**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **NYCOMED US INC., ET AL.,** | : | |
| **Plaintiffs,** | : | **Civil Action No. 10-2635 (KSH)** |
| **v.** | : | |
| **TOLMAR, INC.,** | : | **OPINION** |
| **Defendant.** | : | |

**SHWARTZ, United States Magistrate Judge**

## I. INTRODUCTION

This matter comes before the Court by way of the parties' joint letter, dated April 6, 2011, seeking a ruling as to whether Defendant Tolmar's Paragraph IV Notice Letter ["Paragraph IV Notice Letter"] is a confidential document that should be protected from unrestricted disclosure under the Discovery Confidentiality Order. For reasons stated herein, the Court finds that the Paragraph IV Notice Letter, including the appended Detailed Statement, is not subject to the Discovery Confidentiality Order.

## II. BACKGROUND

Plaintiff Nycomed US Inc. ["Nycomed"] was the applicant for the New Drug Application ["NDA"] for Solaraze, a pharmaceutical product approved by the Food and Drug Administration ["FDA"]. (Compl. ¶ 24, May 24, 2010, ECF No. 1; Redacted Compl. ¶ 24, May 28, 2010, ECF No. 14.) Plaintiff Jagotec AG ["Jagotec"] owns the patents and Nycomed holds the exclusive

licenses to these patents. (Compl. ¶ 26; Redacted Compl. ¶ 26.) The patents are listed in the FDA's "Orange Book" of Approved Drug Products with Therapeutic Equivalence Evaluations. (Compl. ¶ 28; Redacted Compl. ¶ 28.)

Defendant Tolmar, Inc. ["Tolmar"] filed an Abbreviated New Drug Application ["ANDA"] seeking approval for a generic version of Solaraze. (Compl. ¶ 47; Redacted Compl. ¶ 47.) On April 8, 2010, Tolmar sent a letter, known as its Paragraph IV Notice Letter, to Nycomed and Jagotec pursuant to Section 505(j)(2)(b) of the Federal Food, Drug, and Cosmetic Act ["FDCA"], codified at 21 U.S.C. § 355(j)(2)(b). (Compl. ¶ 48; Redacted Compl. ¶ 48.) The Paragraph IV Notice Letter notified the plaintiffs that Tolmar had filed its ANDA contending that its generic version of Solaraze would not infringe the Solaraze patents. (Joint Letter, Ex. B at 2, Apr. 6, 2011.) In pertinent part, the Paragraph IV Notice Letter states that "[a] Detailed Statement of the factual and legal basis of TOLMAR's opinion is appended hereto." (Id.) The Paragraph IV Notice Letter also states that an Offer of Confidential Access ["OCA"], pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), was attached. (Id.; Compl. ¶¶ 56–57; Redacted Compl. ¶¶ 56–57.) Notably, the four-page OCA is followed by the twenty-three-page Detailed Statement and these two documents are one consecutively paginated attachment. (See Joint Letter, Ex. C.)

The plaintiffs found the OCA's restrictions unreasonable and unsuccessfully negotiated with Tolmar to amend those restrictions. (See Compl. ¶¶ 57, 59–65; Redacted Compl. ¶¶ 57, 59–65.) The parties dispute whether the plaintiffs ever requested access to the ANDA before this action was filed. (See, e.g., Compl. ¶ 62; Redacted Compl. ¶ 62; Tr. 15:10–14; May 28, 2010, ECF No. 17; Joint Letter 4 n.5, Apr. 6, 2011). At some point during this case, the parties exchanged the ANDA and NDA as required by the Court's Orders (see Am. Pretr. Sched. Order,

Oct. 19, 2010, ECF No. 42) and the local patent rules. See L. Pat. R. 3.6(a).

On May 21, 2010, the plaintiffs filed a Complaint seeking declaratory and injunctive relief and alleging that Tolmar's Paragraph IV Notice Letter was ineffective and its ANDA infringed the Solaraze patents.[1] (Compl. ¶¶ 83–120; Redacted Compl. ¶¶ 83–120.) On May 25, 2010, Tolmar filed an "emergency motion" to seal portions of the Complaint that allegedly contained confidential information. (Mot. to Seal, May 25, 2010, ECF No. 8; see also Am. Mot. to Seal, May 26, 2010, ECF No. 9.) On May 28, 2010, the Court granted in part and denied in part this motion (Order, May 28, 2010, ECF No. 15), and the plaintiffs filed a Redacted Complaint. (Redacted Compl., May 28, 2010, ECF No. 14.) On June 16, 2010, the Court entered an additional Order to seal attachments that were also the subject of the May 28, 2010 Order. (Order, June 16, 2010, ECF No. 20.)

