a party alleging invalidity must identify "each item of prior art that allegedly anticipates each asserted claim or renders it obvious" in its invalidity contentions), as well as Fed. R. Civ. P. 26(a)(2) and 37. Plaintiffs argue that they are prejudiced through the delayed disclosure because they were deprived of the opportunity to obtain meaningful discovery regarding these prior art references before the close of fact discovery. Plaintiffs also argue that they were likewise unable to timely develop rebuttal expert opinions and that there is no available means for Defendants to "cure" their repeated failure to amend their contentions without placing undue burden on Viva's ability to defend against Defendants' invalidity counterclaims. They note that allowing Defendants to continue to rely on these references would require reopening of fact and expert discovery to permit Viva to develop its defense theories, which would require Viva to redirect time and resources to this issue instead of trial preparation.

[17] Defendants argue that they have not run afoul of any rules, and that they

timely disclosed the prior art references in February 2014 when they first served its invalidity contentions. Defendants argue that Capilene and PPC are not prior art references and have not been asserted as prior art references by CTL or its experts, but that they are mere examples of polymers disclosed in their prior art references (Jacobs and Anon). Defendants argue that in order to confirm that polymers falling within the range of the characteristics taught in the Prior Art References would pass the '094 Patent's ESCR test when injection molded, Dr. Osswald identified Capilene and PPC in September 2015 as examples falling within the scope of the References and found that they were commercially available in their current form prior to the priority date for the '094 Patent. Then, in doing her testing, Ms. Smith requested from Tuboplast in Spain (which had been doing preliminary ESCR testing) injection mold samples—using the same high sheer, long flow injection molding process—from Capilene and PPC for ESCR testing.

Ms. Smith then conducted the ESCR test of the '094 Patent on the Capilene and PPC samples (and others) in October 2015 and determined that tubes made with these polymers meet the ESCR levels claimed in the '094 Patent. Based on these results-and because both Capilene and PPC were commercially available at the time of the Prior Art References (and before the priority date of the '094 Patent)-Dr. Osswald concluded that CTL's invalidity theories were confirmed: the Prior Art References render the '094 Patent invalid as obvious because they teach injection molding of polymers that meet the claim limitations of having an "ESCR as herein defined."

Defendants also argue that Viva had full knowledge of CTL's invalidity theories based on the range of polymer types taught in the Prior Art References for two years—since February 24, 2014, when CTL served its OIC and accompanying claim charts. They also note that Viva did not ask CTL's fact witnesses any questions about prior art or CTL's invalidity contentions during depositions. To the extent Viva required information regarding how Tuboplast injection molded the Capilene and PPC tube samples that Ms. Smith used in her October 2015 ESCR testing, Defendants contend that Viva received considerable information from Tuboplast's and CTL's 30(b)(6) witnesses on the injection molding process that was used. They also argue that they fully complied with the disclosure requirements for expert reports and that Plaintiffs had time to respond and prepare for depositions. They also note that Plaintiff did not attempt to conduct its own testing to confirm or undermine Ms. Smith's findings.

Having considered the parties' arguments, the court will not exclude any of the opinions challenged by Plaintiffs in the instant motion. However, if Plaintiffs wish to request any additional discovery related to the issues raised herein, they may propose (by motion) a specific list of the discovery to which they believe they are entitled for the court's consideration. The court will therefore **DENY** Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith and Tim Osswald.

C. Conclusion

For the reasons stated at the hearing, as well as those stated herein, the court will **DENY** the Motions of the parties as to exclusion of expert testimony. The court believes that all of the issues raised by the parties can be dealt with on cross-examination at trial, except as specifically stated otherwise herein.

III. SUMMARY JUDGMENT MOTIONS

A. Legal Standard

Summary judgment shall be granted "if the movant shows that there is no genuine

dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A fact is material only if it might affect the outcome of the suit under governing law. Id. The movant has the "initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) (internal citations omitted). Once this initial burden is met, the burden shifts to the nonmoving party. That party "must set forth specific facts showing that there is a genuine issue for trial." Id. at 322 n. 3, 106 S.Ct. 2548. The nonmoving party may not rely upon mere allegations or denials of allegations in his pleadings to defeat a motion for summary judgment. Id. at 324, 106 S.Ct. 2548. Instead, that party must present sufficient evidence from which "a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248, 106 S.Ct. 2505; accord Sylvia Dev. Corp. v. Calvert Cnty., Md., 48 F.3d 810, 818 (4th Cir.1995).

When ruling on a summary judgment motion, a court must view the evidence and any inferences from the evidence in the light most favorable to the nonmoving party. Anderson, 477 U.S. at 255, 106 S.Ct. 2505. "'Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial.'" Ricci v. DeStefano, 557 U.S. 557, 586, 129 S.Ct. 2658, 174 L.Ed.2d 490 (2009) (quoting Matsushita v. Zenith Radio Corp., 475 U.S. 574, 587, 106

S.Ct. 1348, 89 L.Ed.2d 538 (1986)). In the end, the question posed by a summary judgment motion is whether the evidence "is so one-sided that one party must prevail as a matter of law." Anderson, 477 U.S. at 252, 106 S.Ct. 2505.

B. Invalidity

[18-20] A patent is presumed valid upon issuance from the United States Patent and Trademark Office, and the "burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. Overcoming this presumption requires the party seeking to invalidate a patent to prove invalidity by clear and convincing evidence. Microsoft Corp. v. I4I Ltd. P'ship, 564 U.S. 91, 95, 131 S.Ct. 2238, 180 L.Ed.2d 131, (2011). This standard applies at the summary judgment stage. Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1378 (Fed.Cir.2005). Thus, in order to prevail at the summary judgment stage, the party seeking summary judgment on the issue of patent invalidity "must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed.Cir. 2001). A patent is invalid if it is indefinite, see 35 U.S.C. § 112(b), cannot be enabled, see id. § 112(a), or if it was anticipated by prior art, see id. § 102. Regarding summary judgment on a motion for patent invalidity, if the decisive determination of invalidity depends on resolution of material factual differences, then summary judgment is inappropriate. See Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052, 1071 (Fed.Cir.2005).

C. Discussion

1. Defendants' Motion for Summary Judgment as to Indefiniteness

Defendants first move for summary judgment on the defense that the patent is invalid because it is indefinite.

a. Legal Framework

[21] The Patent Act of 1952 requires that a patent specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). A lack of definiteness renders the patent or any claim in suit invalid. Id. § 282(b)(3). The Supreme Court set forth a new standard for indefiniteness under § 112 in Nautilus, Inc. v. Biosig Instruments, Inc., — U.S. —, 134 S.Ct. 2120, 189 L.Ed.2d 37 (2014), providing that a patent is invalid for indefiniteness if its language, read in light of the specification and prosecution history, "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Id. at 2124. The Court set forth this standard in order to address the "delicate balance" of the definiteness analysis. Id. at 2128 (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 731, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002)). The definiteness standard must acknowledge "the inherent limitations of language" and "must allow for a modicum of uncertainty" to provide incentives for innovation, but must also require "clear notice of what is claimed, thereby appris[ing] the public of what is still open to them." Id. at 2128-29 (internal citations omitted). The Court noted that "absent a meaningful definiteness check...patent applicants face powerful incentives to inject ambiguity into their claims." Id. at 2129.

[22] Under this standard, a patent does not satisfy the definiteness requirement of § 112 merely because "a court can ascribe some meaning to a patent's claims." Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1369 (Fed.Cir.2014) (quoting Nautilus, 134 S.Ct. at 2130). Rather, "the claims, when read in light of the specification and the prosecution history,

must provide objective boundaries for those of skill in the art." Id. See also Nautilus, 134 S.Ct. at 2130 & n. 8 (indicating that there is an indefiniteness problem if the claim language "might mean several different things and 'no informed and confident choice is available among the contending definitions'") (quoting Every Penny Counts, Inc. v. Wells Fargo Bank, N.A., 4 F.Supp.3d 1286, 1291 (M.D.Fla.2014)). The Court's decision "emphasizes 'the definiteness requirement's public-notice function." Dow Chem. Co. v. Nova Chemicals Corp. (Canada), 803 F.3d 620, 630 (Fed. Cir.2015) (quoting Nautilus, Inc., 134 S.Ct. at 2130).

