UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE A.G., et al., **Plaintiffs,** **v.** **ROXANE LABORATORIES, INC.** **Defendant.**	**Civil Action No. 07-5165 (FLW)** **MEMORANDUM OPINION**

BONGIOVANNI, Magistrate Judge

This matter comes before the Court upon Plaintiffs Medeva Pharma Suisse A.G., Warner Chilcott Pharmaceuticals Inc. and Warner Chilcott Company, LLC's (collectively, "Medeva") motion to preclude Defendant Roxane Laboratories, Inc. ("Roxane") from disputing the location and duration of release of mesalamine from Roxane's generic product and Asacol in the human body. The Court has fully reviewed and considered all of the papers submitted in support of and in opposition to Medeva's motion as well as the arguments set forth by counsel during the November 23, 2010 hearing. For the reasons set forth more fully below, Medeva's motion is GRANTED in part and DENIED in part.

I. Procedural History and Background

Medeva filed the instant Hatch-Waxman patent infringement case against Roxane on October 26, 2007 after Roxane filed an Abbreviated New Drug Application ("ANDA") and Paragraph IV Certification and Notice letter seeking approval to commercially manufacture and market a generic version of Medeva's Asacol product, which is marketed under United States Patent No. 5,541,170 (the "'170 patent") to treat mild to moderate ulcerative colitis. The '170 patent is owned by Plaintiff Medeva Pharma Suisse A.G. Prior to October 30, 2009, the '170

patent was licensed exclusively to Proctor & Gamble Pharmaceuticals, Inc. ("P&G"), now known as Warner Chilcott Pharmaceuticals Inc. On October 30, 2009, Warner Chilcott Company, LLC acquired P&G. Warner Chilcott Company, LLC is now the exclusive licensee of the '170 patent. The '170 patent relates to the formulation of the active ingredient mesalamine, by which a core of mesalamine is specially coated for release to the afflicted gastrointestinal tissues. The '170 patent claims a tablet formulation of mesalamine which includes an acrylic-based resin coating that releases the entire dose of mesalamine "to the right side of the colon" so that it acts topically to relieve symptoms. The infringement issue in this matter relates to whether Roxane's proposed generic product releases its mesalamine dose in accordance with the claim. The validity issues concern whether the claimed invention would have been obvious to a person of ordinary skill in the art.

At issue in the present motion is Medeva's claim that Roxane is responsible for the spoliation of evidence. Specifically, Medeva argues that Roxane (1) destroyed highly-relevant documents concerning Roxane's product development efforts as well as its testing to determine where and when Asacol releases mesalamine and (2) manufactured a "secret batch" of its generic product in order to conduct testing in humans after persuading the Court to preclude Medeva from conducting the same kind of testing without prior Court approval. Both of these arguments as well as Roxane's opposition thereto are discussed in more detail below. As a result of the alleged spoliation, Medeva requests that sanctions be imposed. Initially, Medeva sought to preclude Roxane from disputing the location and duration of release of mesalamine from Roxane's generic product and Asacol in the human body. Medeva then expanded its request for

sanctions to include additional and lesser sanctions such as the spoliation inference, reopening discovery, waiver of the attorney-client privilege and the imposition of attorney's fees and costs.

A. The Destruction of Documents

1. Medeva's Position

Medeva claims that Roxane impermissibly destroyed relevant documents after it anticipated litigation and was under a duty to preserve same. In this regard, Medeva argues that Roxane had a duty to preserve documents as early as July 31, 2001, which corresponds to the date of an entry on Roxane's privilege log that asserts work product protection; Medeva notes that the work product doctrine does not apply unless the document at issue was created in anticipation of litigation. Further, Medeva claims that Roxane certainly had a duty to preserve documents no later than February 2002 as the evidence establishes that Roxane knew at that time that it intended to file an ANDA with a Paragraph IV Certification regarding its generic product. Nevertheless, Medeva claims that Roxane failed to issue a document preservation notice (i.e., a litigation hold) until July 2007.

Additionally, Medeva claims that Roxane's normal document retention policies did not sufficiently protect against spoliation. Indeed, Medeva argues that Roxane's normal document retention policies confirm that Roxane breached its duty to preserve documents because they show that documents were actually destroyed in 2002 and thereafter. Further, Medeva argues that the testimony obtained in this case also confirms that Roxane had annual file clean-up days

during which documents were destroyed.[1] Medeva therefore contends that Roxane failed to take adequate steps to prevent spoliation between July 2001 and July 2007.

Further, Medeva argues that the evidence establishes that relevant documents were actually destroyed. For example, Medeva claims that Roxane destroyed documents relating to its first pharmacokinetic study involving Asacol (the "Anapharm study"). Medeva claims that Roxane failed to produce (1) the protocol for the Anapharm study, which Roxane's Director of Regulatory and Medical Affairs testified would have shown Roxane's objectives and hypotheses for the study and which Roxane confirmed no longer exists; (2) Dr. Kramer's (Roxane's consultant) final report from the Anapharm study and (3) any subsequent correspondence regarding the study, despite the fact that Dr. Kramer sent an email to Roxane asking whether any changes regarding the study should be made. Moreover, Medeva argues that Roxane cannot shift its blame for failing to preserve documents related to the Anapharm study by arguing that Medeva could have, but did not subpoena Anapharm for the missing information. Medeva argues that Roxane had an independent responsibility to preserve the missing information.

Likewise, Medeva claims that it was not in a position to pursue discovery related to the Anapharm study because it was not listed in Roxane's Rule 26(a) disclosures, it is only

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[1]Medeva also argues that Roxane's reliance on a document retention policy which established that documents such as laboratory notebooks, technical reports and developmental and analytical records were preserved for at least 20 years is inadequate because that policy is dated May 28, 2008. As a result, Medeva contends that Roxane cannot establish that it took reasonable steps to preserve all relevant information between July 2001 and July 2007 when Roxane finally issued a litigation hold. Roxane, however, subsequently produced document retention policies dating back to 1998, which show that it was its normal business practice to retain technical information for 30 years. Medeva, however, notes that none of the document retention policies relied on by Roxane specifically reference Roxane's generic mesalamine product.

referenced in a single email, Roxane's witnesses did not mention it in their testimony, Roxane did not produce its research agreement with Anapharm and Roxane would not admit that the study existed. Indeed, Medeva claims that by the time it learned of the Anapharm study, it was the fall of 2009 and fact discovery had closed. As such, Medeva claims that it did not have the opportunity to subpoena Anapharm and that even if it were granted leave to do so out of time, it did not believe that it would get a response from Anapharm in time to make use of it here.