On July 26, 2010, Tolmar filed an Answer and a Counterclaim (Answer, July 26, 2010, ECF No. 22) and sought to seal portions of its Answer. (Mot. to Seal, July 27, 2010, ECF No. 23). The Court entered an Order sealing certain parts of the Answer. (Order, July 29, 2010, ECF No. 26.) On August 16, 2010, the plaintiffs filed a reply to Tolmar's Counterclaim. (Answer, Aug. 16, 2010, ECF No. 30.) On October 19, 2010, the Court held a scheduling conference and thereafter issued a Pretrial Scheduling Order. (Pretr. Sched. Order, Oct. 19, 2010, ECF No. 42.) On November 9, 2010, the Court entered a Discovery Confidentiality Order. (Disc. Confidentiality Order, Nov. 9, 2010, ECF No. 59.)

During a telephone conference on March 31, 2011, the parties advised the Court that a

[1] On April 8, 2011, the plaintiffs filed a motion for leave to file an Amended Complaint that proposes, among other things, to omit the request for declaratory relief concerning the effectiveness of the notice letter. (See Mot. to Amend, Apr. 8, 2011, ECF No. 105.)

dispute had arisen concerning whether Tolmar's Paragraph IV Notice Letter should be subject to the restrictions of the Discovery Confidentiality Order. By Order dated March 31, 2011, the Court directed the parties to file a joint letter setting forth their positions on whether the Paragraph IV Notice Letter is a confidential document restricted under the terms of the Discovery Confidentiality Order. (3d Am. Pretr. Sched. Order, Mar. 31, 2011, ECF No. 102.) The Court ordered the parties to submit the letter directly to Chambers, rather than filing it on the public docket, because Tolmar asserted that the contents of the Paragraph IV Notice Letter are confidential. (See id.)

**III. ARGUMENTS**

**A. Plaintiffs**

Nycomed and Jagotec argue that all paragraph IV notice letters are public disclosures under FDA regulations and determinations. Specifically, they contend that: (1) paragraph IV notice letters provided to an NDA holder and patent owner are public disclosures; (2) paragraph IV certifications are subject to disclosure under the Freedom of Information Act ["FOIA"]; (3) the Court should defer to an FDA letter ruling on this subject; (4) this ruling is consistent with industry custom; (5) Tolmar made the notice letter public by sending it to competitors; and (6) the plaintiffs did not accept the OCA and assert that it is not applicable to a paragraph IV notice letter. (Joint Letter at 2–3.)

**B. Defendant**

Defendant Tolmar argues that: (1) it did not publicly disclose confidential information in its Paragraph IV Notice Letter; (2) its twenty-seven-page OCA contained the Detailed Statement and applied to it; (3) the plaintiffs accepted the OCA's terms by requesting access to the ANDA;

(4) no authority has determined that all paragraph IV notice letters are public disclosures and that the FDA ruling, upon which the plaintiffs rely, is distinguishable; (5) this Court has already recognized Tolmar's expectations in confidentiality; (6) information in the Detailed Statement mirrors the ANDA; and (7) a FOIA request to the FDA would not result in disclosure of a paragraph IV notice letter. (Joint Letter 4–5.)

**IV. DISCUSSION**

Under the Hatch-Waxman Amendments to the FDCA, a pharmaceutical company may seek expedited approval to sell a generic version of a previously approved drug and thereby avoid the normally time-intensive and costly drug approval process. Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1325–27 (Fed. Cir. 2001); see also 21 U.S.C. § 355(j). By these amendments, Congress sought to balance the development of new drugs with the benefit of allowing competitors to market cheaper versions of those drugs. Mylan, 258 F.3d at 1326 (citing Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir.1990) (Edwards, J., dissenting on other grounds)).