Every issued patent enjoys a statutory presumption of validity. 35 U.S.C. § 282. The burden of establishing invalidity of a patent or any of its claims rests on the party asserting invalidity. Id. Governing law "requires patent challengers to prove invalidity by clear and convincing evidence." Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1367 (Fed.Cir.2002). See also Nautilus, 134 S.Ct. at 2130 n. 10 (citing Microsoft Corp. v. i4i Ltd. Partnership, 564 U.S. 91, 131 S.Ct. 2238, 2242, 180 L.Ed.2d 131 (2011)); (Teva Pharms. USA, Inc. v. Sandoz, Inc., 723 F.3d 1363, 1368 (Fed.Cir. 2013)).

[23–26] "In ruling on a claim of patent indefiniteness, a court must determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Bancorp Servs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed.Cir.2004). While indefiniteness is a question of law, it requires underlying factual determinations as to what one skilled in the art would have understood at the time. See BJ Servs. Co. v. Halliburton Energy Servs., Inc., 338 F.3d 1368, 1372 (Fed.Cir.2003) ("definiteness...is amenable to resolution by the

jury where the issues are factual in nature.") (noting conflicting evidence presented by the parties' experts at trial); Teva Pharm. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1348 (Fed.Cir.2015) (Mayer, J.) (dissenting); Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed.Cir.1986). Moreover, where, as here, "expert evidence addressing what one skilled in the art would have understood by looking at [the] patent is in conflict," summary judgment is inappropriate. See WesternGeco L.L.C. v. ION Geophysical Corp., 876 F.Supp.2d 857, 872 (S.D.Tex. 2012); Bancorp Servs., 359 F.3d at 1375-76 (reversing summary judgment of invalidity for indefiniteness because the experts disagreed on whether a term was indefinite); Masimo Corp. v. Philips Elecs. N. Am. Corp., No. CV 09-80-LPS, 2015 WL 7737308, at *6 (D.Del. Dec. 1, 2015) ("Plaintiff has also submitted an expert declaration...which (at minimum) shows a genuine dispute of material fact preventing the Court from granting summary judgment of invalidity due to indefiniteness"): Dow Chem. Co. v. NOVA Chemicals Corp. (Canada), 629 F.Supp.2d 397, 404 (D.Del. 2009) (collecting cases as to district court denials of summary judgment on indefiniteness where questions of fact remained for the jury to resolve). Regarding expert testimony at the summary judgment stage, a moving party may provide support for such motions by submitting affidavits from fact and expert witnesses, so long as such evidence is necessary to support summary judgment in patent cases where the technology is not "easily understandable without" expert's explanatory testimony. Centricut, LLC v. Esab Grp., Inc., 390 F.3d 1361, 1369 (Fed.Cir.2004). The nonmoving party may oppose summary judgment based on expert testimony by pointing "to an evidentiary conflict created on the record at least by a counter statement of fact or facts set forth in detail in an affidavit by a knowledgeable affiant. Mere denials or

conclusory statements are insufficient."

Barmag Barmer Maschinenfabrik AG v.

Murata Mach., Ltd., 731 F.2d 831, 836
(Fed.Cir.1984).

b. Discussion

[27] The court has previously expressed concern about the potential indefiniteness of the patents-in-suit, noting at the claim construction stage of the proceedings:

in light of the fact that these patents do indeed claim broadly, and that CTL's expert witnesses testified that they were unable to ascertain the scope of the patents with reasonable certainty, the court is troubled by the question of how members of the public are able to determine whether they are infringing upon these patents. While the court requires more evidence before making a final decision on invalidity, it is cognizant of the powerful incentives for patent applicants to inject ambiguity into their claims, and will continue to consider what, if anything, these patents have left open to the public.

See (#109) at p. 12 (internal citation and quotations omitted). However, the court found that Defendants had not shown invalidity by clear and convincing evidence at the claim construction stage and that the parties and court would benefit from the completion of discovery before rendering a decision on the issue. Id. Now that discovery has been completed and the parties have fully briefed their legal arguments, the issue before the court is whether Defendants have shown, by clear and convincing evidence, whether one skilled in the art can ascertain the scope of the claim with reasonable certainty.

Defendant argues that discovery has confirmed that the patents-in-suit are indefinite. Generally, they argue that the patents state a desired outcome, but fail to explain how to reach that outcome, which leaves the public in the dark as to what the patent protects. They contend that the ESCR test uses subjective criteria that are insufficient to inform one skilled in the art what the patent protects.

Defendants first argue that the '094 Patent is indefinite due to its reliance on "an ESCR as herein defined." This court construed that term at claim construction as "The ESCR test as defined in column 2, line 62 through column 3, line 13 of U.S. Patent No. 6.547.094." The patent defines a method for determining ESCR, but Defendant argues that it fails to provide parameters which can be followed, fails to narrow the number of potential "polymer blends" that would have to be tested, and thus fails to accomplish its stated purpose. Defendants contend that instead, the '094 Patent simply provides a desired result and purports to claim all blends that achieve this result without providing any concrete guidance as to how to achieve it. They contend that it fails to inform a person of skill in the art at the time of the '094 Patent application how to conduct the test in a way that would determine whether a given polymer blend falls within the scope of the invention with reasonable certainty. Defendants further contend that the failure to define a particular stress crack agent makes the ESCR test impossible to duplicate. The specification lists several possible stress crack agents, such as "mineral oils, cationic surfactants, solvents...which will be apparent to those skilled in the art." Defendants note that Ms. Smith tested two stress crack agents against injection-molded tubes; one failed but one did not. Defendants argue that those tests demonstrate that the choice of stress crack agent affects whether a polymer blend falls within or outside of the scope of claims.

Defendants also contend that the failure to specify molding conditions and postmolding treatments make the ESCR indefinite. Regarding post-molding treatments, the patent requires that the test strips "[incorporate] any post-molding treatment intended for the final article." ('094 Patent, 2:64-65). Defendants argue that Plaintiff's expert admitted that molding conditions affect ESCR properties. Defendants argue that the patent thus attempts to cover "whatever you make and however you make it." Defendants also argue that the vast number of "polymer blends" would have to be tested with vast numbers of "ESCR as herein defined" parameters, which makes the possibilities for testing astronomical. Finally, Defendants also argue that Claims 11-19 and 21 of the '094 Patent are indefinite due to their reliance on "compatible agent" as part of the polymer blend. Defendants argue that it is a subjective, undefined term that makes it impossible for one skilled in the art to ascertain how to act on the patent.

Regarding the '318 Patent, Defendants argue that it is indefinite due to its reliance on "High-Melt Flow Compatible Polymer." This court construed that term at claim construction to mean "the high melt flow polymer of the polymer blend that is compatible with the 'at least one polymer." Essentially, Defendants argue that whether an agent or polymer is "compatible" is a subjective determination that does not allow one skilled in the art to ascertain the scope of the patent. Defendants argue that its experts have repeatedly opined that "compatible polymer" fails to give any sort of meaning that could be interpreted by one of skill in the art.

Plaintiff argues that the motion should be denied because Defendants have failed to show a lack of any disputed issue of material fact, that they have failed to meet their burden, and that contradicting expert testimony on this issue renders this matter appropriate for a jury, not summary judgment. Plaintiffs cite their own expert's testimony, which does indeed contradict the testimony of Defendants' experts on each and every point made by Defendants.

For example, as to "an ESCR as herein defined" in the '094 Patent, Defendants' expert Ms. Smith opines that various aspects of the patent render that claim term indefinite. See Smith Rep. (#193-7) at ¶¶80-94 ("In light of my review of the '094 Patent, its prosecution history and specification, and the data and other information set forth in Exhibit B hereto, together with my knowledge of how such terms are used by a person having ordinary skill in the art, the term 'an ESCR as herein defined,' as it appears in claims 1, 5-7, and 11 of the '094 Patent and as construed by the Court in the Claim Construction Order, does not inform those skilled in the art about the scope of the invention with reasonable certainty."); Osswald Reb. Rep. (#193-6) at ¶1 (agreeing with Smith's indefiniteness opinion). On the other hand, Professor Driscoll-one of Plaintiff's experts—opines in his report that such claim is not indefinite. See Driscoll Reb. Rep. (#193-9) at ¶¶ 71-99. Both experts offer thorough and credible analyses as to their opinions. While the court has ordered additional discovery as to Ms. Smith's opinions on the matter, it has not excluded any testimony. As such, the court finds that the credibility of the experts and the factual determinations to be deciphered from their testimony are issues that cannot be resolved by this court, but are proper for resolution by a jury.