In addition, Medeva argues that Roxane has only produced several documents in traditional paper file form and has failed to produce the corresponding electronic versions of these emails and documents. Such documents relate to analysis of pharmacokinetic studies involving Roxane's prototype formulations as well as correspondence regarding the design of Roxane's clinical study created to test the alleged clinical effectiveness of Roxane's generic product against both Asacol and a placebo. Specifically, Medeva takes issue with Roxane's production of electronic documents and emails from several "key custodians." (Medeva Reply Br. at 4). For example, Medeva claims that no emails or other electronic documents of any kind were collected from Eric Spiller, Roxane's Associate Director of Product Development and the "project leader" responsible for developing Roxane's generic product. During oral argument, Medeva clarified that it is not arguing that Roxane should have produced documents in both paper and electronic format, but instead, that the lack of electronic documents establishes that information was destroyed.

Medeva also argues that Roxane failed to produced signed final reports for studies related to Roxane's development and testing of its generic product. Medeva contends that it knows that these signed final reports exist because it obtained them from third parties, even though Roxane

failed to produce same. Similarly, Medeva argues that discovery obtained from Quintiles, a contractor retained by Roxane to conduct a clinical study, supports the fact that Roxane destroyed documents. In this regard, Medeva points out that Quintiles, but not Roxane, produced a number of emails sent between Quintiles and Roxane employees between 2005 and 2006 that concerned Roxane's evaluation of U.K. Asacol as well as Roxane's representations to foreign regulatory authorities concerning the formulation characteristics of its tablets. Medeva claims that because Roxane did not suspend its routine destruction of documents, there is no way of knowing what other documents and emails were destroyed before Roxane implemented its litigation hold. Medeva also argues that what is clear form the sheer number of destroyed documents is that Roxane is liable for spoliation.

Further, Medeva contends that the destroyed documents are relevant, indeed critical, to this litigation and that it has been prejudiced by their loss. With respect to relevance, Medeva argues that the destroyed documents are relevant to (1) Roxane's efforts to develop its formulation; (2) Roxane's claims of non-infringement; and (3) Roxane's challenge to the validity of the '170 patent. Indeed, Medeva argues that the destroyed documents bear on critical issues such as whether Roxane's generic product releases mesalamine to the right side of the colon and whether Asacol releases mesalamine to the right side of the colon, a fact that Roxane has claimed is central to its defense of this matter. For example, Medeva contends that the Anapharm study, which Medeva claims evaluated the release of Asacol in the gastrointestinal tract, is obviously relevant to Roxane's allegations that Asacol is not a commercial embodiment of the '170 patent and Roxane's claims of non-infringement.

With respect to prejudice, Medeva claims that the fact that relevant evidence was destroyed establishes prejudice. Indeed, Medeva argues that all it has to show to establish prejudice is that its ability to effectively prepare a full and complete trial strategy has been impeded. Medeva argues that its ability to effectively prepare such a trial strategy has in fact been impeded because Roxane destroyed documents that concern the location of the release of mesalamine as well as Roxane's development of its generic product. Given the destruction, Medeva does not have access to the missing documentary evidence and has been prevented from questioning Roxane's witnesses regarding same. What is more, Medeva claims that the destroyed documents appear to support the conclusion that Asacol releases at the terminal ileum, as claimed by the '170 patent. Further, Medeva claims that the destruction of the aforementioned documents is prejudicial because Roxane keeps altering its position regarding the location of where its generic product releases in the body. Medeva claims that because the cite of release has been a moving target, it is prejudiced by the destruction of documents that bear on where and how Roxane designed its product to release in the gastrointestinal tract (*i.e.*, the types of documents that would shed the most light on Roxane's design decisions and testing of its product and Asacol).

In addition, Medeva argues that the prejudice imposed on it has been increased because, not only were relevant documents destroyed, but Roxane sought to evade discovery through deposition testimony and interrogatory responses on the subject matter contained in the destroyed documents. For example, Medeva claims that despite the fact that the FDA was interested in where Roxane's generic product releases in the body and despite the fact that Roxane made statements in documents submitted to the FDA regarding where its product releases mesalamine,

Roxane refused to produce discovery regarding where its generic product releases mesalamine.[2] Indeed, Medeva argues that no deponent, including Roxane's Rule 30(b)(6) witness, was able to testify regarding where Roxane's generic product releases mesalamine in the gastrointestinal tract or the basis for Roxane's characterization of its generic product's release characteristics that is found in Roxane's ANDA, proposed labeling, Paragraph IV Notice letter or patent application.

In addition, Medeva claims that Roxane's supplemental answers to Medeva's interrogatories were insufficient. For example, Medeva's Interrogatory No. 11 sought details regarding the release of mesalamine from Roxane's generic product within the human gastrointestinal tract. Roxane's response pointed to its Paragraph IV Notice letter and its employee Vinay Shukla as sources of responsive information. Medeva contends that Roxane's response is insufficient because, as previously stated, Roxane's witnesses testified that Roxane had no knowledge of the factual bases for the assertions contained in Roxane's Paragraph IV Notice letter and Mr. Shukla specifically testified that he was not the expert in the *in vivo* area as to where Roxane's generic product releases and explicitly refused to answer questions about Roxane's Paragraph IV Notice letter that addressed Roxane's generic product's release characteristics.

Given the alleged magnitude of Roxane's misconduct, Medeva argues that the sanction of preclusion is justified even if such a sanction is tantamount to dismissal of Roxane's claim. As previously stated, Medeva argues that Roxane not only destroyed documents but sought to evade other efforts to obtain the information contained in the destroyed documents. Moreover, Medeva

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[2]Such documents include Roxane's proposed labeling submitted with its ANDA, its ANDA, its Paragraph IV Notice letter and its revised proposed labeling regarding where its product releases mesalamine

claims that Roxane, whose business model is to challenge the intellectual property rights of innovative drug companies, knew what it was doing when it failed to issue a timely litigation hold and destroyed relevant evidence because Roxane's. Medeva, therefore, asks the Court to sanction Roxane by precluding Roxane from disputing where its generic product releases and where Asacol releases in the human body. Medeva also argues that if the Court were to consider additional and/or lesser remedies, then the following may be be appropriate: (1) imposition of adverse inferences regarding where Roxane's generic product and Asacol release; (2) reopening of fact discovery and requiring Roxane to restore all back-up tapes from 2001 through the present; (3) finding that Roxane's conduct constitutes a waiver of work product protection from 2001 through 2007; and (4) imposition of all fees and costs associated with the instant motion to preclude as well as those incurred by Medeva's experts in testing and preparing reports on Lot No. 089226.

