

NOT FOR PUBLICATION**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

RECKITT BENCKISER LLC, et al.,	:	Civil Action No.: 11-6609 (FLW)
	:	
Plaintiffs,	:	
	:	
v.	:	MEMORANDUM OPINION
	:	AND ORDER
AMNEAL PHARMACEUTICALS, LLC,	:	
	:	
Defendant.	:	
	:	

ARPERT, U.S.M.J.**I. INTRODUCTION**

This matter comes before the Court on the informal application of Defendant Amneal Pharmaceuticals, LLC (“Defendant” or “Amneal”), by letter to the Court dated June 12, 2012, for an Order compelling Plaintiffs Reckitt Benckiser LLC and UCB Manufacturing, Inc. (collectively, “Plaintiffs”) to produce (1) “[a]ll relevant facts, expert and other non-privileged materials made of record in *Reckitt Benckiser Inc., et al. v. Tris Pharma, Inc.* (“Tris”), No. 09-cv-3125, (D.N.J.) (“*Tris matter*”)” and (2) “[t]he testing procedures Plaintiffs intend to use on Amneal’s ANDA samples to support its infringement case”. *See* dkt. entry no. 33. The Court directed the Parties to meet and confer, together with Tris, in an attempt to resolve these issues. After a June 19, 2012 meet and confer session, Tris submitted opposition in a letter dated June 26, 2012, Defendant clarified its position in a letter dated June 27, 2012, and Plaintiffs submitted opposition in a letter dated June 29, 2012.

The Court conducted oral argument, by telephone, on July 9, 2012. For the reasons stated on the record and herein, Defendant’s application is **DENIED**, in part without prejudice.

II. BACKGROUND

In sum, Plaintiffs – as the holder of an approved new drug application (“NDA”) no. 18-658 for Delsym® (“Delsym”) extended release liquid suspension which contains the active ingredient dextromethorphan polistirex (“dextromethorphan”) – filed a Complaint against Defendant on November 9, 2011 alleging infringement of United States Letters Patent No. 5,980,882 (“‘882 patent”) which “claims certain pharmaceutical compositions using a drug-resin complex and a chelating agent and certain methods of making these pharmaceutical compositions”. *See* Pl.’s Compl., dkt. entry no. 1 at 1-7. Plaintiffs allege that by submitting an abbreviated new drug application (“ANDA”) under the provisions of 21 U.S.C. § 355 (j) before the expiration of the ‘882 patent – specifically, seeking approval to engage in the commercial manufacture, use, and sale of dextromethorphan polistirex extended release suspension – Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2) and will also infringe one or more claims of the ‘882 patent. *Id.* at 4. As a result, Plaintiffs claim that they are entitled to a Court Order stating that the effective date of any approval of Defendant’s ANDA be no earlier than after the expiration date of the ‘882 patent pursuant to 35 U.S.C. § 271(e)(4) and an award of damages for any commercial sale or use by Defendant with respect to the subject matter claimed in the ‘882 patent. *Id.* at 6-7. Plaintiffs also claim that they are entitled to reasonable attorneys’ fees, judgment that Defendant infringed one or more claims of the ‘882 patent, and a permanent injunction against Defendant from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Defendant’s product. *Id.*

With respect to the materials that Defendant seeks related to the *Tris matter*, in “order to

avoid duplicating discovery efforts on common, overlapping issues such as the invalidity of Plaintiffs' patent", Defendant served discovery requests on Plaintiffs "asking for all relevant materials created and used...[in the *Tris matter*] that relate to the issues being litigated in...[this matter]" including "(a) responses to interrogatory requests; (b) responses to requests for admission; (c) expert reports, declarations, affidavits, and supporting exhibits and attachments; (d) motions, briefs, and supporting exhibits filed with the Court; (e) deposition, hearing, and trial transcripts; (f) responses to requests for production; and (g) documents, communications and other things produced". See Def.'s Letter dated June 12, 2012 at 2. Notably, Defendant is only seeking "non-privileged information relevant to...[its] case that is in Plaintiffs' possession" and is "not interested in any of Tris' proprietary information". *Id.* at 7. Defendant argues that all "non-confidential, non-privileged, relevant information" should be produced and references two (2) Third Circuit cases (*Medeva Pharma Suisse AG v. Par Pharmaceutical, Inc.*, No. 10-4008 (D.N.J. 2010) and *Inventio AG v. Thyssenkrupp Elevator Americas Corp.*, 662 F. Supp. 2d 375, 378-79 (D. Del. 2009)) as support for the procedure it suggests in order to determine what confidential information may be withheld from production. *Id.* at 8-9.