Similarly, as to "At Least One Compatible Agent" in the '094 Patent, Defendants' experts Cakmak and Osswald offer opinions that such claim is indefinite. See, e.g., Cakmak Rep. (#193-3) at ¶¶ 78-83; Osswald Rep. (#193-5) at ¶55; Osswald Reb. Rep. (#193-6) at ¶42. Plaintiffs' expert Dr. Rubinstein opines that the term is not indefinite. See, e.g., Rubinstein Reb. Rep.

(#193-14) at ¶¶ 54–58. Finally, regarding the "high melt flow compatible polymer" claim limitation of the claims of the '318 patent, Defendant offers expert testimony from Dr. Cakmak and Dr. Osswald that the term is indefinite. See, e.g., Cakmak Rep. (#193-3) at ¶¶92-100; Osswald Rep. (#193-5) at ¶¶141-42. On the other hand, Dr. Rubinstein opines that it is not indefinite. See, e.g., Rubinstein Reb. Rep. (#193-14) at ¶¶ 142-47. Once again, the court is faced with expert testimony that offers sharply contrasting opinions. While the court has ruled that to the extent that Defendants' expert testimony conflicts with this court's claim construction Order, such opinions are excluded, the court has also allowed other testimony on indefiniteness from Defendants' experts to be introduced.

Although indefiniteness is a question of law, resolution of that question requires a factual determination as to what one skilled in the art would have understood by looking at the patent. Here, the expert evidence addressing what one skilled in the art would have understood about the scope of the invention when considering the patents-in-suit is in conflict. Thus, Defendants have failed to prove indefiniteness by clear and convincing evidence. As such, the determination of the factual questions underlying this legal issue must be made by a jury, and the court will therefore **DENY** without prejudice Defendants' Motion for Summary Judgment as to Indefiniteness.

2. Defendants' Motion for Summary Judgment as to Lack of Enablement

Defendants also move for summary judgment on the defense that the patent is invalid because it lacks enablement. Its arguments parallel those on indefiniteness, essentially contending that the Patents-in-Suit do not teach one skilled in the art how

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to (1) select polymers that are capable of (2) (a) passing the ESCR test ('094 Patent) or (b) being compatible with the other polymers (both patents); (3) being injection-molded; and (4) removed from the mold—even though each and every one of these steps is required by the claims.

a. Legal Framework

[28, 29] Under 35 U.S.C. § 112, the patent specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains...to make and use the same." Id. To be enabling, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365 (Fed.Cir.1997) (internal quotation marks and citations omitted). Undue experimentation is required "when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out." Id. at 1366. "While every aspect of a generic claim" certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." Id. "It is well-established, however, that a specification need not disclose what is well-known in the art." Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed.Cir.2012).

[30] A determination of enablement "is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737 (Fed.Cir. 1988). The Federal Circuit has provided several factors that may be utilized in determining whether a disclosure would re-

quire undue experimentation, which are referred to as the "Wands factors":

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.; accord Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1378 (Fed. Cir.2009). A court need not review all the Wands factors to find a disclosure enabling, but only those that are relevant, because the factors "are illustrative, not mandatory." Streck, 665 F.3d at 1288 (citing Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed.Cir.1991)).

(31) The determination of enablement is a question of law based on underlying factual inquiries. See Green Edge Enters., LLC v. Rubber Mulch Etc., LLC, 620 F.3d 1287, 1298–99 (Fed.Cir.2010) (citation omitted); Wands, 858 F.2d at 737. Enablement is determined as of the filing date of the patent application. In re '318 Patent Infringement Litigation, 583 F.3d 1317, 1323 (Fed.Cir.2009) (citation omitted). As noted above, "[b]ecause patents are presumed valid, lack of enablement must be proven by clear and convincing evidence." ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed.Cir.2010).

b. Discussion

As the moving party, Defendants bear the burden of producing evidence to demonstrate that the specification of the patents-in-suit do not enable one skilled in the art to practice the invention. Defendants first argue that the patents-in-suits require undue experimentation to select polymers or polymer blends for use in the manufacturing of injection molded tubes.

They argue the selection forces one of ordinary skill in the art to: (1) engage in perpetual research and development to practice the full scope of the claims; (2) that it is only a starting point for research; and (3) that the Plaintiff's experts are improperly attempting to fill in gaps left by the patent through the current litigation. Next, they argue that undue experimentation is required to manufacture the tubes because: (1) they fail to teach molding conditions; (2) they fail to teach the required step of "demolding;" (3) that the claims lack any meaningful disclosure; and (4) that the examples provided in the patents do not work. They contend that Viva and Mr. Jacobs (the inventor) have attempted to claim all potential current and future polymers and polymer blends as within the scope of the patents, and that the patents-in-suit force one of ordinary skill in the art to engage in perpetual research and development to practice the full scope of the claims. Defendants largely rely on the statements of their expert Dr. Osswald in making their arguments that the patents-in-suit lack enablement. See, e.g., Osswald Rep. (#193-5) at ¶¶ 56-90, 141-74 (explaining the basis for his opinion that the patents-in-suit would require undue experimentation). They also argue that Ian Jacobs' deposition testimony, which the court partially observed via video at the hearing, shows that Mr. Jacobs' attempts to cover all potential polymer blends that fit within the scope of the patent, as opposed to teaching one skilled in the art how to manufacture the tubes under the patent.

Plaintiffs, on the other hand, argue that the patents do sufficiently teach how to practice the patent and that Defendants have failed to meet the "clear and convincing" burden. Plaintiffs dispute Defendants' interpretation of expert testimony, as well as the scope of the claims as taught from the patent. Plaintiffs rely on their expert reports opining that the patent sufficiently teaches molding conditions and the "demolding" step, and that the examples in the patents—numbering 26 examples between them—enable the scope of the claims. For example, Plaintiffs argue that the claim limitations of the patents-in-suit limit the scope of claimed polymer blends, citing opinions from Dr. Rubinstein and Professor Driscoll. See, e.g., Rubinstein Reb. Rep (#193-14) at ¶¶71-75, 149-61; Driscoll Reb. Rep. (#193-10) at ¶45. They note that in the '094 Patent, the combina tion of claim limitations—encompassing commercially available polymers that are injection-moldable under long flow/high shear conditions, are flexible, and have the appropriate ESCR—makes the claims much narrower that Defendants contend. Dr. Rubenstein explained, for example, that a person of ordinary skill in the art would typically start by selecting commercially available polymers, of which there are a limited number. See (Rubinstein Reb Rep. (#193-14) at ¶¶ 72, 97). Dr. Rubinstein opined that of those polymers, based on his knowledge and the guidance provided in the patent, he would be restricted to the very narrow subset of polymers that would meet the combination of requirements set forth in even the broadest claims. Id. at ¶¶ 96–101. Only polymers that meet each of the following requirements would be candidates: ability to flow down a long and narrow path (since the claims are limited to injection molded processes for making long, thin-walled flexible articles such as tubes under high shear, long flow length conditions where the flow of polymer is largely monodirectional for greater than 50 mm); flexibility; and those that have good ESCR properties (i.e., having an ESCR value of at least 10 hours) in order to be capable of passing a very stringent ESCR test. (Id.) Dr. Rubinstein opined that each of these requirements alone rules out most of the already-limited number of commercially available polyCite as 197 F.Supp.3d 837 (W.D.N.C. 2016)

mers and that taken together, they leave a very small number of possibilities. (Id.)

For the '318 Patent, Plaintiff argues that the scope of the claims is limited by the requirement that the polymer blend be flexible and capable of flowing so as to be injection molded to form a thin walled article. Id. at ¶¶ 149-61, 168-72. Additionally, Plaintiffs contend that the term "high melt flow compatible polymer," as construed by the court, requires both that the polymer have a high MFI (at least 100 g/10 min) and that it be "compatible" with the "at least one polymer." See Claim Construction Order (#109) at p. 27. Dr. Rubinstein opined that both of the foregoing sets of limitations narrowly limit the universe of polymers that a person of ordinary skill would and could use, since the number of commercially available high MFI polymers for use in the cosmetic industry is low and because most polymers are not compatible with one another. See Rubinstein Reb. Rep. (#193-14) at ¶¶ 149–161, 168–72.