Section 505 of the FDCA, codified at 21 U.S.C. § 355, sets forth the process by which applicants file ANDAs to obtain approval to sell generic drugs. Under 21 U.S.C. § 355(j)(2)(A)(vii), an ANDA applicant must provide the FDA with a certification stating the status of the previously approved drug's patents. Specifically, the ANDA applicant must certify, for each patent of the previously approved drug, that: (I) no patent information has been filed with the FDA, (II) the patent has expired, (III) the patent will expire on a particular date, or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. Mylan, 258 F.3d at 1326 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV)). Such certifications are known as "Paragraph I, II, III, and IV

certifications." Mylan, 258 F.3d at 1326.

When an ANDA applicant files a paragraph IV certification, the applicant must also provide notice of the paragraph IV certification to the drug's NDA holder and patent owners. 21 U.S.C. § 355(j)(2)(B)(iii); 21 C.F.R. § 314.95(a). Such a notice is known as a "paragraph IV notice letter." See, e.g., Medeva Pharma Suisse A.G. v. Roxane Labs., Inc., Civ. No. 07-5165, 2011 WL 310697, at *4 (D.N.J. Jan. 28, 2011). The ANDA applicant must also include an offer of confidential access ["OCA"] to the ANDA with its paragraph IV notice letter in order to seek declaratory relief. 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc); see also 21 U.S.C. § 355 (j)(5)(C)(i)(III) (stating that an OCA "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information"). A request for the ANDA under an OCA is considered an acceptance of the OCA. 21 U.S.C. § 355 (j)(5)(C)(i)(III).

The FDCA and the FDA's regulations require that a paragraph IV notice letter include "a detailed statement of the factual and legal basis of the opinion of the applicant that the [drug's] patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II); see also 21 C.F.R. § 314.95(c)(6) (further requiring that the statement be a "full and detailed explanation"). Even in the face of public comments to the FDA rules that a paragraph IV notice letter's detailed statement "might compromise the applicant's trade secrets and adversely affect the applicant's ability to engage in litigation," the FDA declined to provide such letters the sort of confidential protection the FDA and Congress gave to ANDAs and declined to specify the type or amount of detail that a notice letter must include. Abbreviated New Drug Application Regulations; Patent

and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,350 (Oct. 3, 1994) (to be codified at 21 C.F.R. § 314). Rather, the FDA requires

> that the detailed statement of the factual and legal basis behind the applicant's opinion that the patent is invalid, unenforceable, or will not be infringed include the following: (1) For each claim of a patent alleged not to be infringed, a full and detailed explanation why the claim is not infringed; and (2) for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

Id. (codified at 21 C.F.R. § 314.52(c)(6)(i)–(ii) and 21 C.F.R. § 314.95(c)(6)(i)–(ii)). Disputes regarding the sufficiency of a paragraph IV notice letter are for the parties to resolve. 59 Fed. Reg. at 50,350. Thus, the FDA addressed concerns of potential disclosure of confidential information by declining to give the notice letter any specific protection, not requiring disclosure of any particular information, and leaving decisions about the contents and the sufficiency of the details to the ANDA applicant, the patent owner, and the NDA holder. 59 Fed. Reg. at 50,350; see also id. at 50,342.

After receiving a paragraph IV notice letter, the NDA holder or patent owner has forty-five days to sue the ANDA applicant for infringement; otherwise, the FDA may immediately approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If a suit ensues, the FDA will not approve the ANDA until a court rules that the patent is invalid or not infringed or until thirty months have passed since the receipt of the paragraph IV notice letter, whichever comes first. Id.

Here, the Court first resolves whether Tolmar's Paragraph IV Notice Letter and Detailed Statement are one document and whether the OCA applies to the Detailed Statement.

**A. Whether the Detailed Statement is Part of the Paragraph IV Notice Letter, and Whether the OCA Applies to the Detailed Statement**

Tolmar argues that it did not publicly disclose confidential information in the Paragraph IV Notice Letter sent to the plaintiffs. Tolmar asserts that it "appended" its Detailed Statement to the Notice Letter to the end of the OCA and views the Detailed Statement as part of its OCA. (Joint Letter 4–5.) Indeed, Tolmar paginated the four-page OCA and the twenty-three-page Detailed Statement consecutively, as if they were a single document.

