

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY



MARTIN LUTHER KING JR. FEDERAL BLDG. & U.S. COURTHOUSE  
50 WALNUT STREET, P.O. BOX 419  
NEWARK, NJ 07101-0419  
(973) 645-6340

WILLIAM J. MARTINI  
JUDGE

LETTER OPINION

February 9, 2009

Herbert J. Stern, Esq.  
Stern & Kilcullen, LLC  
75 Livingstone Avenue  
Roseland, New Jersey 07068  
*Attorneys for Plaintiff*

Joyce R. Branda  
Michael D. Granston  
Edward C. Crooke  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice  
P.O. Box 261, Ben Franklin Station  
Washington, D.C. 20004

Charles R. Gross  
Ryan Cobb  
United States Attorney's Office for the Western District of Michigan  
330 Ionia Avenue, N.W., Suite 501  
Grand Rapids, MI 49503  
*Attorneys for Defendants*

Re: *Stryker Corporation v. United States Department of Justice and United States Department of Health and Human Services-- Office of the Inspector General*  
Civil Action No. 08-4111 (WJM)

Dear Counsel:

This is a case involving an investigation by the United States Department of Justice (“DOJ”) and the United States Department of Health and Human Services– Office of the Inspector General (“HHS”) into the business operations of Stryker Corporation (“Stryker”). Plaintiff Stryker seeks judicial relief from an administrative subpoena issued by Defendants DOJ and HHS. Defendants move to dismiss this action pursuant to Fed. R. Civ. P. 12(b)(1), (b)(3), and (b)(6) for lack of jurisdiction, failure to state a claim for which relief can be granted, and lack of venue. Plaintiff has filed a cross-motion for leave to file a second amended complaint. For the reasons stated below, Defendants’ motion to dismiss is **GRANTED** and Plaintiff’s cross motion for leave to amend is **DENIED**.

### **BACKGROUND**

Plaintiff Stryker is a manufacturer of medical devices incorporated in Michigan. (Pl.’s Am. Compl. ¶¶ 2, 7). The federal government is presently investigating Stryker for possible violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b)(2), and the False Claims Act, 31 U.S.C. § 3729 et seq. (Dft.’s Br. 1, 7). Pursuant to their investigation, Defendants DOJ and HHS issued Stryker a subpoena on February 22, 2008. The subpoena sought documents related to Stryker’s sales, corporate structure, and relationships with healthcare providers. (Pl.’s Am. Compl. ¶ 9). It required production of all responsive documents by April 28, 2008. (Dft.’s Br. 1) Prior to the deadline, Stryker requested that Defendants narrow the scope of the subpoena. On March 14, 2008, Defendants sent Stryker a letter purporting to do so but which Stryker claims only broadened the scope. (Pl.’s Am. Compl. ¶ 11.) Since the subpoena’s issuance, Stryker has produced some responsive documents to Defendants but has not complied in full. (Pl.’s Am. Compl. ¶ 9).

On August 8, 2008, Defendants informed Stryker that if an agreement could not be reached regarding a production schedule or the possibility of tolling certain statutes of limitations in the government’s favor, the government would seek judicial enforcement of the subpoena. But before Defendants did so, Stryker on August 15, 2008 filed a complaint and jury demand with this Court. Stryker amended its complaint the following month. The complaint and amended complaint sought judicial relief from the administrative subpoena and also alleged that the subpoena constituted abuse of process by the government. (Dft.’s Br. 8) Defendants responded with a motion to dismiss the amended complaint. Plaintiffs opposed the motion to dismiss and filed a cross-motion for leave to submit a second amended complaint. Defendants replied in further support of their motion to dismiss and in opposition to Plaintiff’s motion to further amend.

On August 26, 2008, after Plaintiff filed its complaint, Defendants filed an action in the Western District of Michigan to enforce the subpoena. This was the first Defendants had sought judicial enforcement of their subpoena. (Dft.'s Br. 8)

Prior to Defendants' investigation into Stryker, the U.S. Attorney's Office for the District of New Jersey ("USAO") from 2005-2007 conducted its own investigation into medical device manufacturers. As a result of that investigation, in 2007 the U.S. Attorney's Office entered into a non-prosecution agreement with Stryker, providing that the USAO would not prosecute Stryker's N.J. subsidiary Howmedica Osteonics Corp., more commonly referred to as Stryker Orthopaedics ("Stryker Orthopaedics"). (Pl.'s Am. Compl. ¶ 8). In exchange, Stryker Orthopaedics agreed to comply with specific remedial measures. This agreement applied to Stryker Orthopaedics only, not Stryker as a whole. (Pl.'s Rep. Br. 3-4).

## ANALYSIS

There are two motions presently before the Court: (1) Defendants' motion to dismiss Plaintiff's amended complaint; and (2) Plaintiff's motion for leave to file a second amended complaint. They will be addressed in turn.