In addition, Plaintiffs argue, citing Dr. Rubinstein's report, that the dependent claims of both patents are even more severely limiting because based on requirements of the claims, they are limited by practical commercial considerations, which restrict the choice of polymers to those polymers that would produce tubes acceptable for use in the cosmetics industry. See id. at ¶ 72, 97, 149. Further, they contend that the scope is additionally limited by the fact that a person of ordinary skill in the art would typically start working with commercially available polymers (and the relative amounts of each of these) identified in one or more of the working examples and by "incrementally modify[ing] the example to suit their needs and preferences." Id. ¶¶ 75, 107, 178.

Plaintiffs also argue that the limitations imposed by the "compatible agent" and "high melt flow compatible polymer" terms further limit the scope of the claims, and

that the many examples taught between the two patents-in-suit rebut Defendants' arguments that the patents-in-suit fail to specify the formulation of suitable polymer blends they claim. Plaintiffs also note that the parties' experts dispute what would constitute routine experimentation in the field. See Osswald Rep. (#193-5) at ¶¶ 56-90; 143-174; 1/5/2016 Driscoll Dep. Tr. (#244) at 102:6-103:4, 97:23-98:10, 99:2-25, 104:19-105:8; Rubinstein Reb. Rep. (#193-14) at ¶¶ 93-114; 167-185.

As to the '318 Patent, Plaintiffs cite expert testimony and other evidence indicating that the patents sufficiently teach molding conditions and the "demolding" step. See, e.g., Rubinstein Reb. Rep. (#193-14) ¶¶ 76-78; 96; 165); 1/5/2016 Driscoll Dep. Tr. (#224) at 72:10-73:8, 89:11-96:4, 68:14-20, 316:13-317:4. They also argue that the examples enable the patent.

[32] (Having considered the evidence and the arguments before it, the court finds that Plaintiffs have raised genuine issues of material fact as to the amount and type of experimentation required, and that those facts that will determine whether such experimentation is undue for one of ordinary skill in the art. These disputed facts affect several of the Wands factors: the quantity of experimentation necessary. the amount of direction or guidance presented, the nature of the invention, and the breadth of the claims. While ultimately a trier of fact may reach the conclusion that the required experimentation is undue, Plaintiffs' experts have refuted Defendants' arguments by convincingly opining that one of ordinary skill in the art could make and use the full scope of the claimed invention without undue experimentation. It is not the role of the court to weigh expert credibility, and where qualified experts on both sides of the case offer competing opinions as to the ability to practice the patent, summary judgment is improper. See, e.g., Evonik Degussa GmbH v. Materia Inc., No. 09–CV–636 (NLH/JS), 2016 WL 337378, at *8 (D.Del. Jan. 26, 2016) (denying summary judgment due to competing expert testimony on the issue of enablement). Accordingly, the court finds that Defendants have not proven through clear and convincing evidence that either patent-in-suit is invalid for non-enablement, and that summary judgment is therefore inappropriate. Defendants' Motion for Summary Judgment as to lack of Enablement is therefore **DENIED**.

3. Defendants' Motion for Summary Judgment of No Willful Infringement

Plaintiff seeks treble damages in this action under 35 U.S.C. § 284, which permits an enhanced damages award for willful infringement. The Supreme Court recently decided in Halo Elecs., Inc. v. Pulse Elecs., Inc., — U.S. —, 136 S.Ct. 1923, 1928, 195 L.Ed.2d 278 (2016) that the Federal Circuit's two-part test, as adapted in In re Seagate Technology, LLC, 497 F.3d 1360 (2007) (en banc), for determining when a district court may increase damages under § 284 was inconsistent with the statute. Under Seagate, to establish willful infringement, the patentee had to show "by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Id. at 1371. Establishing willful infringement of a valid patent required a two-prong showing involving both an objective and a subjective inquiry. Seagate held that "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Id. at 1368. Second, if the "threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." Id. at 1371.

[33, 34] The Supreme Court explained in Halo:

The principal problem with Seagate's two-part test is that it requires a finding of objective recklessness in every case before district courts may award enhanced damages. Such a threshold requirement excludes from discretionary punishment many of the most culpable offenders, such as the "wanton and malicious pirate" who intentionally infringes another's patent-with no doubts about its validity or any notion of a defense for no purpose other than to steal the patentee's business. Under Seagate, a district court may not even consider enhanced damages for such a pirate, unless the court first determines that his infringement was "objectively" reckless. In the context of such deliberate wrongdoing, however, it is not clear why an independent showing of objective recklessness-by clear and convincing evidence, no less—should be a prerequisite to enhanced damages.

<u>Id.</u> at 1932 (internal citation omitted). Under <u>Halo</u>, "[t]he subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." <u>Id.</u> at 1933. The Court advised:

[a]s with any exercise of discretion, courts should continue to take into account the particular circumstances of each case in deciding whether to award damages, and in what amount. Section 284 permits district courts to exercise their discretion in a manner free from the inelastic constraints of the Seagate test. Consistent with nearly two centuries of enhanced damages under patent law, however, such punishment should

generally be reserved for egregious cases typified by willful misconduct.

<u>Id.</u> at 1933–34. Finally, the Court noted that the appropriate burden of proof in proving recklessness was preponderance of the evidence, not clear and convincing. <u>Id.</u> at 1934.

[35] While the legal standard for analyzing willful infringement has changed in the course of this litigation, the court need not apply it to the facts of this case at this time. Several district courts have found that determining the issue of willful infringement is more appropriate once the court has received findings of fact from the jury as to infringement and validity arguments. See, e.g., Fujitsu Ltd. v. Belkin Int'l, Inc., No. 10-CV-03972-LHK, 2012 WL 4497966, at *39 (N.D.Cal. Sept. 28, 2012) ("While the Court denies Defendants' motion for summary judgment of invalidity, the Court recognizes that Defendants have raised significant invalidity arguments that are worthy of jury consideration...Defendants' anticipation and obviousness arguments, at this point, turn on questions of fact for a jury to decide.... the Court determines that it would be more appropriate to decide the legal issue of willfulness with the benefit of the jury's factual findings on anticipation and obviousness."); Cook Inc. v. Endologix, Inc., 1:09-CV-01248-TWP, 3779198, at *2 (S.D.Ind. Aug. 30, 2012)). The court finds significant logic in such a course of action and will therefore refrain from entering a decision on this issue until after the jury has made the requisite factual findings as to the infringement and validity arguments presented by the parties here. See 01 Communique Lab., Inc. v. Citrix Sys., Inc., No. 1:06-CV-253, 151 F.Supp.3d 778, 806-07, 2015 WL 9268913, at *23 (N.D.Ohio Dec. 21, 2015); Fujitsu, 2012 WL 4497966, at *39; Cook, 2012 WL 3779198, at *2. The court will therefore **DENY** without prejudice Defendants' Motion for Summary Judgment of No Willful Infringement.

4. Plaintiffs' Motion for Partial Summary Judgment of No Anticipation of United States Patent No. 6,547,094

Plaintiffs have moved for partial summary judgment of no anticipation as to both patents-in-suit.

a. Legal Standards

[36] "To meet the requirements of patentability, an alleged invention must be new." TecSec, Inc. v. Int'l Bus. Machines Corp., 763 F.Supp.2d 800, 814 (E.D.Va. 2011), aff'd, 466 Fed.Appx. 882 (Fed.Cir. 2012) (quoting 35 U.S.C. § 102). A patent claim is not valid if the invention was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a). "Invalidity based on lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee." Hoover Group v. Custom Metalcraft, 66 F.3d 299, 302 (Fed.Cir.1995).

[37] A patent is presumed valid, and each claim of a patent is presumed valid independently of the validity of other claims. 35 U.S.C. § 282. Consequently, a party who would establish a patent's invalidity by anticipation shoulders "an especially heavy burden." Koito Mfg. Co. v. Turn–Key–Tech, LLC, 381 F.3d 1142, 1151 (Fed.Cir.2004). To overcome this presumption of validity, the patent's challenger must prove facts supporting a determination of invalidity by clear and convincing evidence. Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1377 (Fed.Cir. 2002).

