

[D.E. 21]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK VICINAGE

UNITED STATES OF AMERICA,

Plaintiff,

v.

ALL ARTICLES OF OTHER-SONIC
GNERIC ULTRASOUND TRANSMISSION
GEL, WHETHER LABELED OR
UNLABELED, IN ANY SIZE OR TYPE OF
CONTAINER, THAT ARE IDENTIFIED
BY LOT NUMBER, OR BY OTHER MEANS,
AS HAVING BEEN MANUFACTURED BY
PHARMACEUTICAL INNOVATIONS,
INC., NEWARK, NEW JERSEY,
BETWEEN JUNE 2011 AND DECEMBER
2011, AND ARE LOCATED ANYWHERE ON
THE PREMISES OF PHARMACEUTICAL
INNOVATIONS, INC.,
FRELINGHUYSEN AVENUE, NEWARK,
NEW JERSEY 07114-2122,

Defendant.

Civil No. 12-2264-ES-SCM

**OPINION AND ORDER
ON MOTION TO STAY DISCOVERY**

I. INTRODUCTION

This matter comes before the Court on the motion of the United States to stay discovery for 180 days [D.E. 21]. Claimant Pharmaceutical Innovations, Inc., opposes the motion. For the reasons set forth below, the Court will grant the United States' motion.

II. BACKGROUND

This case arises from a February 2012 report from the U.S. Food and Drug Administration ("FDA") alleging that patients in a Michigan hospital were infected by a bacterial pathogen from an ultrasound gel manufactured by Claimant Pharmaceutical Innovations ("Claimant"). (See D.E. 22, Claimant's Brief in Opposition, at *7). Upon learning of the Michigan hospital incident, Claimant allegedly requested information from the FDA relating to the allegation that it had distributed contaminated ultrasound gel. *Id.* at *8. The FDA allegedly denied most of Claimant's requests for information, but did supply Claimant with a limited number of documents, including a Health Risk Assessment indicating that the FDA believed that there had been a similar incident in 2006 involving ultrasound gel that had also originated from Claimant Pharmaceutical Innovations. *Id.*

On April 16, 2012, the United States filed a Verified Complaint for Forfeiture *In Rem* under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399d, alleging that devices manufactured by Pharmaceutical Innovations identified as Other-Sonic Generic Ultrasound Transmission Gel ("Other-Sonic Gel" or "Claimant's *in rem*") were contaminated with bacterial pathogens and thus subject to seizure, forfeiture, and condemnation. (See D.E. 21-1, Plaintiff's Brief in Support of Motion, at *5) (citing D.E. 1, Compl. ¶¶ 7-8). Pursuant to a Warrant for Arrest *In Rem*, the United States

Marshalls for the District of New Jersey seized Claimant's *in rem* on April 17, 2012. *Id.*

Claimant filed a claim to its *in rem* on May 17, 2012 [D.E. 6], and an Answer on June 7, 2012 [D.E. 11]. Claimant then served the government with requests for the production of thirteen categories of documents, including: 1) documents relating to the allegation that the seized products are contaminated with bacterial pathogens; 2) documents relating to FDA administrative inspections in 2012 in which the FDA gathered evidence underlying this seizure case; 3) documents relating to the Michigan hospital incident that led to this seizure case; 4) documents relating to Pharmaceutical Innovations' withdrawal of products from the market following the report by the FDA of the Michigan hospital incident; 5) documents relating to the Health Risk Assessment provided by the FDA to Pharmaceutical Innovations as support for its concerns about the Michigan hospital incident; 6) documents relating to the New Jersey state embargo that was the prelude to the seizure action; and other documents relating to this seizure case and Pharmaceutical Innovations. (See D.E. 22, Claimant's Brief in Opposition, at *9). Before its responses were due, the United States filed the instant motion to stay this case for 180 days in light of a pending related criminal investigation. (See D.E. 21-1, Plaintiff's Brief in Support). Specifically, the United States Attorney's Office and the FDA Office of Criminal