Plaintiffs have "agreed to cooperate with both Tris and [Defendant] as long as...[their cooperation] does not put Plaintiffs in violation of the protective order in...[the *Tris matter*]. See Pl.'s Opp'n Letter dated June 29, 2012 at 1. Tris maintains that "there is a disagreement as to the discoverability of certain categories of...[its] documents (*e.g.*, Tris'...expert reports)...and no disagreement as to the discoverability of other categories of documents (*e.g.*, Tris'...confidential manufacturing information)". See Tris' Opp'n Letter dated June 26, 2012 at 1. Tris suggests following the procedure in order to "identify the specific documents that are in controversy" –

that is, (1) Plaintiffs will “prepare a Confidentiality Log describing the relevant materials being withheld”, (2) Tris will “review...[Plaintiffs’ Confidentiality Log] to identify what documents should not be produced at all...and what documents should be redacted”, (3) Defendant will review Plaintiffs’ Confidentiality Log together with Tris’ position on relevant documents in order to “determine what (if any) objections by Tris it deems inappropriate”. *Id.*

With respect to the information that Defendant seeks related to the testing procedures Plaintiffs intend to use on Defendant’s ANDA samples to support its infringement case, Defendant maintains that Plaintiffs “will necessarily need to perform a 12-month-long study on [Defendant’s] samples” in order “to meet their burden of proving infringement of the only asserted claims (claims 34 and 36)”. *See* Def.’s Letter dated June 12, 2012 at 2. Defendant contends that it “has a compelling need for...[the procedures that Plaintiffs will utilize in their testing]...so that it can...independently run ‘parallel’ studies using Plaintiffs’ protocols to corroborate Plaintiffs’ test results”. *Id.* “Rather than produce this information once it is created”, Plaintiffs “have indicated...[that] they will provide...[same] only after...[they] produce their opening expert reports on infringement in August 2013”. *Id.* Defendant argues that this is “unworkable” and that Plaintiffs should be compelled to “produce these procedures as soon as they are created”. *Id.* at 2-3. Defendant also claims that “[t]hese procedures are factual...and not subject to...[the] attorney-work product” privilege, noting that it is “not asking for the identification of experts or any expert discovery” but only “the test procedures and protocols that it needs to independently perform Plaintiffs’ 12-month tests”. *Id.* at 9. However, “even if...[Plaintiffs’ testing procedures] are held to be subject to the attorney-work product doctrine, [Defendant maintains that its] substantial need for this information overrides any production

immunity”. *Id.* at 3, 10-11. Pursuant to FED. R. CIV. P. 26(b)(3)(A)(ii), *In re Cendant Corp. Securities Litig.*, 343 F.3d 658, 663 (3d Cir. 2003), and *In re Seagate Tech., LLC*, 497 F.3d 1360, 1375 (Fed. Cir. 2007), Defendant argues that “the work product doctrine is not an absolute bar to the discovery of such information” and that “[u]pon a showing of substantial need and inability to obtain the information through other means, a court may order the production of work product that does not involve counsel’s mental impressions, opinions, and legal theories”. *Id.* at 10. Citing *Sandvik Intellectual Prop. AB v. Kennametal, Inc.*, 2011 WL 466696, at *4 (W.D. Pa. 2011) and *Medeva Suisse AG, et al. v. Roxane Laboratories, Inc.*, No. 07-5165 (D.N.J. July 21, 2010), Defendant maintains that because it is seeking “factual information needed to perform Plaintiffs’ 12-month infringement tests”, because “such test information is unavailable elsewhere”, and because “Plaintiffs’ tests will take twelve months to complete”, Defendant can “overcome the work product protection” given that it “needs twelve months to perform Plaintiffs’...tests to prepare its non-infringement case” and a delay until after expert reports are produced would “foreclose [Defendant’s] ability to independently attempt to reproduce...test results before the close of discovery”. *Id.* at 10-11; *see also* Def.’s Letter dated June 27, 2012 at 2. Thus, “[u]nless Plaintiffs’ indicate they will not rely on any testing results for purposes of infringement, ...there is no explanation for Plaintiffs’ refusal to produce this information now...other than to prejudice [Defendant’s] ability to prepare its defenses to infringement”. *See* Def.’s Letter date June 27, 2012 at 2.