### A. Defendants' Motion to Dismiss

#### 1. Legal Standard—Standard of Review for a Motion to Dismiss For Lack of Subject Matter Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(1)

Federal courts only have authority to adjudicate cases over which they have subject-matter jurisdiction. *Brown v. Francis*, 75 F.3d 860, 866 (3d Cir. 1996). Indeed, even after a court has proceeded completely through a case to a final judgment, if the court lacked subject-matter jurisdiction, the judgment must be vacated. *Caterpillar Inc. v. Lewis*, 519 U.S. 61, 76–77 (1996) (“[I]f, at the end of the day and case, a *jurisdictional* defect remains uncured, the judgment must be vacated.”). A court without subject-matter jurisdiction has no choice but to decline to entertain the suit. *Bender v. Williamsport Area School District*, 475 U.S. 534, 541 (1986).

A district court lacks subject-matter jurisdiction to review administrative orders that are not yet final. *See 3-21 Administrative Law § 21.01; see also Shea v. Office of Thrift Supervision*, 934 F.2d 41, 45 (3d Cir. 1991). As the Third Circuit has explained, administrative subpoenas are not self-enforcing and thus cannot be considered final until the issuing agency has sought and obtained judicial enforcement. *See Shea*, 934 F.2d at

45. The Supreme Court has upheld this basic tenet of administrative law, refusing to consider pre-enforcement disputes arising out of agency subpoenas on the grounds that such claims are not yet ripe. *See Reisman v. Caplin*, 375 U.S. 440, 450 (1964) (declining to grant equitable relief to the recipient of an administrative summons that had not been judicially enforced). Because an agency subpoena does not become final until judicial enforcement is granted, as opposed to when it is requested, a court's lack of jurisdiction is unaltered by the filing of an enforcement action by the agency while a pre-enforcement claim by the subpoenaed party is still pending.

Thus, a recipient of an administrative subpoena who wishes to challenge the document has only two options: (1) appeal directly to the agency itself, although the agency has no obligation to modify the subpoena, or (2) ignore the subpoena and fail to comply. *See 3-21 Administrative Law § 21.01*; *see also Shea*, 934 F.2d at 45 (a party in receipt of an administrative subpoena that has not been judicially enforced "can really do nothing."). Certainly, the recipient cannot turn to the federal courts because they do not have jurisdiction. If the recipient chooses to ignore the subpoena and fail to comply, the agency's only recourse is to file a judicial enforcement action. The agency cannot issue sanctions or enforce the subpoena itself. *Shea*, 934 F.2d at 45-46. Thus, as the Supreme Court has noted, no harm accrues to the subpoenaed party nor is it deprived of an adequate remedy at law, because it can raise all substantive and procedural objections to the subpoena in the agency's enforcement action. *Reisman*, 375 U.S. at 446.

Simply put, a judicial enforcement action filed by a government agency provides the sole opportunity for a subpoenaed party to raise objections to an administrative subpoena. A district court cannot entertain pre-enforcement motions. *Reisman*, 375 U.S. at 445; *Shea*, 934 F.2d at 46.

In the present case, Plaintiff filed its initial complaint on August 15, 2008. Defendants filed a judicial enforcement action in the Western District of Michigan on August 26, 2008. At the time Plaintiff initiated its complaint, Defendants had not yet sought, let alone obtained, an enforcement order. Thus, the complaint is clearly a pre-enforcement objection to an administrative subpoena over which this Court has no subject-matter jurisdiction. Moreover, Plaintiff's allegation that it lacks an adequate remedy at law is without merit. As the Supreme Court has indicated, the recipient of an administrative subpoena has a full opportunity to litigate in court if and when the agency brings an enforcement action. Thus, Plaintiff can fully contest the subpoena in the action brought by Defendants in the Western District of Michigan action. Equitable relief is not warranted. This will not result in any harm to Plaintiff because no sanctions can be issued for failure to comply with the subpoena unless and until Defendants' prevail in Michigan.

**2. Legal Standard– Standard of Review for Motion to Dismiss for Failure to State a Claim Pursuant to Fed. R. Civ. P. 12(b)(6)**

Because this Court lacks subject-matter jurisdiction to hear Plaintiff's pre-enforcement action, the complaint must be dismissed in its entirety. It is therefore not necessary to address the remaining grounds for dismissal raised by Defendants' motion, namely lack of venue, failure to state a claim, and sovereign immunity. *See Wachovia Bank v. Schmidt*, 546 U.S. 303 (2006) (stating that lack of subject matter jurisdiction is weightier than lack of venue); see also *Bender*, 475 U.S. at 541 (if a court lacks subject-matter jurisdiction, it cannot proceed with a case). However, it is worth noting that, jurisdictional defects aside, Counts II and III of Plaintiff's Complaint fail to state claims upon which relief can be granted and would also have to be dismissed for this additional reason.