2. Roxane's Position

Roxane opposes Medeva's motion to preclude as well as its request for additional and/or lesser remedies arguing that there has been no spoliation of evidence. In the first instance, Roxane claims that no documents were actually or intentionally destroyed. Roxane argues that from June 2002 forward it had a formal document retention policy in place that required laboratory notebooks, technical reports and developmental and analytical records to be retained for 20 years. Indeed, Roxane argues that from 1998-2004, its document retention policy required Roxane to preserve technical information for at least 30 years. Further, Roxane claims that its document retention policy did not permit documents to be purged without safeguards; instead, on the file clean-up days that occurred under Roxane's document retention policies, employees paid

close attention to the document retention policies to ensure that no technical information, including all such information related to mesalamine, would have been destroyed. In addition, Roxane contends that the evidence shows that no documents relating to mesalamine were destroyed. In this regard, Roxane notes that its Rule 30(b)(6) witness on document retention issues explicitly testified that any and all documents concerning mesalamine were not destroyed. Roxane also argues that the litigation hold put in place in 2007 "merely modified the ongoing document retention policy to suspend any potential destruction of documents." (Roxane Opp. Br. at 4). Roxane claims that it would be unreasonable to have required Roxane to institute a litigation hold in 2001, four years before its first ANDA product was ever manufactured. Moreover, Roxane claims that such a litigation hold would only have continued the preservation of documents already being preserved under Roxane's document retention policies.

With respect to the allegedly destroyed documents identified by Medeva, Roxane argues that the documents are not critical to this matter and also claims that Medeva has failed to show that Roxane actually and intentionally destroyed same. For example, with respect to the Anapharm study, Roxane argues that while witnesses testified that a protocol for the study must have existed, nothing in the record establishes that Roxane itself had the protocol. Further, Roxane notes that while a protocol describing how the Anapharm study would be performed was not produced, Roxane did produce other documents relating to the study, including Dr. Kramer's principal and supplemental reports, which detail how the Anapharm study was actually carried out. Moreover, Roxane claims that there is no evidence that Dr. Kramer prepared other documents related to the study or that the study results were ever memorialized in any other format.

In addition, Roxane claims that the Anapharm study is not relevant to this litigation, and certainly not of critical importance, because it does not relate to Roxane's generic product or a prototype thereof, but instead relates to Medeva's Asacol product and Roxane never asked Dr. Kramer to examine where Asacol releases mesalamine in the gastrointestinal tract. Further, Roxane argues that Medeva's conduct establishes that the Anapharm study is not important to this litigation. In this regard, Roxane notes that Medeva did not pursue discovery on this study directly from Anapharm. Roxane also notes that in its deposition of Dr. Kramer, Medeva asked almost nothing about the Anapharm study and did not even inquire into the existence of a protocol. Further, Roxane claims that despite the fact that Medeva had the results of the Anapharm study and could have had its experts analyze same, it did not.

Roxane also contends that it was not obligated to make a duplicate production of documents that were produced in the traditional paper file format. Indeed, Roxane argues that it was not required to produce both paper and electronic versions of documents and emails. Consequently, Roxane argues that the fact that certain documents and emails were only produced in paper format and were not electronically produced does not support the conclusion that these documents and emails were destroyed. In addition, with respect to Eric Spiller's files, Roxane claims that the evidence shows that Mr. Spiller maintained all of his mesalamine related documents in a specific file and that this file was produced to counsel. Indeed, Roxane argues that there is no testimony that either Mr. Spiller or any other employee ever deleted or destroyed a single document concerning mesalamine.

More importantly, Roxane claims that there is no evidence that the allegedly missing documents are important to this case. For example, Roxane argues that there is no evidence that

the allegedly missing product development documents would have contained information about where either Roxane's generic product or Asacol releases. Further, Roxane notes that there could have been no such documents concerning its generic product until April 2005 because Roxane's generic product was not manufactured until that time. Similarly, Roxane claims that the allegedly missing documents concerning Roxane's prototype formulations are not relevant to this matter and would not have contained information regarding the release of either its generic product or Asacol.

Roxane also argues that the record does not support Medeva's contention that Roxane ever possessed the allegedly missing final study reports related to Roxane's development and testing of its generic product that Medeva obtained from Quintiles. Indeed, Roxane notes that Elizabeth Ernst, Roxane's Director of Regulatory Medical, testified that she did not recall ever receiving the final study reports. In addition, with respect to the remainder of the Quintiles production, Roxane claims that the "vast majority" of same is made up of raw data generated from a clinical study that was conducted in a dozen countries and which was never forwarded to Roxane. (Roxane Opp. Br. at 6). Roxane claims that the fact that a "stray email or two" was produced by Quintiles, but not Roxane, does not support Medeva's claim of spoliation. (*Id.*)

In addition, Roxane argues that it did not violate any discovery orders entered by this Court, nor did it engage in discovery misconduct. For example, Roxane claims that it did not evade discovery on where its generic product releases mesalamine; instead, it simply did not know the answer to Medeva's questions. Roxane contends that prior to expert discovery it had no information regarding where its generic product releases mesalamine because it never conducted any experiment or study that would provide such information as it did not design its

product to target a specific site of action. Indeed, Roxane claims that the specific site of release was not important to its development of its generic product or to the FDA's evaluation of same. Instead, Roxane claims that the only matter of importance was whether Roxane's generic product showed equivalent efficacy to Asacol. Roxane claims that the fact that certain documents submitted to the FDA comment on where its generic product releases mesalamine are of no moment because the statements were not purposefully made. For example, Roxane contends that the fact that its original draft label submitted to the FDA contained the statement "delays release of mesalamine until it reaches the terminal ileum and beyond" is an artifact of the fact that Roxane initially copied Asacol's label verbatim. Roxane notes that it made amendments to the label for its generic product as the application process proceeded. Similarly, Roxane argues that its interrogatory responses regarding where its generic product releases mesalamine are not deficient because they incorporate Roxane's expert reports which describe in detail where its product releases mesalamine. Further, Roxane argues that it cannot be held responsible for any issues Medeva had in obtaining discovery from Quintiles because Quintiles is a third party and Roxane was not involved in its production of documents.

Further, Roxane argues that Medeva has not established that it has been prejudiced by Roxane's failure to produce the allegedly missing documents. Indeed, Roxane claims that Medeva does not explain how the missing documents would impede its ability to put on its infringement and validity case. Roxane argues that that is because Medeva is fully informed on Roxane's efforts to develop its generic product and both Roxane's claims of non-infringement as well as its challenge to the validity of the '170 patent. Roxane notes that previously in this litigation, Medeva represented that it was ready to go to trial and that that ability has not been

impaired. In this regard, Roxane notes that no expert referenced the subject matter of the missing documents in their opening expert reports and argues that Medeva has made no showing that the missing documents, including the Anapharm protocol, would have been favorable to its case or that they would have been any more useful than the information already produced.

As a result, Roxane argues that there is no basis for the Court to enter sanctions against it. First, Roxane argues that preclusion is an extreme sanction that is only granted in rare circumstances that do not exist here. Consequently, Roxane claims that it should not be precluded from disputing the location and duration of release of mesalamine from either its generic product or Asacol in the human body.