[38-40] Anticipation analysis is a twostep process. The first step is claim construction, a question of law for the court. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed.Cir.2000). "The second step of the process involves a comparison of the asserted claims with the prior art, a fact-finding endeavor for the jury." Free-Gerber Products Co., F.Supp.2d 1304, 1307 (D.Kansas 2003) (citing Key Pham. v. Hercon Labs. Corp., 161 F.3d 709, 714 (Fed.Cir.1998)). To establish anticipation under § 102, "every limitation of a claim must identically appear in a single prior art reference." Diodem LLC v. Lumenis, Inc., 2005 WL 6225366 (C.D.California 2005) (quoting Gechter v. Davidson, 116 F.3d 1454, 1457 (Fed.Cir.1997)). "When more than one reference is required to establish unpatentability of the claimed invention[,] anticipation under § 102 [cannot] be found." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1267 (Fed.Cir.1991).

[41–43] To establish anticipation, a party must show that there is "no difference" between the patented claim and that which is disclosed by the prior art, as viewed by a person of ordinary skill in the field of invention. Round Rock Research, SanDisk Corporation, F.Supp.3d 674, 680 (D.Delaware 2014) (citing Scripps Clinic & Research Found. v. Genetech, Inc., 927 F.2d 1565, 1576 (Fed. Cir.1991) (overruled on other grounds)). If a prior art reference lacks any claimed element, then as a matter of law the court cannot find anticipation. Freeman, 269 F.Supp.2d at 1308 (citing Kloster Speedsteel AB v. Crucible, Inc., 793 F.2d 1565, 1571 (Fed.Cir.1986), cert. denied, 479 U.S. 1034, 107 S.Ct. 882, 93 L.Ed.2d 836 (1987) (overruled on other grounds)). Further, the prior art must disclose all of the claim elements arranged or combined in the same way as recited in the challenged patent...clearly and unequivocally [disclosing the claimed invention...without any need for picking, choosing, [or] combining various disclosures not directly related to each other by the teachings of the cited reference." TecSec, Inc. v. Int'l Bus. Machines Corp., 763 F.Supp.2d 800, 814 (E.D.Va.2011), aff'd, 466 Fed.Appx. 882 (Fed.Cir.2012) (internal citations and quotation marks omitted). "To anticipate, the reference must also enable one of skill in the art to make and use the claimed invention." Transclean Corp. v. Bridgewood Services, Inc., 290 F.3d 1364, 1370 (Fed.Cir. 2002).

[44–46] A prior art reference may anticipate by disclosing claim limitations either expressly or inherently. Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1043 (Fed. Cir.1995). Express anticipation is determined by reading the claims "in the context of the patent specification in which they arise and in which the invention is described." Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed.Cir.1995). "[T]he trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history[,] and identify corresponding elements disclosed in the allegedly anticipating reference." Maschinenfabrik Lindemann GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458 (Fed.Cir.1984).

[47] A prior art reference may be found to inherently disclose a claim limitation if the limitation is "necessarily present [in the reference] and a person of ordinary skill in the art would recognize its presence." Crown Operations, 289 F.3d at 1377. "[I]t is not sufficient that a person following the [prior art] disclosure sometimes obtain the result set forth in the claim, it must invariably happen." Glaxo, 830 F.Supp. at 874. "[A]n inherent limitation is one that is necessarily present and not one that may be established by probabilities or

possibilities." <u>Round Rock</u>, 75 F.Supp.3d at 681 (D.Delaware 2014).

[48, 49] "[W]hen the [prior art] reference is silent about an asserted inherent characteristic, such [a] gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described[.]...This modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference[.]" Continental Can, 948 F.2d at 1268. However, in considering the anticipatory teaching of a reference, extrinsic evidence may only be considered when it is used to explain, not expand, the meaning of a reference. In re Baxter Travenol Labs., 952 F.2d 388, 390 (Fed.Cir.1991).

[50, 51] "Regardless of whether the prior art's disclosure is asserted to be express or inherent, the Federal Circuit teaches that:

Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the [witness's] interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference. The testimony is insufficient if it is merely conclusory.

It is not....the task of the district court[] to attempt to interpret confusing or general testimony to determine whether a case of invalidity has been made out, particularly at the summary judgment stage. Indeed, to accept confusing or generalized testimony as evidence of invalidity is improper.

Diodem LLC v. Lumenis, Inc., 2005 WL 6225366 (C.D.California) (quoting Schumer v. Lab. Computer Sys., 308 F.3d 1304, 1315–16 (Fed.Cir.2002)).

[52, 53] Regarding the standards for summary judgment as to anticipation in the context of a patent case, "[a]lthough anticipation is a question of fact, it still may be decided on summary judgment if the record reveals no genuine dispute of material fact." Oney v. Ratliff, 182 F.3d 893, 895 (Fed.Cir.1999). Because a patent enjoys a presumption of validity which can be overcome only by clear and convincing evidence, "a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent." Eli Lilly, 251 F.3d at 962 (emphasis added).

[54, 55] When a party moving for summary judgment on the issue of "no anticipation" points to the absence of evidence to support the non-moving party's case, and the non-moving party produces no evidence, the court should grant summary judgment to the moving party. Gen-Probe Inc. v. Becton Dickinson and Co., 899 F.Supp.2d 971, 983 (S.D.California 2012) (citing Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1389 (Fed.Cir.1992)). Additionally, for a non-moving party to establish a genuine dispute of material fact as to "no anticipation," the non-moving party "is required to do more than establish that the experts disagree." Volterra Semiconductor Corp. v. Primarion, Inc., 796 F.Supp.2d 1025, 1092 (N.D.California 2011). Rather, "an accused infringer must point to sufficient evidence for a reasonable jury to conclude by clear and convincing evidence that the asserted claims are anticipated." Id.

[56] Under <u>Schumer</u>, such clear and convincing evidence of anticipation must generally consist of expert testimony which explains in detail how each claim

element is disclosed in the prior art reference. Schumer. 308 F.3d at 1315–16. Where the party alleging a patent's invalidity instead presents expert testimony which cites to prior art by setting forth some but not all claim elements, or which makes conclusory statements regarding anticipation, no triable issue of fact thereby arises. See Lucent Technologies, Inc. v. Microsoft Corp. 544 F.Supp.2d 1080, 1092 (S.D.California 2008). See also Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1353 (Fed.Cir.2001) (upholding summary judgment of "no anticipation" where patent challenger's expert merely opined that prior art anticipated without explaining why and further holding that it is not the trial court's burden "to search through lengthy technologic documents for possible evidence.")

On the other hand, where a non-moving party presents an expert who "quote[s] particular portions of the references that [are] relevant for each of the claim limitations...[does] not simply make conclusory statement[s] that, in his opinion, the claims [are] invalid...and for each claim limitation...connect[s] it with disclosures in the prior art that he believe[s] [teach] each particular limitation," then to the extent that such assertions conflict with similarly specific testimony by the patent holder's expert, there exists a triable issue of fact. Medical Instrumentation and Diagnostics Corp. v. Elekta AB, 344 F.3d 1205, 1220 (Fed.Cir.2003).

b. Discussion

Viva moves the court for summary judgment that the claims of the '094 Patent are not anticipated by prior art. Specifically, Viva asks the court to make a finding of no anticipation as to the following prior art references: Thin Walled Injection Molding Study: Effect of Melt Temperature on Structure-Property Relationships, an academic study by Troy A. Miller ("Miller");

and U.S. Patent No. 5,889,120 ("O'Donnell").

i. O'Donnell

CTL has chosen to forgo arguing that the asserted claims of the '094 Patent are anticipated by prior art reference O'Donnell. See (Defs.' Mem. Opp'n (#221) at 7). Accordingly, the court GRANTS Viva's motion for summary judgment of no anticipation as to O'Donnell.

ii. Miller

[57] Next, Viva asserts that CTL has failed to meet its burden of showing by clear and convincing evidence that claims 1-7, 11-15 and 17 of the '094 Patent are anticipated by Miller. Of these, only claims 1 and 11 are independent; the remaining claims are dependent. A dependent claim refers back to and further limits another claim in the same patent and must be construed to include all the limitations of the claim incorporated by reference into the dependent claim. See 37 C.F.R. § 1.75(c). If a prior art does not anticipate an independent claim, it cannot, as a matter of law, anticipate associated dependent claims. Duhn Oil Tool, Inc. v. Cooper Cameron Corp., 818 F.Supp.2d 1193, 1220 (E.D.California 2011) (citing RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440 (Fed.Cir.1984)).