In opposition, Plaintiffs object to producing the “testing procedures that...[their] non-testifying expert will use to test [Defendant’s] product” as “premature...[because] expert discovery is not scheduled to being until August 30, 2013”, because “such testing may not be

needed if [Defendant's] documents show its product meets the 12-month stability limitation", and because "these testing procedures constitute work product protected from discovery...[given that] they will be developed by Plaintiffs' non-testifying consultant at the request of counsel". See Pl.'s Opp'n Letter dated June 29, 2012 at 1. Plaintiffs also maintain that Defendant's request is "premature because...no testing procedures...[have been developed] yet...and testing has not yet commenced". *Id.* at 2. In fact, "[s]ince [Defendant] has yet to complete its document production, Plaintiffs do not know if they will need to conduct or complete the contemplated testing". *Id.* Citing *In re Chevron Corp.*, 633 F.3d 153, 164 (3d Cir. 2011) and *Banks v. United States*, 90 Fed. Cl. 707, 709 (Fed. Cl. 2009), Plaintiffs contend that "[e]ven assuming the request for testing procedures is not premature", "[Defendant's application] should be denied" given that "the work product doctrine protects the confidentiality of papers prepared by or on behalf of attorneys in anticipation of litigation" and the fact that "the testing procedures...fall squarely within that protection". *Id.*

Citing *Sicurelli v. Jeneric/Pentron Inc.*, 2006 WL 1329709, at *2 (E.D.N.Y. 2006), *Banks*, 90 Fed. Cl. at 712, and *U.S. ex rel. Dye v. ATK Launch Sys., Inc.*, 2011 WL 996975, at *4 (D. Utah 2011), Plaintiffs argue that "[Defendant] can obtain substantially equivalent information from its own experts...by performing its own tests" without undue hardship and that "[c]ourts addressing this issue have refused to compel production of materials developed by a non-testifying expert". *Id.* Citing *Hendrick v. Avis Rent A Car System, Inc.*, 916 F. Supp. 256, 260-61 (W.D.N.Y. 1996), Plaintiffs argue that despite having the "burden to demonstrate both its substantial need for Plaintiffs' work product and its inability to obtain the equivalent without undue hardship", Defendant "has offered no explanation why it is unable to conduct its own tests

of the stability of its own product”. *Id.* at 2-3. Further, citing *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010) and *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000), Plaintiffs contend that Defendant “should have conducted...testing already since it has an obligation to determine whether its product avoids the stability limitation of the claims”. *Id.* at 3. Noting that Defendant “has indicated that it will conduct its own stability tests, and in fact should readily be able to do so since it conducted stability testing as part of its ANDA submission”, Plaintiffs maintain that “[s]tability testing is a common procedure that is required by the FDA” and “[t]hose of skill in the art could readily conduct this type of test”. *Id.* Further, Plaintiffs claim that “[u]nder [Defendant’s] theory, all testing conducted in connection with the litigation would be produced prior to expert discovery so a party could replicate it” and this “is plainly not the law”. *Id.* Plaintiffs argue that Defendant “mistakenly relies on *Sandvik Intellectual Prop. AB v. Kennametal Inc.*, 2011 WL 466696, at *2-4 (W.D. Pa. 2011)”, noting that the documents at issue in that case “related to tests that were performed by the party without counsel’s involvement...and thus...not protected by the work product doctrine”. *Id.* Similarly, Plaintiffs argue that Defendant’s belated identification of *Medeva Pharma Suisse AG, et al. v. Roxane Laboratories, Inc.*, (D.N.J. 2010) to support its position is also “wrong” because “[e]xpert reports in that case were served as early as December...2009, ...well before the court ordered production of expert testing protocols”. *Id.* at 3-4.