Second, Roxane claims that the adverse inferences sought by Medeva, that Roxane destroyed documents that established that Roxane's generic product releases to the right side of the colon and that Roxane destroyed documents that established that Asacol releases to the right side of the colon, bear no relation to the content of the allegedly missing documents and are not warranted. For example, Roxane claims that the missing Anapharm protocol cannot speak to where Roxane's generic product releases because the study was conducted on Asacol. Further, Roxane argues that it would be unfair to use the missing Anapharm protocol to support an adverse inference regarding Asacol because there is no evidence that Roxane possessed the protocol or that it intentionally destroyed it. Roxane argues that this is particularly true given the fact that it produced other information from the Anapharm study, including the test results. Indeed, Roxane claims that there is no evidence in the record that the allegedly missing documents might or would have been unfavorable to Roxane. Similarly, Roxane claims that Medeva has not established that the missing documents have impeded its ability to put on either

its infringement or validity case. As a result, Roxane claims that there is no basis to impose either of the requested adverse inferences on it.

Third, Roxane argues that there is no reason for the Court to reopen discovery or to permit Medeva to obtain back-up tapes from Roxane. In this regard, Roxane claims that there has been no spoliation of evidence and consequently Medeva has no need for more discovery. Roxane also notes that Medeva's request for additional discovery is insincere because Medeva has claimed that additional discovery will not cure the alleged spoliation. Further, Roxane argues that the parties entered a stipulation agreeing that back-up tapes not be produced and Medeva's request for the wholesale restoration of same is unfairly burdensome, unnecessary, duplicative, time-consuming, expensive and would needlessly delay this matter and open the door for additional discovery motions.

Fourth, Roxane argues that there is no basis for finding a wholesale waiver of Roxane's assertion of the attorney-client privilege and work product doctrine. Roxane claims that Medeva has not challenged a single entry on Roxane's privilege log and therefore it would be inappropriate to find that Roxane's conduct amounts to the broad waiver requested by Medeva. In fact, Roxane argues that the only basis for a claim of waiver is Roxane's nondisclosure and failure to log a claim of privilege regarding the existence of Lot No. 089226. As a result, Roxane argues that there is no reason to give Medeva "unfettered access" to all of Roxane's documents containing attorney work product and attorney-client communications. (Roxane's Sur-Reply at 9). Moreover, as explained below in more detail, while Roxane denies that it waived work product protection regarding Lot No. 089226, even if the Court were to find that such a waiver

occurred, no case law supports Medeva's request that such a limited waiver supports the wholesale production of all of Roxane's protected information.

Finally, Roxane argues against the imposition of fees and costs. Roxane argues that the imposition of fees and costs is not warranted because Roxane has not engaged in any improper behavior. Roxane argues that it properly produced documents and that it properly invoked work product to protect the existence of the Concealed Lot, which was made at the direction of outside counsel. As a result, Roxane claims there is no need for the Court to punish Roxane or deter future misconduct by imposing fees and costs.

B. The Concealment of Lot No. 089226

1. Medeva's Position

Medeva argues that Roxane impermissibly concealed the existence of a batch of its generic product, Lot No. 089266 (the "Concealed Lot"), that it manufactured in November 2008. Roxane used the Concealed Lot to conduct gamma scintigraphy testing on humans and intended to use the results of that testing as evidence of non-infringement.[3] Medeva argues that it sought discovery regarding all batches of mesalamine tablets manufactured by Roxane, including samples thereof. Medeva claims that Roxane initially refused to provide Medeva with any samples of its product and did so only after the Court entered an Order precluding Medeva from conducting human testing using the samples produced. Despite Medeva's request for all samples, Medeva argues that Roxane only produced tablets from three lots, Lot No. 059013,

[3]After this motion was fully briefed, Roxane learned that there was something wrong with the Concealed Lot. The Concealed Lot was not manufactured properly and, as such, the tablets did not work as Roxane intended. Consequently, while initially intending to rely on its experts' testing of the Concealed Lot, Roxane is no longer doing so.

which pertained to expired tablets, and Lot Nos. 089050 and 079138, which pertained to unexpired tablets; Roxane did not provide any tablets from the Concealed Lot.

Further, Medeva claims that despite having requested information regarding all samples of Roxane's mesalamine product, Roxane neither referenced the Concealed Lot in its discovery responses nor explicitly claimed that information concerning same was being withheld based on the attorney-client privilege or work product doctrine. For example, Medeva notes that Interrogatory No. 5 directed Roxane to:

> Identify by batch number, lot number, date, location, and number any quantities of any Delayed Release Dosage Form containing Mesalamine, including without limitation the Generic Product made by or for You or on Your behalf, or any quantities of any tablets, capsules, or other dosage form containing a coating component or other agent intended for use with any Delayed Release Dosage Form containing Mesalamine.

(Decl. of Paul A. Ainsworth in Support of Medeva's Motion ("Ainsworth Decl."), Ex. 32 at 3). Medeva argues that neither Roxane's response nor supplemental response to this interrogatory, which follow, disclosed the existence of the Concealed Lot or claimed that any information regarding same was being withheld based on the attorney-client privilege or work product doctrine:

> **RESPONSE TO INTERROGATORY NO. 5**
>
> Roxane objects to this interrogatory as vague. To the extent understood, Roxane also objects to this Interrogatory as overly broad, unduly burdensome and not calculated to lead to the discovery of admissible evidence in that it seeks information concerning products and formulations other than the product proposed in ANDA No. 79-073.

> Subject to the foregoing objections and its General Objections, Roxane states that information responsive to this interrogatory may be ascertained from documents that will be produced pursuant to Federal Rule of Civil Procedure 33(d).
>
> **SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 5**
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> Roxane incorporates its original response and further responds as follows: Information responsive to this Interrogatory may be ascertained from documents already produced . . . . Roxane reserves the right to supplement its response further at a future time.

(*Id*. at 4) Medeva argues that the Concealed Lot represents Roxane's ANDA product because Roxane's documents establish that these tablets were for "product development use" and "manufactured to support in-vivo studies." (Medeva Reply Br. at 25 (emphasis in original)). As such, Medeva argues that Roxane should have disclosed the Concealed Lot.

In addition, Medeva argues that to the extent Roxane claims that the Concealed Lot and information related thereto is protected by the work product doctrine, Roxane waived that protection when it failed to include such a claim on its privilege log and when it did not assert same in response to Medeva's numerous direct questions regarding the existence of Roxane's tablets. Medeva also argues that, even if properly logged, the Concealed Lot and certain information pertaining thereto would not be entitled to work product protection.