The Court finds that Tolmar's assertion is incorrect under the FDCA and the terms of the OCA itself. First, Tolmar cannot separate the Paragraph IV Notice Letter from the Detailed Statement. A detailed statement that contains a "full and detailed explanation" is a necessary part of a paragraph IV notice letter. 21 C.F.R. § 314.95(c)(6); see also 21 U.S.C. § 355(j)(2)(B)(iv)(II). The Detailed Statement cannot, as Tolmar suggests, be separate from the Paragraph IV Notice Letter because without the Detailed Statement, Tolmar's Paragraph IV Notice Letter alone fails to satisfy the FDA's requirement to provide the patent owner a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). Paginating the OCA and Detailed Statement consecutively does not eliminate the requirement that the Detailed Statement must be part of the Paragraph IV Notice Letter. Moreover, by the Paragraph IV Notice Letter's own text, the Detailed Statement is incorporated into it. (See Joint Letter, Ex. B at 2; see also id., Ex. C at 5 (stating that "[t]his detailed statement is hereby incorporated by reference into the [Paragraph IV] Notice [Letter] to which it is appended").

Second, the Paragraph IV Notice Letter discusses the OCA and the Detailed Statement in separate sections and lists them as separate enclosures. (See Joint Letter, Ex. B at 2–3.) This further undercuts Tolmar's position that the OCA and the Detailed Statement are the same

document.

Third, an OCA pertains to access to an ANDA and not to a paragraph IV notice letter. See 21 U.S.C. § 355(j)(5)(C)(i)(III). An OCA allows access to the "application," referring to the ANDA. See 21 U.S.C. § 355(j)(5)(C)(i)(III). Further, an OCA "accompanie[s]" a paragraph IV letter notice, 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc), and is thus not a part of a notice letter itself or a notice letter's detailed statement. (See also Joint Letter, Ex. A at 7 (stating "by [§ 505(j)(5)(C)(i)(III)'s] terms, the confidential access provision protects only information contained in an ANDA, not information found elsewhere, such as in a paragraph IV letter"). Consecutive pagination of the OCA and the Detailed Statement does nothing to make an OCA apply to a paragraph IV notice letter's detailed statement.

Fourth, viewing the OCA and the Detailed Statement as one and the same is inconsistent with the FDCA. The statute provides a sequence to ensure the contents of the ANDA are not misused, namely, by an offer of confidential access and acceptance of that offer either explicitly or through a request for the ANDA itself. See 21 U.S.C. § 355(j)(5)(C)(i)(III). Thus, "collapsing" the step of offering confidential access and actually providing that access does not follow "the process clearly set forth in the confidential access provision of the Act, which contemplates an offer of confidential access, acceptance of the offer by requesting access to the ANDA, and review of the ANDA." (Joint Letter, Ex. A at 5 n.5.) Moreover, the confidential access provision "does *not* indicate that use of information provided in a paragraph IV notice letter or failure to object to the proposed terms of confidentiality contained in a paragraph IV notice letter constitutes acceptance of such terms." (See id. at 7 (emphasis in original).)

Accordingly, the Court finds that Tolmar's Detailed Statement is part of the Paragraph IV

Notice Letter and the OCA does not govern them.

**B. Whether the Paragraph IV Notice Letter Is a Public Disclosure**

The Court next considers whether the Paragraph IV Notice Letter is a public disclosure. Nycomed and Jagotec assert that the Court must defer to the FDA's statement in the Federal Register and an FDA letter ruling, dated January 7, 2010, pursuant to Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). (Joint Letter 2.) Tolmar does not dispute the assertion that the Court should defer to these authorities but instead argues that they are distinguishable and inapplicable. (See Joint Letter 3–4.) Under Chevron, courts owe deference to agency interpretations of statutes and regulations that the agency administers. NVE, Inc. V. Dep't of Health & Human Servs., 436 F.3d 182, 186 (3d Cir. 2006). Letter rulings, however, are not necessarily entitled to this level of deference. See Madison v. Res. for Human Dev., Inc., 233 F.3d 175, 185 (3d Cir. 2000) (noting that opinion letters and other informal agency interpretations are not entitled to Chevron deference). But see Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1279–80 (D.C. Cir. 2004) (applying Chevron deference to an FDA letter decision). Even if the January 7, 2010 letter ruling is not entitled to Chevron deference, but only "entitled to respect . . . to the extent they have the power to persuade," the Court finds it is persuasive. Madison, 233 F.3d at 186–87 (citations and internal quotation marks omitted). Thus, the Court may consider the January 7, 2010 letter ruling together with other authorities but need not defer to it.