Investigations have allegedly been investigating whether Pharmaceutical Innovations and its officers and employees committed crimes in selling devices, such as Other-Sonic Gel, contaminated with bacterial pathogens. (See D.E. 21-1, Plaintiff's Brief in Support of Motion, at *7). The ongoing criminal investigation allegedly seeks to determine the extent to which the devices are contaminated, and the knowledge of Claimant and its officers and employees regarding the contamination. *Id.*

III. DISCUSSION

The United States Supreme Court acknowledged a district court's inherent power to stay a proceeding in *Landis v. North American Co.*, 299 U.S. 248, 254-55 (1936). "[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the cases on its docket with economy of time and effort for itself, for counsel, and for litigants. How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an even balance." *Id.* While courts are not required to stay civil proceedings where there is a pending, related criminal action, a stay may be warranted in some circumstances. *Walsh Securities, Inc. v. Cristo Property Management, Ltd.*, 7 F.Supp.2d 523, 526 (D.N.J. 1998). The scope of a stay may encompass all of the proceedings in a civil action, or may be limited to particular parts of them, based on the sound discretion of the court.

See *United States v. Mellon Bank*, 545 F.2d 869, 872-73 (3d Cir. 1976) (finding that it was within the power of the district court to stay civil actions completely pending the resolution of related criminal proceedings).

A stay of a civil case is an "extraordinary remedy." *Weil v. Markowitz*, 829 F.2d 166, 174 n. 17 (D.C. Cir. 1987). In determining whether to grant a stay, courts consider the following factors: (1) the extent to which the issues in the criminal and civil cases overlap; (2) the status of the case, including whether the defendants have been indicted; (3) the plaintiff's interest in proceeding expeditiously weighed against the prejudice to plaintiff caused by a delay; (4) the private interests of and burdens of the defendants; (5) the interest of the court; and (6) the public interest. *Walsh Securities*, 7 F.Supp.2d at 527 (citing *Trustees of Plumbers and Pipefitters Nat'l Pension Fund v. Transworld Mechanical, Inc.*, 886 F.Supp. 1134, 1139 (S.D.N.Y. 1995)). The Court will address each of the relevant factors in turn.

1. The Extent to Which the Issues in the Criminal & Civil Cases Overlap

The similarity of the issues presented in a criminal and civil case is the most important factor in determining whether or not to grant a stay of the civil case. *Walsh Securities*, 7 F.Supp.2d at 527. Here, it is evident that the civil and criminal cases share

common issues arising from the same set of facts and occurrences. The civil case and the government's criminal investigation both arise from the sale of allegedly contaminated medical devices, including the Claimant's *in rem*. Therefore, it stands to reason that the same conduct and products will be relevant to both cases, and that the civil and criminal cases are likely to share common witnesses and documents. Accordingly, the Court finds that this factor weighs in favor of a stay.

2. Stage of Parallel Criminal Proceeding

The strongest case for a stay of discovery in a civil case occurs during a criminal prosecution after an indictment is returned, as it is then that the potential for self-incrimination is greatest. See *Walsh Securities*, 7 F.Supp.2d at 527 (citing Milton Pollack, *Parallel Civil and Criminal Proceedings*, 129 F.R.D. 201, 203 (1989)). However, it is still possible to obtain a stay, even though an indictment or information has not yet been returned, if the government is conducting an active parallel investigation. *Id.* (granting stay where search warrants had been executed and subpoenas issued); *Kashi v. Gratos*, 790 F.2d 1050, 1057 (2d Cir. 1986) (stay of civil proceedings granted pending U.S. Attorney's decision whether to indict).

Here, no indictment has issued, but the government has indicated that it is actively conducting a parallel criminal investigation.

(See D.E. 21-1, Plaintiff's Brief in Support of Motion, at *7). While Claimant has represented that its document requests are narrowly tailored, the Court notes that the government contends that those same document requests encompass evidence that is critical to the ongoing investigation. (See D.E. 23, Plaintiff's Brief in Reply, at *7). In light of the above, the Court finds that this factor does not weigh against staying the civil proceedings.