For example, Medeva claims that the mere existence of the Concealed Lot is not protected by the work product doctrine and contends that the tablets themselves do not disclose any attorney's mental impressions. Medeva also argues that the fact that none of the documents relating to the Concealed Lot refer to litigation and the fact that Roxane did not disclose the existence of the Concealed Lot on its privilege log weigh against Roxane establishing that the

work product doctrine applies. In this regard, Medeva notes that in its documents concerning the Concealed Lot: (1) Roxane described the testing of the Concealed Lot as being for "product development purposes"; (2) Roxane never informed the Institutional Review Board/Independent Ethics Committee ("IRB/IEC"), the entity that approved Roxane's testing of the Concealed Lot in humans, or the prospective study participants that the study would be used for litigation; and, (3) when informing the IRB/IEC as well as prospective study participants about who may receive the results of same, Roxane never identified this Court, Medeva, or Medeva's experts as possible recipients, despite having identified various other people and entities, including the FDA.[4]

Further, Medeva argues that the case law relied upon by Roxane to support their non-disclosure of the Concealed Lot and information related thereto is either inapposite or supports a finding in Medeva's favor. First, Medeva claims that only two of the cases relied upon by Roxane (*Novartis Pharm. Corp. v. Abbott Lab.*, 203 F.R.D. 159 (D. Del. 2001) and *Vardon Gold Co. v. BBMG Golf Ltd.*, 156 F.R.D. 641 (N.D. Ill. 1994)) discuss product testing and in those cases the issue was the disclosure of the testing methods and test results, not the actual product. Moreover, Medeva argues that in six of the seven cases cited by Roxane, the non-disclosing party raised timely privilege and work product objections to the disclosure of the concealed information (*see* Medeva Reply Br. at 14, n.20), and in the remaining case, the court determined that a waiver had occurred due to the party's failure to timely raise a claim of privilege. (*See Id.* at 14-15).

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[4]Medeva does not argue that Roxane should have disclosed its testing protocol or test results related to the Concealed Lot prior to its experts' reliance thereon. Medeva does, however, claim that Roxane was obligated to disclose, at a minimum, the existence of the tablets.

Medeva also claims that the parties' stipulation regarding expert discovery does not justify Roxane's nondisclosure of the Concealed Lot. The parties' joint stipulation regarding expert discovery provides that:

> 4. Pursuant to this agreement, the following categories of data, information, or documents need not be disclosed by any party, and are outside the scope of permissible discovery, except to the extent required by ¶ 5, and except to the extent required by FED.R.CIV.P. 26(a)(2):
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> ***
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> b. draft reports, draft studies, or draft workpapers; preliminary calculations, computations, or data runs; or other preliminary or draft materials prepared by, for, or at the direction of an expert witness[.]

(Decl. of David H. Silverstein in Support of Roxane's Opp. to Medeva's Motion (the "Silverstein Decl."), Ex. EE ¶ 4). Medeva argues that there was nothing "draft" or "preliminary" about the final tablets manufactured by Roxane that make up the Concealed Lot and, as such, the parties' stipulation did not protect their disclosure. In addition, Medeva claims that Roxane cannot shield otherwise discoverable information by forwarding it to an expert witness. Further, to the extent Roxane attempts to use the fact that Medeva drafted the parties' joint stipulation to suggest that Medeva should have more precisely drafted same to make clear that information like the Concealed Lot was not protected by the stipulation, Medeva notes that Roxane also had an active hand in drafting the stipulation and argues that Roxane, being the party who knew it would be manufacturing the Concealed Lot, could have sought an express stipulation excluding such tablets from the scope of permissible discovery.

Additionally, Medeva takes issue with the fact that Roxane conducted human testing using the Concealed Lot. Medeva argues that based on ethical concerns regarding the

uncontrolled administration of an unapproved drug product, Roxane convinced the Court to prohibit Medeva from conducting human testing using expired samples of Roxane's generic product produced in discovery. Medeva further claims that Roxane then insisted that Medeva also agree not to conduct human testing with unexpired samples of its generic drug product before producing same. Medeva argues that Roxane obtained the aforementioned prohibition knowing full well that it intended to conduct human testing using the Concealed Lot. Medeva contends that given the Court Order, Roxane's testing in humans was inappropriate because the same ethical considerations applied to Roxane as Medeva.

Finally, Medeva argues that it has been prejudiced by Roxane's impermissible withholding of the Concealed Lot. While Medeva acknowledges that some of the harm caused by Roxane's nondisclosure of the Concealed Lot has been alleviated, given Roxane's admission that the Concealed Lot is not representative of its ANDA product as well as Roxane's decision not to rely on its testing of same in this matter, Medeva also argues that it nevertheless has been prejudiced by Roxane's failure to timely disclose the existence of the Concelaed Lot. In this regard, Medeva argues that Roxane's late disclosure of the Concealed Lot resulted in Medeva being forced to seek an extension of expert discovery and conduct expedited testing on the Concealed Lot over Christmas and New Years at considerable expense in order to establish that the Concealed Lot was not representative of Roxane's generic ANDA product. Further, Medeva argues that but for this costly expedited testing, this case would have been tried with Roxane relying on the Concealed Lot as being representative of its ANDA product. As a result, Medeva requests that the Court sanction Roxane. In addition to seeking reimbursement of its expert fees and costs incurred in testing the Concealed Lot, Medeva also seeks the same sanctions described

above with respect to Roxane's alleged destruction of documents. Medeva claims that such sanctions are appropriate especially in light of the fact that Roxane's nondisclosure of the Concealed Lot further establishes Roxane's distortion of discovery.

2. Roxane's Position

Roxane argues that the Concealed Lot was protected from disclosure by the work product doctrine and was not discoverable until its experts relied on the results of the testing conducted using the Concealed Lot. In support of this argument, Roxane claims that the Concealed Lot was developed at the request of outside counsel for use by outside counsel's retained experts in conducting an experimental study for use at trial in this litigation. Specifically, Roxane claims that the Concealed Lot, which differs from Roxane's ANDA product because it contains a "very small amount of samarium oxide," was developed to permit Roxane's experts to use gamma scintigraphy to examine where Roxane's generic product releases in the gastrointestinal tract. (Roxane Opp. Br. at 19).

Roxane contends that the Concealed Lot and Roxane's testing thereof were protected by the work product doctrine because the Concealed Lot was prepared for use at trial by Roxane. Roxane argues that regardless of whether the actual tablets that make up the Concealed Lot disclose Roxane's attorneys' mental impressions, they are still protected attorney work product because the work product doctrine is not limited to the protection of counsel's mental impressions. Moreover, Roxane claims that the tablets, themselves, do contain its attorneys' mental impressions because the only purpose of adding samarium oxide to the tablets is to enable a scientist to conduct gamma scintigraphy testing. For this reason, Roxane argues that even disclosing the existence of the Concealed Lot would have disclosed Roxane's attorneys'

selection of the specific test for which the Concealed Lot was created. Indeed, Roxane claims that the facts surrounding the creation, manufacture and existence of the Concealed Lot are facts created during the pendency of this litigation at the direction of counsel for use at trial and were thus protected from disclosure.

In addition, Roxane claims that the fact that certain labeling uses the phrase "product development" neither changes the fact that the Concealed Lot was made at the direction of counsel, nor indicates that the Concealed Lot was not made in anticipation of litigation. Roxane argues that it is clear that the Concealed Lot was not made in the ordinary course of Roxane's business both because the FDA never requested that Roxane perform gamma scintigraphy testing and because Roxane has not indicated that it will submit the gamma scintigraphy test results to the FDA. Further, Roxane argues that even Medeva's experts recognized that the Concealed Lot was not created in Roxane's ordinary course of business as they described the Concealed Lot as being created in anticipation of litigation in their expert reports. As such, Roxane claims that it is clear that the Concealed Lot and related testing are protected by the work product doctrine.