III. LEGAL STANDARDS

A. Discovery

Pursuant to FED. R. CIV. P. 26(b)(1), “parties may obtain discovery regarding any

nonprivileged matter that is relevant to any party's claim or defense" and "the court may order discovery of any matter relevant to the subject matter involved in the action", although "relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence". *See also Pearson v. Miller*, 211 F.3d 57, 65 (3d Cir. 2000). At the same time, "the Court has a responsibility to protect privacy and confidentiality interests" and "has authority to fashion a set of limitations that allow as much relevant material to be discovered as possible...while preventing unnecessary intrusions into legitimate interests that may be harmed by the discovery of material sought". *Schmulovich v. 1161 Rt. 9 LLC*, 2007 U.S. Dist. LEXIS 59705, at *3-4 (D.N.J. 2007); *see also Pearson*, 211 F.3d at 65; FED. R. CIV. P. 26(c).

B. Work-Product Privilege

Pursuant to FED. R. CIV. P. 26(b)(3),

(A) Documents and Tangible Things. Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent). But, subject to Rule 26(b)(4), those materials may be discovered if:

- (i) they are otherwise discoverable under Rule 26(b)(1); and
- (ii) the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means.

(B) Protection Against Disclosure. If the court orders discovery of those materials, it must protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of a party's attorney or other representative concerning the litigation.

“Even where the applicability of the work product doctrine has been established, factual material may be ordered produced upon a showing of substantial need and inability to obtain the equivalent without undue hardship”. *Sicarelli v. Jeneric/Pentron Inc.*, 2006 WL 1329709, at *3 (E.D.N.Y. 2006). “Substantial need is not evaluated in a vacuum, and in order to overcome work product protection, [a party] must demonstrate that it cannot obtain the substantial equivalent of the information it seeks”. *Id.* “That does not mean that a party seeking the document must show an absolute impossibility, but rather that it is significantly more difficult, time-consuming or expensive to obtain the information from another source”. *Id.* In addition, “[discovery under] FED. R. CIV. P. 26(b)(3)(A) is also limited by [FED. R. CIV. P. 26(b)(4)(D)]” which provides:

- (D) Expert Employed Only for Trial Preparation. Ordinarily, a party may not, by interrogatories or deposition, discover facts known or opinions held by an expert who has been retained or specially employed by another party in anticipation of litigation or to prepare for trial and who is not expected to be called as a witness at trial. But a party may do so only:
 - (i) as provided in Rule 35(b); or
 - (ii) on showing exceptional circumstances under which it is impracticable for the party to obtain facts or opinions on the same subject by other means.

Banks v. The United States, 90 Fed. Cl. 707, 709-13 (Fed. Cl. 2009).

“Unlike the attorney client privilege, the work product privilege is governed, even in diversity cases, by a uniform federal standard embodied in Federal Rule of Civil Procedure 26(b)(3)”. *United Coal Cos. v. Powell Constr. Co.*, 839 F.2d 958, 966 (3d Cir. 1988). A party may not ordinarily “discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party’s attorney, consultant, surety, indemnitor, insurer, or agent)” absent a showing by the requesting

party of “substantial need for the materials to prepare its case” and an inability, “without undue hardship, [to] obtain their substantial equivalent by other means”. FED. R. CIV. P. 26(b)(3)(A). “If the court orders discovery of those materials, it must protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of a party’s attorney or other representative concerning the litigation”. FED. R. CIV. P. 26(b)(3)(B); *see also Quinn Construction, Inc. v. Skanska USA Building, Inc.*, 263 F.R.D. 190, 193 (E.D. Pa. 2009).

Importantly, “the party asserting work product protection bears the burden to show the doctrine applies”. *Sealed Air*, 253 F.R.D. at 306; *see also Conoco, Ins. v. U.S. Dep’t of Justice*, 687 F.2d 724, 730 (3d Cir. 1982). The Third Circuit has adopted a “two part test for ascertaining whether the documents or things at issue should be protected under the work-product doctrine”. *Id.*; *see also In re Gabapentin Patent Litig.*, 214 F.R.D. 178, 183 (D.N.J. 2003); *Muse-Freeman v. Bhatti*, 2008 WL 2165147, at *1 (D.N.J. 2008); *Paris v. R.P. Scherer Corp.*, 2006 WL 1982876, at *2 (D.N.J. 2006). The first inquiry is “the reasonable anticipation test, which requires that the court determine whether litigation could reasonably have been anticipated...[with the] relevant inquiry [being] whether in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation”. *Id.*; *see also In re Gabapentin*, 214 F.R.D. at 183; *Maertín v. Armstrong World Indus.*, 172 F.R.D. 143, 148 (D.N.J. 1997); *Martin v. Bally’s Park Place Hotel & Casino*, 983 F.2d 1252, 1258 (3d Cir. 1993); *Rockwell Int’l*, 897 F.2d at 1266. The second inquiry “is whether the documents were prepared primarily for the purpose of litigation, ...as documents prepared for other purposes that prove useful in subsequent litigation are not attorney work-product”. *Id.* at 307; *see also Paris*, 2006 WL 1982876, at *2; *In*