[58] Claims 1 and 11 of the '094 Patent both describe (1) a process for the manufacture of flexible, thin-walled articles comprising the steps of: (2) using a polymer blend; (3) having "an ESCR as herein defined" greater than 10 hours; (4) melting said polymer blend; (5) ramming the molten polymer blend into a mold having a cavity that produces a thin-walled article (6) having a thin section of 1 mm or less in thickness, the thin section being substantially continuous for greater than 50 mm in the direction of flow of the molten polymer; and (7) removing the thin-walled arti-

cle from the mold. Claim 11 also requires that the polymer blend include "at least one polymer and at least one of a compatible agent and a nucleating agent."

In its Claim Construction Order, the court construed "an ESCR as herein defined" to mean "the ESCR test as defined in column 2, line 62 through column 3, line 13 of U.S. Patent No. 6,547,094." This ESCR test provides a method for identifying polymers that can successfully be used in the invention. Among other limitations, the "ESCR test as herein defined" requires that test strips be injection molded under "high shear, long flow length" conditions similar to those which would also be used in the manufacture of a flexible, thinwalled tube (i.e., the finished product).

In its memorandum of law in support of summary judgment, Viva asserts that CTL has failed to produce evidence sufficient to create a triable issue of fact as to whether Miller teaches (1) the "high shear, long flow length conditions required by the ESCR test" and (2) "a thin-walled article having a thin section of 1 mm or less in thickness, the thin section being substantially continuous for greater than 50 mm in a direction of flow of the molten polymer."

a. $\underbrace{High\ shear,\ long\ flow\ length\ conditions}$

Viva argues that Miller does not expressly or inherently disclose high shear, long flow length conditions for the manufacture of test strips as required by the ESCR test "as herein defined." CTL responds, in part, by questioning whether the existence of high shear, long flow length conditions during the manufacture of test strips is pertinent to an inquiry of whether the '094 Patent has been infringed by CTL or is anticipated by Miller. CTL asserts that "the claims [of the '094 Patent] themselves do not require that the finished product be molded under 'high shear, long flow' conditions," and that

therefore the test strips referred to by the "ESCR as herein defined" need not exist in order for the patent to be practiced or infringed. Defs.' Mem. Opp'n (#221) at 9-10. Accordingly, CTL would have the court find that Miller can anticipate the "ESCR as herein defined" element of claims 1 and 11 of the '094 Patent without any teaching of high shear, long flow length conditions.

The court, however, is persuaded by Viva's interpretation of "ESCR as herein defined" to the extent that this claim limitation teaches high shear, long flow conditions. The '094 Patent expressly requires that test strips be manufactured using high shear, long flow length conditions "similar to those intended for use in the manufacture of the [final product]." '094 Patent (#193-1) at 2:67-3:3. In other words, after a suitable polymer blend is identified in "test strip" form, this same blend is then injection molded under similar conditions to produce the final product—a tube. Thus, the '094 Patent would seem to teach that both the test strips as well as the subsequently manufactured tubes be injection molded under high shear, long flow length conditions.

In any case, CTL has not pointed to opinion evidence from its experts that supports its position that claims 1 and 11 of the '094 Patent do not require the use of high shear, long flow conditions during the injection molding of either the test strips or the subsequently manufactured tubes. Viva correctly notes that nowhere in Miller is there any express mention of high shear, long flow length conditions. Therefore, Viva concludes, Miller must either: (1) fail to disclose the high shear, long flow length limitation or (2) inherently disclose it. Viva asserts that none of CTL's invalidity contentions or expert reports explicitly states where in Miller the high shear, long flow length conditions are inherently disclosed.

For a non-moving party to establish a genuine dispute of material fact as to no anticipation, the non-moving party "is required to do more than establish that the experts disagree." Volterra Semiconductor Corp. v. Primarion, Inc., 796 F.Supp.2d 1025, 1092 (N.D.California 2011). Rather, with respect to inherent anticipation, the non-moving party must present evidence that the challenged claim limitation is "necessarily present [in the prior art reference] and a person of ordinary skill in the art would recognize its presence." Crown Operations, 289 F.3d at 1377. "[I]t is not sufficient that a person following the [prior art] disclosure sometimes obtain the result set forth in the claim, it must invariably happen." Glaxo, Inc. v. Novopharm, Ltd., 830 F.Supp. 871, 874 (E.D.N.C.1993), aff'd, 52 F.3d 1043 (Fed. Cir. 1995).

Here, in lieu of presenting opinion evidence from its own experts, CTL seeks to meet its evidentiary burden by relying on the opinion of Viva's expert, Dr. Driscoll. CTL argues that Dr. Driscoll has admitted that "injection molding under 'high shear, long flow' conditions is inherently required" for the manufacture of an article having dimensions matching those described by the '094 Patent. Defs.' Mem. Opp'n (#221) at 10 (citing Driscoll Rep. (#193-9) at ¶¶149-150). Be that at is may, CTL's task at summary judgment is to present clear and convincing evidence that Miller—not the '094 Patent—teaches such conditions. Even if CTL were to establish that the articles manufactured in Miller precisely matched the dimensional and flow direction limitations required the '094 Patent, Dr. Driscoll's purported "admission" would not, by itself, be enough for CTL to show that the high shear, long flow conditions were necessarily present in Miller. Dr. Driscoll's rebuttal report explicitly disputes CTL's assertion that the articles manufactured in Miller were subject to high shear, long flow conditions. See Driscoll Reb. Rep. (#193-10) at ¶¶116125. Specifically, Dr. Driscoll notes that the two-second fill time and the nine-ounce injection molding machine used by Miller would not be sufficient to produce high shear, long flow length conditions. <u>Id.</u> at ¶¶124-125. CTL has presented no expert testimony which can be interpreted as refuting this assertion by Dr. Driscoll.

At best for CTL, Dr. Driscoll's opinions on this particular issue are contradictory. The court finds that by failing to point to any testimony from its own expert which specifically states where in Miller the high shear, long flow length conditions are expressly or inherently disclosed, CTL has failed to meet its evidentiary burden. The seemingly contradictory testimony of Viva's expert does not constitute clear and convincing evidence by which a reasonable jury could conclude that Miller inherently discloses high shear, long flow length conditions. As the Federal Circuit noted in Schumer,

[t]ypically, [expert] testimony concerning anticipation...must identify each claim element, state the [witness's] interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference....It is not...the task of the district court[] to attempt to interpret confusing or general testimony to determine whether a case of invalidity has been made out, particularly at the summary judgment stage. Indeed, to accept confusing or generalized testimony as evidence of invalidity is improper.

<u>Id.</u> at 1315–16 (internal citations and quotation marks omitted).

In order to survive Viva's motion for summary judgment, CTL must present clear and convincing evidence that each and every limitation of claims 1 and 11 of the '094 Patent are disclosed by Miller. Because CTL has failed to establish a triable issue of fact with respect to whether Miller discloses high shear, long flow length conditions as required by the "ESCR as herein defined," the court finds as a matter of law that Miller does not anticipate the '094 Patent.

<u>b. Dimensional and flow direction requirements</u>

In its Summary Judgment Motion, Viva also argues that neither CTL's Invalidity Contentions nor its expert reports specifically identify where Miller teaches the injection molding of an article "having a thin section of 1mm or less in thickness, the thin section being substantially continuous for greater than 50 mm in a direction of flow of the molten polymer blend in the mold." Viva asserts that CTL instead relies (improperly) on supplemental reference Jacobs WO '024 to show that the dimensional and flow direction limitations of the '094 Patent are inherently disclosed by Miller. Viva also argues that CTL is procedurally barred from arguing that Figure 1 of Miller discloses the requisite dimensional and directional limitations because Figure 1 was not identified as the source of these limitations in CTL's invalidity contentions or its expert charts.

While the court has considered the argument, because Viva's partial motion for summary judgment succeeds due to CTL's failure to present clear and convincing evidence that Miller teaches high shear, long flow length conditions, it is unnecessary for the court to address the parties' arguments regarding the dimensional and mono-directional flow limitations. Likewise, the court declines to rule on the related issues of whether it was proper for CTL and its expert Dr. Osswald to rely on supplemental reference Jacobs WO '024 and whether CTL is procedurally barred from arguing that Figure 1 of Miller expressly discloses the dimensional and flow direction limitations.

c. Conclusion

For the reasons stated herein, the court will **GRANT** Plaintiffs' Motion for Partial Summary Judgment of No Anticipation as to claims 1-7, 11-15 and 17 of the '094 Patent.