In evaluating a motion to dismiss under Fed. R. Civ. P. 12(b), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. *See Warth v. Seldin*, 422 U.S. 490, 501 (1975); *Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). When deciding a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the plaintiff's claims are based upon those documents. *See Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). If, after viewing the allegations in the complaint in the light most favorable to the plaintiff, it appears that no relief could be granted "under any set of facts that could be proved consistent with the allegations," a court may dismiss a complaint for failure to state a claim. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984).

Although a complaint does not need to contain detailed factual allegations, "the 'grounds' of [the plaintiff's] 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1965, 167 L. Ed. 2d 929 (2007). Thus, the factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level. *See id.* at 1964-65. Furthermore, although a court must view the allegations as true in a motion to dismiss, it is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. McGreevey*, 481 F. 3d 187, 211 (3d Cir. 2007).

In Count II of the Amended Complaint, Plaintiff asks the court to quash Defendants' subpoena pursuant to Fed. R. Civ. P. 45(c), alleging that the information

requested contains confidential information and trade secrets. However, Plaintiff does not provide any details about the nature of the allegedly confidential information as caselaw requires. *See R.J. Reynolds v. Philip Morris Inc.*, 29 Fed. Appx. 880, 882 (3d Cir. 2002) (a party seeking to quash pursuant to Fed. R. Civ. P. 45(c)(3)(B)(i) has the burden of proving that its documents are confidential or trade secrets and must provide more than a skeletal description). Here, Plaintiff's statement that the documents are confidential merely lays out the elements of the claim without more and thus, under *Twombly*, cannot survive a motion to dismiss. This count must be dismissed.

Count III of the complaint also fails to state a claim for which relief can be granted and should also be dismissed pursuant to Fed. R. Civ. P 12b(6). Count III alleges that Defendants' actions constitute an abuse of process. However, the tort of abuse of process refers to an abuse of judicial process, and it is not until the government files an enforcement action that it has begun to use the court's process. *See U.S. v. Stuart*, 489 U.S. 353, 359 (1989). At the time the amended complaint was filed, Defendants had not yet turned to the judicial system seeking enforcement of the subpoena. Without having used the judicial process, Defendants could not have abused it. Therefore, there exist no set of facts that could warrant relief for Plaintiff, and this count must also be dismissed.

#### **B. Plaintiff's Cross-Motion for Leave to File A Second Amended Complaint**

As Plaintiff accurately states, the Federal Rules of Civil Procedure provide that leave to amend should be freely granted when justice so requires. However, the Third Circuit has consistently held that justice does not so require when amendment would be futile. *Grayson v. Mayview State Hospital*, 293 F.3d 103, 108 (2002) (amendment need not be permitted when inequitable or futile); *see also Shane v. Fauver*, 213 F.3d 113, 115 (2000). Thus, if a claim would still be deficient even after the pleading was amended, leave to amend should not be granted.

Here, even if Plaintiff amended its complaint a second time, this Court, for the reasons set out above, would still lack subject-matter jurisdiction. No matter what changes Plaintiff made, a district court does not have the authority to adjudicate claims arising out of a pre-enforcement objection to an administrative subpoena. Furthermore, Plaintiff's attempt to invoke the Administrative Procedures Act ("APA"), 5 U.S.C. § 701, *et. seq.* and the Mandamus Act, 28 U.S.C. § 1361 to confer jurisdiction is of no avail. The APA only applies to final agency orders. *Shea*, 934 F.2d at 46. As discussed above, until an administrative subpoena has been judicially enforced, it cannot be deemed a final agency order. Thus, the APA does not apply to the current situation.

The Mandamus Act is equally unavailing, because it only applies to individual government employees, not to the government itself or government agencies. *See* 28 U.S.C. § 1361 (providing in pertinent part that "district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff."); *see also* *Muirhead v. Mecham*, 427 F.3d 14, 18 (1<sup>st</sup> Cir. 2005) (stating that "[T]he mandamus statute applies only to officers and employees of the United States, rather than to the United States itself.") Plaintiff does not allege that any specific government officer or employee owes it a duty that was not performed. Thus, the Mandamus Act cannot be used as a source of jurisdiction.

Finally, Plaintiff's argument that it wishes to object to the entire government investigation, not merely the subpoena, also does not alter this Court's lack of jurisdiction. Plaintiff can raise any and all objections to the entire government investigation in the Michigan action. *See Reisman*, 375 U.S. at 449. Any attempts to amend Plaintiff's already amended complaint would be futile and thus the motion is denied.

#### CONCLUSION

For the reasons stated above, Defendants' motion to dismiss is **GRANTED** in its entirety and Plaintiff's cross-motion for leave to file a second amended complaint is **DENIED**. An appropriate Order follows.

/s/ William J. Martini  
**William J. Martini, U.S.D.J.**