Before adopting 21 C.F.R. § 314, the FDA addressed the question "Should all Paragraph IV Certifications Be Made Public . . . ?" Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,690 (June 18, 2003) (codified at 21 C.F.R. § 314). In pertinent part, the

FDA ruled that

> [w]e decline to amend the proposed rule to make public all paragraph IV certifications . . . . Under current practice, paragraph IV certifications are subject to public disclosure under the Freedom of Information Act (FOIA) and FDA's public disclosure regulations once the notice of the paragraph IV certification has been provided to the NDA holder and patent owner. **Because the notice to the NDA holder or patent owner of the paragraph IV certification is considered a public disclosure after notice has been given**, the certification is available under FOIA.

68 Fed. Reg. at 36,690 (emphasis added). Thus, in considering whether paragraph IV certifications are subject to disclosure under FOIA, the FDA relied upon its view that paragraph IV notice letters are public disclosures once given to the NDA holder or patent holder. Therefore, when the notice letters are disclosed to the NDA holder and patent owner, the paragraph IV notices are deemed public disclosures.

The FDA reached the same determination about notice letters in a letter dated January 7, 2010. (Joint Letter, Ex. A.) In that decision, an ANDA applicant sent a paragraph IV notice letter to an NDA holder, including detailed information about the composition of the new drug. (Id. at 1–2.) The notice letter stated that the information was confidential. (Id. at 2.) The NDA holder submitted a citizen petition to the FDA and attached a copy of the paragraph IV notice letter, thereby making the notice letter publicly available. (Id. at 2.) The ANDA applicant requested that the FDA remove the petition and the notice letter because they contained confidential information. (Id. at 2.) The FDA denied the request. The FDA stated that "paragraph IV notice letters are considered public disclosures." (Id. at 4 (citing 68 Fed. Reg. at 36,690).) The FDA explained that the notice letter "is an integral part of a public process" and that "the statutory scheme contemplates that the paragraph IV notice letter is the first step in an inherently public process." (Id. at 5.) The FDA also stated that an ANDA applicant's decision to

market a generic product before the expiration of a patent, thereby requiring a paragraph IV notice letter, "reflects a deliberate decision by an ANDA applicant to publicly disclose certain information about its ANDA so that it may be eligible for FDA approval of its generic drug product prior to the expiration of the relevant patent." (Id. at 5.) By disclosing information in its ANDA to the NDA holder through the paragraph IV notice letter, the FDA found that the ANDA applicant had publicly disclosed that information. (Id. at 4–5, 8.)

Importantly, other FDA regulations make it clear that an ANDA applicant must decide how much detail to put in a paragraph IV notice letter. Although the FDA requires a "full and detailed explanation" in a paragraph IV notice letter, 21 C.F.R. § 314.95(c)(6), the FDA has refused to provide any more guidance on what will constitute sufficient notice. 59 Fed. Reg. at 50,350. Specifically, it has stated that "the agency does not have the expertise or the desire to become involved in issues concerning patent law and sufficiency of notice." Id. Moreover, "[d]isputes involving the sufficiency of the notice must be resolved by the applicant, patent owner, and holder of the approved application rather than by action on the part of FDA." Id. Critically, the FDA made these determinations directly in the face of public comments that "information and statements [in the notice letter] **might compromise the applicant's trade secrets** and adversely affect the applicant's ability to engage in litigation." Id. (emphasis added). By declining to address this concern by providing any confidentiality or further guidance concerning the type of information to be disclosed, the FDA has placed the decision of what to disclose squarely in the hands of the ANDA applicant. The FDA's regulations do not specifically insist on disclosure of all, or any, information contained in an ANDA, and the ANDA applicant must decide how much to put in its paragraph IV notice letter. This is

consistent with the conclusion in the January 7, 2010 FDA letter, which contemplates that the ANDA applicant may release some, but not all, ANDA information to provide sufficient notice and then disclose the ANDA under the terms of a NOCA. (See, e.g., Joint Letter, Ex. A at 3 (stating that "the Act provides a 'confidential access' mechanism for an ANDA applicant to share **more detailed information in its ANDA** with the NDA sponsor or patent owner while also restricting access to, and imposing limitations on the use or the disposition of, that confidential information") (citing 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc)) (emphasis added).)