5. Plaintiffs' Motion for Partial Summary Judgment of No Anticipation Of United States Patent No. 8,518,-318

Viva asserts that CTL has failed to meet its burden of showing by clear and convincing evidence that claims 4-5, 8 and 10-12 of the '318 Patent are anticipated. Specifically, Viva asks the court to find on summary judgment that (1) claims 4-5, 8, and 10-12 are not anticipated by prior art reference Jacobs WO '409, which is the publication of PCT application PCT/AU98/00255 that eventually matured into the '094 patent-in-suit, and (2) claims 5 and 10-12 are not anticipated by U.S. Patent No. 6,159,566 ("Barre").

With regards to anticipation by Jacobs WO '409 of claims 8, 10, and 11 and anticipation by Barre of claims 5, 10, and 11, CTL has chosen to forego argument. Accordingly, the court **GRANTS** Viva's partial motion for summary judgment that claims 8, 10 and 11 are not anticipated by Jacobs WO '409 and claims 5, 10 and 11 are not anticipated by Barre.

Thus, what remains in dispute is whether claims 4, 5 and 12 are anticipated by Jacobs WO '409 and whether claim 12 is anticipated by Barre.

a. Jacobs WO '409

Of the '318 Patent claims at issue, claim 4 depends from claim 1; claim 5 depends from claim 4; and claim 12 depends from claim 1. Claim 1 describes "[a] process for the manufacture of flexible thin-walled articles including: injection molding a blend of (a) at least one polymer and (b) at least

one high melt flow compatible polymer having an MFI of greater than 100."

i. Claim 4

Claim 4 describes a process "according to claim 1, wherein at least one of (a) and (b) includes a polymer formed using a metallocene or similar catalyst system." Thus, to survive summary judgment as to no anticipation of claim 4, CTL must present clear and convincing evidence that Jacobs WO '409 discloses each and every limitation of both claim 1 and claim 4. 37 C.F.R. § 1.75(c).

Viva does not contest CTL's assertion that claim 1 of the '318 Patent is anticipated by Jacobs WO '409 but rather focuses its argument on the additional "metallocene" limitation found in claim 4. Specifically, Viva asserts that CTL has failed to identify, both in their invalidity contentions and expert reports, any "single embodiment or combination of directly related embodiments in Jacobs WO '409 that teaches both the metallocene catalyzed polymer and a high MFI compatible polymer [as required by claim 1]." Pls.' Mem. Supp. (#199) at 12. Instead, Viva argues, "Defendants merely allege that [Jacobs WO '409 at 6:21-23] teaches the metallocene catalyzed polymer limitation of claim 4. Defendants do not show that this disclosure teaches the high MFI compatible polymer limitation required by claim 1. Nor do Defendants show how the disclosure [at 6:21-23] is related to Example 1 (which Defendants allege teaches the limitations of claim 1) such that combining the two would be appropriate." Id.

In response, CTL argues that Jacobs WO '409 provides "general teaching" regarding the use of polymers formed using a metallocene or similar catalyst system. This general teaching, found in Jacobs WO '409 at 6:21-23, provides that a wide variety of polymers may be suitable for use in the invention, including those which "may be made by a wide variety of meth-

ods including high and low pressure processes, using a wide variety of catalysts such as Ziegler-Natta and metallocenes." Jacobs WO '409 (#193-25) at 6:21-23. Both CTL's invalidity charts and the invalidity charts created by its expert, Dr. Osswald, identify this language from Jacobs WO' 409 at 6:21-23 as the location where the metallocene catalyst limitation of claim 4 is disclosed by the prior art.

However, in its memorandum of law in opposition to Viva's partial motion for summary judgment, CTL seems to concede that this language, considered alone, is not sufficient to anticipate claim 4. Rather, CTL asserts that "[t]hese teachings, when combined with Jacobs WO '409's teachings on 'compatibility' and the use of [a particular polymer called Exact 4038 in Examples 1-3 [of Jacobs WO '409,] teach each and every element of claim 4 of the '318 Patent." Defs.' Mem. Opp'n. (#222) at 9 (emphasis added). Alternatively, CTL suggests that the court "need not even rely on combination of elements within the fourcorners of Jacobs WO '409 to find that it anticipates Claim 4...[because] Examples 1-3....teach the use of Exact 4038, a 125 MFI polymer...[which] is 'a semicrystalline ethylene-butene copolymer made by using a metallocene catalyst." Id. In other words, CTL argues, the use of Exact 4038 in Examples 1-3 inherently discloses each and every limitation of claims 1 and 4.

Thus, CTL expressly relies on the fact that Exact 4038, as used in Examples 1-3 of Jacobs WO '409, is manufactured using a metallocene catalyst in order to show that claim 4 is anticipated. However, CTL does not point to any statement by any of its experts which establishes that Exact 4038 is in fact manufactured using a metallocene catalyst. Instead, the quotation in the preceding paragraph which declares Exact 4038 to possess this characteristic is found in an unrelated patent for a "hot

melt adhesive," the inventors of which are not involved in this case and may or may not be experts about metallocene catalysts. See U.S. Patent No. 6,143,818 (#227-30) at 10:44-49. CTL's expert, Dr. Cakmak, cites to lines 10:44-49 of this unrelated patent to support his expert opinion that "Exact 4038 is a poly(ethylene-co-1-butene) which is an "ultra low density, very low density, low density, medium density and high density polyethylene and copolymers thereof." Cakmak Rep. (#193-3) at ¶86. Dr. Cakmak does not expressly reference the brief mention of metallocene catalysts in Patent No. 6,143,818 and nowhere else does Dr. Cakmak opine that Exact 4038 is manufactured using a metallocene catalyst.

Even if the court found that, through this tenuous reference to an unrelated patent, CTL had presented clear and convincing evidence that Exact 4038 is manufactured using a metallocene catalyst, the fact remains that none of CTL's expert reports identify the use of Exact 4038 in Examples 1-3 as the portion of Jacobs WO '409 where claim 4 is anticipated. Rather, this particular argument is made by CTL's attorneys in their opposition brief.

[59] As a sister court recently noted, "the field of polymer chemistry is a complex area of technology, and where patent claims involve complex issues of technology, expert testimony is required to aid the fact finder." INVISTA North America S.A.R.L. v. M & G USA Corporation, 951 F.Supp.2d 626 (D.Delaware 2013) (further holding that where defendant disclosed a particular obviousness argument for the first time during summary judgment briefing, and this argument was unsupported by expert testimony, defendant could not carry its burden of presenting clear and convincing evidence).

This court hereby finds that no reasonable jury could find that CTL has shown by clear and convincing evidence that claim 4 of the '318 Patent is anticipated by

the "general teaching" in Jacobs WO '409, where such teaching states that polymers made using metallocene catalysts—among a variety of other suitable polymers—<u>may</u> be used in the claimed injection molding process.

Furthermore, CTL has failed to present expert testimony or reports that show by clear and convincing evidence that Exact 4038, as used in Examples 1-3, is manufactured using a metallocene catalyst. And finally, this court finds that CTL has failed to present an expert opinion that explains how the use of Exact 4038 in combination with the "general teaching" of metallocene catalysts in Jacobs WO '409 discloses each and every limitation of claim 4. Instead, Dr. Osswald's invalidity chart simply mentions the "general teaching," and his expert report makes no mention of metallocene catalysts.

Because CTL has failed to point to specific factual allegations such that a reasonable jury could find by clear and convincing evidence that claim 4 of the '318 Patent is anticipated by Jacobs WO '094, the court **GRANTS** Viva's partial motion for summary judgment that claim 4 is not anticipated.

ii. Claim 5

Claim 5 of the '318 Patent depends from claim 4, which in turn depends from claim 1. A dependent claim refers back to and further limits another claim in the same patent and must be construed to include all the limitations of the claim incorporated by reference into the dependent claim. See 37 C.F.R. § 1.75(c). Therefore, in order for CTL to defeat Viva's motion for summary judgment of no anticipation as to claim 5, CTL must once again present clear and convincing evidence that Jacobs WO '409 discloses each and every limitation of claims 1 and 4. As discussed above, CTL has failed to meet this evidentiary burden. CTL has failed to present sufficient expert

testimony to create a triable issue of fact as to whether claim 4 is anticipated by Jacobs WO '409. Therefore, the court **GRANTS** Viva's partial motion for summary judgment that claim 5 is not anticipated.

iii. Claim 12

Claim 12 of the '318 Patent depends from claim 1. Viva has declined to argue that claim 1 is not anticipated by Jacobs WO '409 and instead asserts that CTL has failed to present clear and convincing evidence of "any single embodiment" in the prior art that teaches each limitation of claims 1 and 12. Claim 12 teaches the injection molding process "according to claim 1, wherein the flexible thin-walled article is a tube."