re Gabapentin, 214 F.R.D. at 184. “To be protected by the work-product doctrine, a document must have been created for use at trial or because a lawyer or party reasonably anticipated that specific litigation would occur and prepared the document to advance the party’s interest in the successful resolution of that litigation”. *Willingham v. Ashcroft*, 228 F.R.D. 1, 6 (D.C. Cir. 2005). “The decision that a document is protected by the work product doctrine is not a linear conclusion and is necessarily dependent on both the content of the document and the factual showing by the party seeking disclosure”. *Coregis Ins. Co. v. Law Offices of Carole F. Kafriksen, P.C.*, 57 Fed. Appx. 58, 60 (3d Cir. 2003).

“Courts have recognized that studies or tests conducted after a party is aware of potential litigation are within the scope of the work product immunity doctrine”. *U.S. ex rel. Dye v. ATK Launch Systems Inc.*, 2011 WL 996975, at *5 (D. Utah 2011). “[E]ven tests which generate factual data – when conducted at the direction of counsel and in preparation for litigation – are strongly indicative of the mental impressions, conclusions, opinions, or legal theories of [a party’s] attorneys” and are therefore “protected by the work product doctrine”. *Id.* Further, where a party has the ability to “perform its own tests”, “[s]uch testing would not be [considered] an undue hardship”. *Id.*

IV. CONCLUSION

With respect to the materials that Defendant seeks related to the *Tris matter*, given the Parties’ respective representations (*see* Def.’s Letter dated June 12, 2012 at 2, 7-9; *see also* Tris’ Opp’n Letter dated June 26, 2012 at 1), the Court adopts the procedure outlined by Tris. Specifically:

- (1) Plaintiffs are directed to prepare a Confidentiality Log

describing any relevant materials being withheld and to serve Defendant and Tris with a copy of same by **July 20, 2012**;

(2) Tris is directed to review Plaintiffs' Confidentiality Log and to prepare a corresponding Objection Log identifying what documents can be produced, what documents can be produced in redacted form, and what documents should be withheld, and to serve Plaintiffs and Defendant with a copy of same by **August 3, 2012**;

(3) Defendant is directed to review Plaintiffs' Confidentiality Log together with Tris' Objection Log and, thereafter, to serve Plaintiffs and Tris in writing with any challenges by **August 17, 2012**;

(4) The Parties are directed to meet and confer with respect to any challenges by **August 31, 2012**; and

(5) Defendant is directed to raise any remaining issues related to production of materials from the *Tris matter* in a letter to the Court and all counsel by **September 14, 2012**.

Therefore, this aspect of Defendant's application is **DENIED** without prejudice.

With respect to the information that Defendant seeks related to the testing procedures Plaintiffs intend to use on Defendant's ANDA samples to support its infringement case, initially the Court notes that Plaintiffs have represented that "testing has not yet commenced", "no testing procedures" have been developed yet, and "such testing may not be needed". *See* Pl.'s Opp'n Letter dated June 29, 2012 at 1.

Nonetheless, to the extent Plaintiffs elect to test Defendant's ANDA samples in order to meet their burden of proving infringement, the Court finds that the testing procedures and protocol fall within the work-product privilege. It is undisputed that such testing described above, if conducted and utilized by Plaintiffs' testifying or non-testifying expert, will be at the direction of Plaintiffs' counsel, for purposes of "trial by or for...[Plaintiffs]" (FED. R. CIV. P.