3. Prejudice to Non-Moving Party & Burden to Moving Party

Pharmaceutical Innovations asserts that it will be prejudiced by a delay of 180 days because "the government has already obtained its sought-after remedy" in this forfeiture action. (See D.E. 22, Claimant's Brief in Opposition, at *15). However, the Court notes that a delay of 180 days is not uncommon in civil cases. Furthermore, the Court is not persuaded that only permitting the discovery of documents to proceed while staying all other discovery, as suggested by Claimant, would significantly advance the civil case. As such, the Court finds that a 180 day stay of civil discovery would not ultimately impede Claimant's litigation of this civil matter, but merely delay it.

In contrast, denying a stay of the proceedings would potentially burden the government's investigation in the ongoing criminal investigation. Other courts have recognized that where, as here, there is significant similarity between parallel civil and criminal

proceedings, the target of a criminal investigation "may exploit civil discovery for the advancement of his criminal case." See *U.S. v. Mellon Bank, N.A.*, 545 F.2d 869, 873 (3d Cir. 1976). Accordingly, the Court is mindful that, in light of the inherent differences between civil and criminal discovery, cases such as this present the potential hazard of criminal discovery limitations being circumvented via civil discovery. See *Campbell v. Eastland*, 307 F.2d 478, 487 (5th Cir. 1962) (noting that judicial discretion should be exercised in harmonizing conflicting civil and criminal rules, and "preventing rules and policies applicable to one suit from doing violence to those pertaining to another").

Here, permitting Claimant to take its requested discovery could potentially compromise the government's ongoing criminal investigation. In light of the fact that the criminal investigation is focused on Claimant's contaminated devices, the requested documents are likely to encompass materials gathered in the course of the criminal investigation. Thus, Claimant would ostensibly be provided with an opportunity to evaluate evidence relevant to the ongoing criminal investigation that it would not otherwise have access to. Therefore, the Court finds the burden that not granting the government's motion to stay would cause outweighs any potential prejudice to Claimant that may result from a 180 day stay of the civil proceedings.

4. *Interests of the Court*

The Court has an interest in ensuring that its caseload is managed efficiently. *Walsh Securities*, 7 F. Supp. 2d at 528. Here, the government is not requesting an indefinite stay of the proceedings, but is instead only requesting a stay of 180 days. Additionally, while a stay will delay civil proceedings for a period of time, the advancement of criminal proceedings may narrow issues pertinent to the instant matter and ultimately streamline the proceedings. See *Texaco Inc. v. Borda*, 383 F.2d 607, 609 (3d Cir. 1967). Considering that the United States does not request an indefinite stay of the proceedings, the Court finds that this factor does not weigh against granting the government's motion.

5. *Public Interest*

Finally, the Court must consider the public interest. The public interest in a criminal case is entitled to precedence over a civil litigant, and substantial weight should be given to the public interest in balancing the policy against the right of a civil litigant to a reasonably prompt determination of his civil claims or liabilities. *In re Ivan F. Boesky Sec. Litig.*, 128 F.R.D. 47, at 49 (S.D.N.Y. 1989) (citing *Campbell v. Eastman*, 307 F.2d at 487). The United States asserts that the public has an interest in the government's unimpeded investigation into potential criminal activities of Claimant, its officers and employees, and others

regarding the seized devices. (See D.E. 23, Plaintiff's Reply in Support of Motion, at *6). The United States further argues that, "ascertaining [...] knowledge regarding the contaminated articles and the extent of contamination is critically important to the public, which cannot determine that information itself." *Id.* at *7. This Court agrees. A six month postponement of civil discovery will have no effect on the public, aside from potentially benefiting the public by allowing the government to pursue its criminal investigation unimpeded by responding to potentially compromising civil discovery requests.

IV. CONCLUSION

In light of all of the above, the United States' motion to stay civil discovery for 180 days is hereby granted.

IT IS on this 25th day of March, 2013,

ORDERED that the United States' motion for a stay of discovery for 180 days is granted; and it is

FURTHER ORDERED that discovery in this matter is stayed for a period of 180 days from the date of this Order.

s/ Steven C. Mannion

**HONORABLE STEVEN C. MANNION
UNITED STATES MAGISTRATE JUDGE**

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Date: March 26, 2013