Both in its invalidity charts and in the expert charts created by Dr. Osswald, CTL identifies language at 1:3-5 in Jacobs WO '409 as disclosing the "tube" limitation required by claim 12. On the first page of the prior art, under a heading which reads "Injection Molding," lines 3-5 state that "[t]he present invention relates to injection molding processes, in particular to a process for injection molding articles having thin sections such as thin-walled tubular containers as used in the cosmetics industry for lotions, moisturizers and the like." Jacobs WO '409 (#193-25) at 1:3-5. The prior art goes on to explain, generally, the process by which thin-walled tube manufacturing takes place, the relative benefits of injection molding such tubes, difficulties associated with producing such injection molded tubes, and the purported advance that the claimed invention brings to the field of thin-walled tube manufacturing. Jacobs WO '409 at 1-3.

[60] The court finds that there is, at the least, a genuine dispute of material fact as to whether the language at 1:3-5 in Jacobs WO '409, which was cited by CTL and Dr. Osswald in their invalidity charts, teaches that the injection molding process

disclosed in that prior art should be practiced specifically for the manufacture of tubes. A reasonable jury could find that CTL has shown by clear and convincing evidence that claim 1 is anticipated by the "process for injection molding articles...such as thin-walled tubular containers" which is referred to at lines 3-5 and taught in more precise detail elsewhere in the prior art. Dr. Osswald identifies the more precise teaching of claim 1 in his invalidity chart. Likewise, a reasonable jury could find that this same language teaches the manufacturing of thin-walled tubes.

Accordingly, the Court **DENIES** Viva's partial motion for summary judgment of no anticipation by Jacobs WO '409 as to claim 12 of the '318 Patent.

b. Barre

U.S. Patent No. 6,159,566 ("Barre") teaches the manufacture of a "flexible package...made of plastic" which "can be an injection-molded tube...suitable for the packaging of small volumes of cosmetic and/or dermatological products." Barre Abstract (#193-24). Viva moves the court for summary judgment that Barre does not anticipate claims 5 and 10-12 of the '318 Patent. CTL does not oppose Viva's motion as to claims 5, 10 and 11. Therefore, the lone claim which must be subjected to anticipation analysis is claim 12.

As they did with regard to the Jacobs WO '409 prior art, Plaintiffs here argue that CTL has failed to produce clear and convincing evidence showing "any single embodiment or combination of directly related embodiments" in Barre which disclose each and every limitation of claims 1 and 12. Pls.' Mem. Supp. at 22. As with Jacobs WO '409, Viva declines to argue that Barre does not anticipate claim 1.

In its invalidity charts and its expert invalidity charts, CTL identifies the abstract and lines 3:10-12 of Barre as the locations where this prior art discloses the limitations of claim 12. The abstract broadly states that the manufacturing process claimed is used for the creation of a "package" which "can be an injection-molded tube." Barre Abstract (#193-24). Immediately below this language there is a graphic depicting a tube. Lines 3:10-12 indicate that the tubes which are to be created using the claimed process are thin-walled, being between .2 mm and 1.0 mm in thickness.

[61] The court finds that there is, at the least, a genuine dispute of material fact as to whether the language in Barre cited by CTL and Dr. Osswald teaches the manufacture of tubes using the injection molding process described in claim 1. A reasonable jury could find by clear and convincing evidence that claim 1 is anticipated by language in the Barre Abstract that describes a "method for producing the [flexible plastic] package by injection molding the [plastic] blend in a suitable mold" which "can be an injection molded tube," where the process this language refers to is taught in more precise detail elsewhere in the prior art and identified as such by Defendants' expert. See Osswald Rep. (#193-5) at Exhibit J-1. Likewise, a reasonable jury could find that this same language teaches the manufacturing of tubes.

Therefore, the court **DENIES** Viva's partial motion for summary judgment of no anticipation by Barre as to claim 12 of the '318 Patent.

(c) Conclusion

For the reasons stated herein, the court will **GRANT** Plaintiffs' Motion for Partial Summary Judgment of No Anticipation by Jacobs WO '409 as to claims 4-5, 8, and 10-11 of the '318 Patent; **GRANT** Plaintiff's Motion for Partial Summary Judgment of No Anticipation by Barre as to claims 5, 10, and 11; and **DENY** Plaintiffs' Motion for Partial Summary Judgment of No Anticipation Summary Summar

ticipation by Jacobs WO '409 and Barre as to claim 12.

IV. CONCLUSION

For the reasons explained herein, the court will term the motions as stated below, and therefore enters the following Order.

ORDER

IT IS, THEREFORE, ORDERED that the following Motions are termed as follows:

- Defendants' Motion for Summary Judgment as to Indefiniteness (#178) is DENIED without prejudice:
- Defendants' Motion for Summary Judgment as to Lack of Enablement (#180) is DENIED without prejudice;
- 3. Defendants' Motion for Summary Judgment of No Willful Infringement (#182) is **DENIED without prejudice**;
- Plaintiffs' Motion for Partial Summary Judgment of No Anticipation of United States Patent No. 6,547,094 (#196) is GRANTED;
- 5. Plaintiffs' Motion for Partial Summary Judgment of No Anticipation Of United States Patent No. 8,518,-318 (#198) is GRANTED in part and DENIED in part, as explained herein;
- Defendants' Motion to Exclude Certain Opinions by Expert Witness Stephen Driscoll (#184) is DENIED;
- Defendants' Motion to Exclude Certain Testimony of Expert Dr. Michael Rubinstein (#186) is DENIED;
- 8. Plaintiffs' Motion to Exclude Certain Purported Expert Testimony of Tim Osswald and Mukerrem Cakmak (#190) is **GRANTED** in part and **DENIED** in part, as explained herein;

- 9. Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith (#203) is **DENIED without prejudice**; and
- Plaintiffs' Motion to Exclude Purported Expert Testimony of Cynthia Smith and Tim Osswald (#208) is DENIED.



MINNESOTA LAWYERS MUTU-AL, INSURANCE CO., Plaintiff/Counter-Defendant,

v.

PROTOSTORM, LLC, et al., Defendants/Counterclaimants. 1:15-cv-1485 (JCC/JFA)

United States District Court, E.D. Virginia, Alexandria Division.

Signed 06/22/2016

Background: Professional liability insurer brought action against insured law firm, seeking a declaratory judgment that its indemnification obligation for an underlying malpractice lawsuit was limited to \$5 million. Insured counterclaimed, seeking a declaration that insurer was liable for \$10 million. Parties cross-moved for summary judgment.

Holding: The District Court, James C. Cacheris, J., held that policy's \$5 million limit of liability applied.

Insurer's motion granted and insured's motion denied.

1. Insurance \$\iins1813\$

Virginia courts interpret insurance policies, like other contracts, in accordance with the intention of the parties gleaned from the words they used in the document.

2. Insurance €=1810

When considering the meaning of any phrase or clause within a policy, a Virginia court should construe the contract as a whole.

3. Insurance \$\infty\$1809, 1822

Under Virginia law, if the terms of a policy are plain and clear, a court must adhere to those terms and give them their plain meaning.

4. Insurance ⇐=1832(1)

If policy language is ambiguous, rather than clear, a Virginia court must construe the policy against the insurer.

5. Insurance €=1808, 1827

Under Virginia law, the mere fact that the parties dispute the meaning of policy language does not itself render the policy ambiguous, and courts must not strain to find ambiguities.

6. Insurance €=1808

An ambiguity exists under Virginia law when a policy provision can reasonably have more than one meaning given its context, when two constructions are equally possible, or when reasonable persons could reach reasonable, but opposite, conclusions based on the policy's language.

7. Insurance ⋘2268

Under Virginia law, unlike the duty to defend, which is based on the allegations in the underlying complaint, the duty to indemnify relies on litigated facts.

8. Insurance ≈2268

In evaluating whether an insurer has a duty to indemnify under Virginia law, a court must look to the underlying proceedings, the trial transcript, and the jury verdict to determine the facts actually discovered or proven.

9. Insurance \$\infty 2266, 2281(1)

Under Virginia law, underlying malpractice judgment against insured law firm