26(b)(3)), and not within “the ordinary course of business” (*Sealed Air*, 253 F.R.D. at 306). The Court “has no basis to doubt” same. *Banks*, 90 Fed. Cl. at 711. Despite Defendant’s claim that it is only seeking “the factual information needed to perform Plaintiffs’ 12-month infringement tests” (Pl.’s Opp’n Letter dated June 12, 2012 at 10), the Court finds that Defendant has failed to demonstrate that it has a “substantial need...[for Plaintiffs testing procedures and protocol]” to prepare its case and cannot, “without undue hardship[,] obtain the substantial equivalent of the materials by other means” (*In re Cendant Corp. Securities Litig.*, 343 F.3d 658, 663 (3d Cir. 2003); *see also U.S. ex rel. Dye*, 2011 WL 996975, at *5). Defendant “has not demonstrated why it could not and cannot now obtain the substantial equivalent of the information” that may be contained in the results obtained from Plaintiffs’ testing procedures and protocol by conducting its own stability tests. *Sicurelli*, 2006 WL 1329709, at *3; *see also U.S. ex rel. Dye*, 2011 WL 996975, at *5. While “[it] is true that...[conducting its own stability tests using its own procedures and protocol] may be more expensive or burdensome than the production of...[Plaintiffs’ requested testing procedures and protocol]”, other “discovery devices...[such as the exchange of expert reports and conducting expert depositions] do provide an alternative means for [Defendant] to obtain the substantial equivalent and, perhaps more, without undue hardship and without impinging upon [P]laintiffs’ work product”. *Id.*; *see also U.S. ex rel. Dye*, 2011 WL 996975, at *5. Even if Defendant had demonstrated a substantial need for Plaintiffs’ testing procedures and protocol and the inability to obtain the substantial equivalent by other means without undue hardship, the Court finds that Defendant has failed to show “exceptional circumstances under which it is impracticable...to obtain facts” held by Plaintiffs’ non-testifying expert. FED. R. CIV. P. 26(b)(4)(D); *see also Banks*, 90 Fed. Cl. at 709-13; *U.S. ex rel. Dye*, 2011

WL 996975, at *5.

The Court acknowledges Defendant's desire to "independently run 'parallel' studies using Plaintiffs' protocols to corroborate Plaintiffs' test results" and, thus, the fact that Defendant would require Plaintiffs' testing procedures and protocol as soon as possible in order to complete such 12-month study. *See* Def.'s Letter dated June 12, 2012 at 2. However, the Court finds that "[s]tability testing is a common procedure that is required by the FDA" and that "[t]hose of skill in the art [can] readily conduct this type of test". *See* Pl.'s Opp'n Letter dated June 29, 2012 at 3. Given that Defendant is "fully capable of conducting its own tests" and fully capable of engaging in thorough expert discovery related to Plaintiffs' testing procedures, protocol, and results, the Court notes that Defendant has failed to cite any authority to support its position that "reproduc[ing] a party's testing trumps the work-product doctrine or meets the substantial need prong". *Id.*; *see also Sicurelli*, 2006 WL 1329709, at *3. Specifically, the Court finds those cases cited by Defendant distinguishable from the instant litigation. Unlike *Sandvik Intellectual Property AB v. Kennametal, Inc.*, 2011 WL 466696, at *3-5 (W.D. Pa. 2011), here there is no claim by Defendant that Plaintiffs engaged in internal testing prior to the initiation of this lawsuit and, further, there is no claim by Defendant that Plaintiffs have "made testing parameters a central issue on the invalidity...[or infringement] of the subject patent-in-suit". Unlike the Order issued in *Medeva Pharma Suisse A.G. v. Roxane Laboratories, Inc.*, Civ. Action No. 07-5165 (D.N.J. July 21, 2010) requiring the disclosure of expert testing protocol after expert reports had already been exchanged, here the Court notes that the Parties have not completed fact discovery or engaged in any expert discovery.

Having considered the papers submitted and the opposition thereto, and having conducted

oral argument on July 9, 2012, and for the reasons stated on the record and set forth above;

IT IS on this 12th day of July, 2012,

ORDERED that Defendant's application for an Order compelling Plaintiffs to produce all relevant facts, expert and other non-privileged materials made of record in the *Tris matter* [dkt. entry no. 33] is **DENIED** without prejudice as set forth above; and it is further

ORDERED that Defendant's application for an Order compelling Plaintiffs to produce the testing procedures Plaintiffs intend to use on Defendant's ANDA samples to support its infringement case [dkt. entry no. 33] is **DENIED** as set forth above.

s/ Douglas E. Arpert _____

DOUGLAS E. ARPERT
UNITED STATES MAGISTRATE JUDGE