Moreover, Roxane contends that it did not waive work product protection by failing to include the Concealed Lot and related documents on its privilege log or by failing to assert a privilege regarding same during its employees' depositions. In this regard, Roxane argues that it was not obligated to log the existence of the Concealed Lot or any documents concerning same on its privilege log because the Concealed Lot was created after the Complaint in this matter was filed and there is no rule requiring an ongoing privilege log. Roxane also claims that it was not bound to assert work product protection during its employees' depositions because the questions asked by Medeva involved Roxane's prototype formulations and generic ANDA product, not

litigation tablets that contained samarium oxide. Similarly, Roxane claims that it did not need to assert that any documents were being withheld based on the work product doctrine in its response to Medeva's Interrogatory No. 5 because Roxane only agreed to produce "proposed ANDA batches" meaning that the Concealed Lot fell outside the scope of discovery that Roxane agreed to provide. (Roxane Opp. Br. at 23, n.16).

Further, Roxane argues that it was not obligated to include the Concealed Lot or any related documents on its privilege log because the parties' joint stipulation regarding expert discovery put same outside the scope of permissible discovery until Roxane's experts relied on Roxane's testing using the Concealed Lot. In this regard, Roxane claims that the tablets that made up the Concealed Lot as well as its testing represented "preliminary [] materials" and "draft studies" within the meaning of the parties' joint stipulation and thus were outside of the scope of permissible discovery and not required to be logged.

Roxane also argues that Medeva's conduct shows that no privilege log entry was required. Specifically, Roxane claims that Medeva's privilege log does not contain entries regarding expert witnesses. Further, Roxane claims that Medeva's previous complaints about Roxane's privilege log did not involve Roxane's failure to identify documents related to its expert witnesses.

In addition, Roxane argues that it did not violate any Court Orders when it conducted human testing using the Concealed Lot. Roxane notes that the Court entered an Order precluding Medeva from conducting human testing using Roxane's expired generic product without prior Court approval, approval which Medeva never sought. Roxane argues that the Court did not limit Roxane's ability to test its own product and that Roxane was entitled to assume any risks

inherent in its own testing of that product. As such, Roxane argues that it did not engage in any misconduct when it tested a "modified version" of its generic product in humans under stringent study conditions and the supervision of a medical monitor, and with prior approval of a medial board.

Furthermore, Roxane claims that even if it should have disclosed the Concealed Lot and related documents to Medeva, either in total or on its privilege log, Medeva has not been prejudiced. In this regard, Roxane claims that because the Court extended expert discovery, Medeva has not been denied the opportunity to conduct additional testing. Moreover, Roxane claims that this issue is now moot since Roxane is no longer relying on its testing of the Concealed Lot. Additionally, Roxane argues that Medeva could have conducted human testing using Roxane's expired and unexpired generic product if it had sought the Court's permission to do so, but Medeva never did. Roxane contends that Medeva's failure to request permission to conduct human testing had nothing to do with Roxane's obstructing Medeva's ability to conduct same. As a result, Roxane claims that the imposition of any sanctions is unwarranted.

II. Analysis

A. Standard of Review

Spoliation is "the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 430 (S.D.N.Y. 2004) (internal quotation marks and citations omitted). It occurs "when a party has intentionally or negligently breached its duty to preserve potentially discoverable evidence[.]" *Kounelis v. Sherrer*, 529 F.Supp.2d 503, 518-519 (D.N.J. 2008). The duty to preserve evidence arises when a party reasonably believes that

litigation is foreseeable and, as such, may arise "many years before litigation commences[.]" *Micron Technology, Inc. v. Rambus Inc.*, 255 F.R.D. 135, 148 (D.Del. 2009).

Evidence of spoliation may give rise to sanctions, which include: dismissal of a claim or granting judgment in favor of a prejudiced party; suppression of evidence; an adverse inference (i.e., the spoliation inference); fines; and attorney's fees.[5] *Mosaid Tech., Inc. v. Samsung Elec. Co., Ltd.*, 348 F.Supp.2d 332, 335 (D.N.J. 2004). The imposition of sanctions is warranted "when there is evidence that a party's spoliation of evidence threatens the integrity of th[e] Court." *Id*. Spoliation sanctions serve the following three functions: remedial, punitive and deterrent. They level the playing field so that the prejudiced party is restored to the position it would have been in absent the spoliation. They punish the spoliator for its misconduct and they warn other potential litigants that spoliation of evidence will not be tolerated and will be dealt with by the Court if necessary. *See Id*.

The Court has authority to impose spoliation sanctions pursuant to both the Federal Rules of Civil Procedure and its inherent authority, and the choice of which sanction should be imposed rests in the sound discretion of the Court. *Id*. Of the sanctions that can be imposed, dismissal and suppression of evidence are considered the two most drastic and should only be levied in the most extraordinary of circumstances. *Id*. In determining whether such drastic sanctions are warranted, the Court considers: "(1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the

[5]The imposition of sanctions in patent cases is controlled by regional circuit law. *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1380 (Fed. Cir. 2004). Therefore the Court relies on Third Circuit law in analyzing what, if any, sanctions should be imposed on Roxane.

offending party is seriously at fault, will serve to deter such conduct by others in the future." *Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 79 (3d Cir. 1994). In order to establish prejudice, the party seeking spoliation sanctions must "come forward with plausible, concrete suggestions as to what [the missing] evidence might have been (*Id* at 80), and must show that its "ability to prepare effectively a full and complete trial strategy" has been impeded. *Ware v. Rodale Press, Inc.*, 322 F.3d 218, 222 (3d Cir. 2003). Generally, however, absent a showing of bad faith and substantial prejudice, dispositive sanctions should not be imposed. *See Schmid*, 13 F.3d at 80.

Of the lesser sanctions often considered by courts faced with spoliation is the spoliation inference. "The spoliation inference is an adverse inference that permits a jury to infer that 'destroyed evidence might or would have been unfavorable to the position of the offending party.'" *Mosaid*, 348 F.Supp.2d at 336 (quoting *Scott*, 196 F.R.D. at 248). In order for the spoliation inference to apply, the party seeking the adverse inference must establish that the following four factors have been satisfied: "First, it is essential that the evidence in question be within the party's control. Second, it must appear that there has been actual suppression or withholding of the evidence. Third, the evidence destroyed or withheld was relevant to claims or defenses. And fourth, it was reasonably foreseeable that the evidence would later be discoverable." *Mosaid*, 348 F.Supp.2d at 336 (internal quotation marks and citations omitted); see also *Aurelio v. Bd. of Educ. of the Borough of Carteret*, Civil Action No. 06-3146 (JLL), 2009 WL 1794800, *9 (D.N.J. June 23, 2009) (indicating that burden fell on Plaintiff, party seeking adverse inference, to show that all four factors were met)).