Here, Tolmar submitted an ANDA seeking approval of its generic product before the expiration of Solaraze's patents and thereby made a deliberate decision to follow the FDCA's requirements to send a paragraph IV notice letter to its competitors without any agreement to keep its contents confidential. In following these requirements, Tolmar disclosed certain information from its ANDA to Nycomed and Jagotec through its Paragraph IV Notice Letter. Accordingly, the information disclosed in its Paragraph IV Notice Letter is now part of "an inherently public process" and therefore constitutes a public disclosure. (Joint Letter, Ex. A at 5.)

Tolmar's arguments to the contrary are unavailing. As discussed above, an OCA does not apply to information in a paragraph IV notice letter. The argument that, because Tolmar disclosed information from its ANDA in the notice letter, it should also be protected by an OCA is unpersuasive as the statutory scheme contemplates that "an ANDA applicant . . . publicly disclose certain information about its ANDA so that it may be eligible for FDA approval of its generic drug product prior to the expiration of the relevant patent." (Id. at 5.) Indeed, the FDA specifically declined to dictate the contents of a paragraph IV notice letter, even whether it needs

to include information from the ANDA. See 59 Fed. Reg. at 50,350. Thus, the mere fact it contains information from the ANDA does not alone convert it into a nonpublic disclosure.

Further, the Court's prior sealing order granting emergent relief does not dictate a different result. Specifically, the Court considered Tolmar's Paragraph IV Notice Letter and found that

> While there could be a circumstance, and indeed, **in later proceedings in this case**, **it may be found that it is -- that type of disclosure might be a waiver**, the Court is not prepared to make that finding **at this point**, and finds that -- that it would be -- that there is a legitimate reason to **at least at this point** seal limited portions of paragraphs 66, 70 through 74 and 76 that disclose formulation information of the proposed ANDA product. . . . The Court notes there's been a representation -- [that there was] no agreement to keep it confidential, and **of course, the level of detailed disclosure may at a later time be found to be a waiver**.

(Tr. 25:22–26:5, 26:11–14, May 28, 2010, ECF No. 17 (emphasis added).) Thus, the OCA and the prior ruling that sealed part of the plaintiffs' Complaint, which contained information from the Paragraph IV Notice Letter, do not shield the document from the public eye.

**C. Whether the Paragraph IV Notice Letter is Subject to the Discovery Confidentiality Order**

Because the Paragraph IV Notice Letter is not shielded from public view, it is not subject to the Discovery Confidentiality Order. The Detailed Statement, as part of the Paragraph IV Notice Letter, is a public disclosure. The Discovery Confidentiality Order does not restrict access to or use of documents that are public. (See Disc. Confidentiality Order ¶ 15.) Consequently, the Discovery Confidentiality Order does not restrict use of Tolmar's Paragraph IV Notice Letter.

Lastly, the Court finds that the joint dispute letter and its supporting documents should be

filed electronically on the public docket. Based on the discussion above, there is no reason why the underlying materials, including the joint letter, the FDA letter ruling, the OCA, and the Detailed Statement, should remain undisclosed to the public. See Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984) (recognizing the right of public access to judicial proceedings and records by the common law and First Amendment); c.f. LEAP Sys., Inc. v. Moneytrax, Inc., Civ. No. 10-3107, 2011 WL 871266, at *3 (3d Cir. Mar. 15, 2011) (noting that judicial records do not include documents which have not been filed with, interpreted by, or enforced by the court). Accordingly, the parties shall file the joint dispute letter and its supporting documents on the electronic public docket.

**V. CONCLUSION**

For the reasons set forth herein, the Court finds that information contained in Tolmar's Detailed Statement is not subject to the Discovery Confidentiality Order. The Court also directs the parties to electronically file the April 6, 2011 joint submission and attachments on the public docket.

s/Patty Shwartz
**UNITED STATES MAGISTRATE JUDGE**

Dated: April 28, 2011