With respect to the second factor (i.e. "actual suppression"), "negligent destruction of relevant evidence can be sufficient to give rise to the spoliation inference." *Id*. at 338. A party need not show that its adversary "*intentionally* or *knowingly* destroyed or withheld" evidence. *Id*. at 337. This is true because "[i]f a party has notice that evidence is relevant to an action, and either proceeds to destroy that evidence or allows it to be destroyed by failing to take reasonable precautions, common sense dictates that the party is more likely to have been threatened by the evidence" and, regardless of the "offending party's culpability[,] . . . it cannot be denied that the opposing party has been prejudiced." *Id*. at 338.[6]

In addition, with respect to the third factor, that the destroyed or withheld evidence is "relevant," while not explicitly addressed by the Third Circuit or the District of New Jersey, typically, where the culpability of the offending party is negligence, gross negligence or even recklessness (as opposed to willful or knowing) the party seeking the spoliation inference must establish not only that the destroyed or withheld evidence is probative under Fed.R.Evid. 401, but also "must adduce sufficient evidence from which a reasonable trier of fact could infer that the destroyed or unavailable evidence would have been of the nature alleged by the party affected by its destruction." *Zubulake*, 229 F.R.D. at 431, n. 67 (internal quotation marks and citation omitted). In other words, the party seeking the spoliation inference must make a sufficient showing from which a fact finder could reasonably determine that the destroyed or withheld evidence would have been favorable to the movant.

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[6]As described above, where one of the more drastic sanctions such as dismissal or suppression of evidence is sought, a greater showing of culpability may be required. *Schmid*, 13 F.3d at 80; *see Mosaid*, 348 F.Supp.2d at 338, n. 11.

B. The Destruction of Documents

The Court finds that spoliation sanctions are not warranted for Roxane's alleged destruction of documents. While the court cannot fathom why Roxane failed to institute a litigation hold prior to July 2007 when it clearly anticipated litigation and had a duty to preserve information at least as early as February 2002, when it knew it would be filing a Paragraph IV Certification, and perhaps as far back as July 31, 2001 if its privilege log claiming work product protection over a document with that date is to be credited, the Court finds that Roxane adequately maintained its mesalamine files pursuant to its normal document retention policies. These policies required Roxane to retain technical information such as laboratory notebooks, technical reports and developmental and analytical records for a minimum of twenty years. Further, while those policies did not specifically reference Roxane's ANDA product, the record establishes that documents concerning same were in fact retained. This is true despite the fact that Roxane held file clean-up days prior to instituting a litigation hold and after it had a duty to preserve evidence. Indeed, the quantity and more importantly quality of documents produced by Roxane in this litigation establish that Roxane diligently preserved mesalamine related information. As such, this matter is easily distinguishable from *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, Civil Action No. 07-CV-5855 (DMC-JAD), *9 (D.N.J. July 1, 2010), where the Court imposed an adverse inference against the defendants after determining that they practiced systematic document destruction when no litigation hold was in place.

While Medeva points to several categories of documents that are allegedly missing, Medeva simply has not established that Roxane intentionally or negligently destroyed the vast

majority of these documents. Indeed, of all of the documents identified by Medeva as having been destroyed by Roxane, the Court finds that the record at best supports the conclusion that Roxane at one point possessed but failed to produce the Anapharm contract and protocol and two emails produced by Quintiles. Moreover, the Court finds that Roxane's failure to produce these documents does not warrant the imposition of spoliation sanctions. In this regard, the Court finds that Medeva has not been prejudiced by Roxane's failure to produce the Anapharm contract and protocol and the two emails produced by Quintiles.

With respect to the Anapharm documents, the Court notes that the Anapharm study did not deal with Roxane's ANDA product or any prototypes thereof, but instead examined Medeva's product. As such, the Anapharm study was not submitted to the FDA and was not important to Roxane's ANDA. Further, while the Anapharm study addressed Medeva's product, Medeva's experts do not appear to have relied upon or even considered the study in rendering their opinions. More importantly, while Roxane failed to produce its contract with Anapharm or the Anapharm protocol, which would have outlined what the study was going to entail, Roxane did produce the principal and supplemental reports related to the Anapharm study which set forth how the study actually proceeded and the results of the study, including a full data analysis with tables, graphs and explanatory text. Given Roxane's production of these reports coupled with the fact that neither Medeva nor Roxane's experts rely on the Anapharm study, the Court simply cannot see how Medeva's "ability to prepare effectively a full and complete trial strategy" has

been impeded by Roxane's failure to produce its contract with Anapharm or the Anapharm protocol. *Ware*, 322 F.3d 218, 222 (3d Cir. 2003).[7]

The Court likewise does not believe that Medeva's ability to effectively prepare a full and complete trial strategy has been impeded by Roxane's failure to produce the two emails that it once possessed and were produced by Quintiles. In this regard, the Court notes that while Roxane did not produce these emails, Quintiles did. As such, Medeva has obtained the information missing from Roxane's production. Moreover, while the fact that these emails were missing from Roxane's production may, under certain circumstances, raise a serious concern over what other information is missing from Roxane's production, such a concern is simply not present here where the breadth and quality of Roxane's document production establishes that Roxane met its duty to preserve information. Further, the substance of the two missing emails establishes that they are not of critical importance to this matter: one discussed whether the Russian equivalent to the FDA wanted to receive information in writing or via telephone and the second discussed where Asacol could be purchased in Europe.

Under these circumstances, the Court finds that spoliation sanctions are not warranted. Indeed, the record does not support the conclusion that Roxane's destruction/non-production of documents has threatened the integrity of this Court. *See Mosaid*, 348 F.Supp.2d at 335. The Court finds that Medeva's ability to fairly participate in this matter and effectively prepare a full and complete trial strategy has not been impeded by Roxane's alleged destruction of documents. *See Ware*, 322 F.3d at 222. As such, the Court finds no reason to punish Roxane for its conduct

[7]While not necessary for the Court to reach this conclusion, the fact that Medeva never sought to obtain the missing Anapharm documents directly from Anapharm, reinforces the Court's determination that Medeva has not been prejudiced by their nonproduction.

or to deter other potential litigants from engaging in same. *See Mosaid*, 348 F.Supp.2d at 335 (describing three functions served by imposing spoliation sanctions).

C. The Concealment of Lot No. 089226

Unlike with Roxane's alleged destruction of documents, the Court finds that sanctions are warranted for Roxane's concealment of Lot No. 089226. In coming to this conclusion, the Court does not reach the issue of whether the Concealed Lot was entitled to attorney-client privilege and/or work product protection, but, instead, assumes for purposes of this motion that it was. As such, the Court focuses its inquiry on whether the existence of the Concealed Lot should have been disclosed by Roxane on its privilege log and whether Roxane's failure to log same warrants the imposition of sanctions. The Court finds that both questions should be answered in the affirmative.

With respect to Roxane's decision not to include the existence of the Concelaed Lot on its privilege log, the Court finds Roxane's reasons for failing to do so completely unavailing. In this regard, the Court finds that Roxane has not provided any legal support that stands for the proposition that it was not required to include the existence of the Concealed Lot on its privilege log. To the extent, Roxane relies on *Grider v. Keystone Health Plan Cent., Inc.*, 580 F.3d 119 (3d Cir. 2009) to argue that it was not required to do so because there is no requirement to maintain an ongoing privilege log, the Court finds Roxane's reliance on the *Grider* decision to be misplaced. First, *Grider* does not hold that litigants are not required to maintain ongoing privilege logs. Instead, in a footnote, the Court in *Grider* merely acknowledges that "a privilege log may not be required for communications with counsel that take place after the filing of a law suit." *Id*. at 140, n.22. Second, what is clear from the context of the footnote, the *Grider* case

did not contemplate the requirement or lack thereof to log the existence of a product, as opposed to a communication, created at the request of counsel. *Id.*

Further, none of the other cases relied upon by Roxane supports its contention that it had no duty to include the existence of the Concealed Lot on its privilege log. In this regard, the Court notes that Roxane did not cite to a single case in which the Court affirmed a company's decision to refrain from including a product manufactured at its facilities on the advice of counsel on its privilege log. The closest cases cited by Roxane are *Novartis*, 203 F.R.D. 159 and *Vardon*,156 F.R.D. 641, which address claims of privilege raised over the methods used and results obtained from product testing conducted for use in pending litigation; they did not address the nondisclosure of the product being tested. More importantly, in both cases claims of privilege were timely made by the party from whom discovery concerning the testing was sought. Indeed, in the only case cited by Roxane in which a party withheld information it deemed to be protected by the work product privilege without logging the privilege, the court determined that a waiver had occurred given the responding party's failure to include an index of the withheld documents on its privilege log. *Feacher v. Intercontinental Hotels Group*, Civ. Action No. 3:06-cv-877 (TJB/DEP), 2007 WL 3104329, *5-6 (N.D.N.Y. Oct. 22, 2007).

Similarly, neither Roxane's Response to Medeva's Interrogatory No. 5 nor the parties' joint stipulation regarding expert discovery exempted it from having to include a notation regarding the existence of the Concealed Lot on its privilege log. With respect to Medeva's Interrogatory No. 5, Roxane's statement that it objects to this interrogatory "as overly broad, unduly burdensome and not calculated to lead to the discovery of admissible evidence in that it seeks information concerning products and formulations other than the product proposed in

ANDA No. 79-073[,]" is insufficient. Information regarding the existence of the Concealed Lot fell within the scope of Medeva's Interrogatory No. 5 and clearly is relevant to this litigation. While the composition of the Concealed Lot differs slightly from Roxane's ANDA product in that it contains a "very small amount of samarium oxide," a material that can be made radioactive, which would permit Roxane to do testing to determine where its product releases in the gastrointestinal tract, Roxane intended the Concealed Lot to be functionally representative of its ANDA product. (Roxane Opp. Br. at 19). As such, if Roxane intended to withhold information regarding the existence of the Concealed Lot based on the work product doctrine, it had an obligation to specifically notify Medeva that it was doing so by including an entry in its privilege log regarding same; the aforementioned objection was simply inadequate.

Likewise, the parties' joint stipulation regarding expert discovery, which put "outside the scope of permissible discovery . . . draft reports, draft studies, or draft workpapers; preliminary calculations, computations, or data runs; or other preliminary or draft materials prepared by, for, or at the direction of an expert witness" does not excuse Roxane's failure to make note of the existence of the Concealed Lot on its privilege log. (Silverstein Decl., Ex. EE ¶ 4). First, the Court agrees with Medeva that there is nothing "preliminary" or "draft" about the final tablets manufactured by Roxane that make up the Concealed Lot. Second, according to the Court's reading of the parties' joint stipulation regarding exert discovery, it does not appear that a lot of tablets falls within the types of materials intended to be covered by the stipulation. If Roxane had such an intent, then it should have made sure that the joint stipulation was written more clearly to disclose same.

Thus, the Court finds no justification for Roxane's failure to include a notation on its

privilege log regarding the Concealed Lot. To be clear, the Court does not find that Roxane had to disclose the purpose behind the Concealed Lot. Indeed, Roxane had no obligation to disclose that the Concealed Lot contained samarium oxide or that Roxane intended to use the Concealed Lot to conduct gamma scintigraphy testing in order to determine where Roxane's ANDA product releases in the gastrointestinal tract. Instead, Roxane simply had to disclose that it was withholding samples of and identifying information regarding a batch of tablets created at the direction of counsel. Such a notation would have put Medeva on notice that information was being withheld and would have allowed Medeva to have filed a timely petition with the Court to determine whether Roxane's privilege claim was appropriate.

Roxane's failure to appropriately log its claim of work product protection regarding the Concealed Lot effectively precluded Medeva from challenging Roxane's claim of privilege and forced Medeva, perhaps unnecessarily, to engage in costly, expedited expert testing on the Concealed Lot when Roxane finally disclosed the existence of same at the end of expert discovery. Further, Roxane's failure precipitated the filing of the instant motion. As such, it not only harmed Medeva, but also thwarted the Court's efforts to resolve this case in an efficient and economic fashion by preventing the Court from addressing Roxane's claim of privilege in the first instance and necessitating the Court's decision on this otherwise unnecessary motion. As such, the Court finds that the imposition of sanctions is warranted for Roxane's unjustified failure to include a notation on its privilege log regarding the existence of the Concealed Lot.

In this regard, the Court finds that the imposition of Medeva's reasonable expert fees and costs associated with its expedited testing of the Concealed Lot along with its reasonable attorneys' fees and costs incurred in briefing and arguing the portion of the instant motion related

to Roxane's nondisclosure of the Concealed Lot are an appropriate sanction. The Court believes that the imposition of the aforementioned costs and fees will fairly compensate Medeva for the harm it suffered from Roxane's nondisclosure of the existence of the Concealed Lot and will also effectively deter Roxane and future litigants from further engaging in this type of conduct. The Court notes that under other circumstances in lieu of imposing all of the fees and costs noted above, or perhaps even in addition to same, it may have deemed Roxane to have waived privilege with respect to the Concealed Lot. The Court, however, finds that such a sanction would be ineffectual here given the fact that Roxane no longer intends to rely on its testing of the Concealed Lot in this litigation.

III. Conclusion

For the reasons stated above, Medeva's motion for the imposition of spoliation sanctions is GRANTED in part and DENIED in part. An appropriate Order follows.

Dated January 28, 2011

s/Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE