UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* JEFFREY J. BIERMAN, Plaintiffs, v. ORTHOFIX INTERNATIONAL, N.V., *et al.*, Defendants.	Case No. 05-cv-10557

DJO, INCORPORATED'S AND REABLE THERAPEUTICS, INC.'S OPPOSITION TO RELATOR'S MOTION REGARDING GOVERNMENT PRODUCTION OF DOCUMENTS PURSUANT TO RULE 45 SUBPOENA

Defendants DJO, Incorporated and ReAble Therapeutics, Inc. (collectively, "DJO"), through undersigned counsel, hereby oppose Relator's Motion Regarding Government Production Of Documents Pursuant To Rule 45 Subpoena, Dkt. No. 213 (hereinafter, "Relator's Motion"). Relator's Motion asks the Court to permit Relator to circumvent established discovery procedures by serving the United States Department of Justice with a Rule 45 subpoena to require the government to provide Relator with all documents, whether or not they are relevant to this litigation, produced by DJO to the government in the course of a parallel, but separate, investigation by the government.

Relator's Motion should be denied because Relator fails to establish good cause – or any credible justification – for the requested end-run around the discovery process. Moreover, the production of the documents would unfairly prejudice DJO and other third parties.

FACTS

In 2005, the Relator filed this *qui tam* case alleging that multiple defendants violated the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, in the sale and distribution of bone growth stimulators, which are medical devices used to treat fractures. The Relator alleged that DJO caused false claims to be filed for Medicare reimbursement related to the use of these devices. Upon information and belief, after a lengthy investigation, the government decided in 2009 not to intervene as a plaintiff in this case.[1] Under the False Claims Act, where the government has decided not to join a case as a plaintiff, the Relator can nevertheless elect to proceed with the litigation. *Id.* § 3730(c)(3).

After the Relator filed his complaint, the government began a parallel, but separate, investigation as to whether DJO and others may have committed certain health care offenses in the sale and distribution of its bone growth stimulators. As part of that investigation, the government issued two subpoenas to DJO for the production of documents. While there is some commonality to the issues in this case, the documents requested by the government concern some issues, persons and entities that are not relevant to the Relator's complaint. In addition, upon information and belief, production of the documents produced by DJO to the government will reveal third parties who are or have been part of a continuing government investigation.

While the manner in which a *qui tam* complaint is initially filed is somewhat different (because it is filed under seal and *in camera*), once a *qui tam* complaint is unsealed, it is treated like any other complaint under the Federal Rules of Civil Procedure. That is, in the ordinary

[1] Under the False Claims Act, the government has 60 days within which it must decide whether to intervene in a qui tam complaint. 31 U.S.C. § 3730(b)(2). During this 60 day period, the complaint remains under seal. *Id.* This 60 day period may be extended upon a showing by the government of "good cause". *Id.* § 3730(b)(3). Upon information and belief, the government sought and received several extensions of the period in which this case remained under seal. On or about May 5, 2009, the government notified the Court that it decided not to intervene. (Dkt. No. 26).

course there is a Rule 26(f) conference and thereafter, discovery commences, including the issuance to parties of Rule 34 Requests for Production of Documents. Nevertheless, in the eight years since he filed his initial complaint, the Relator has never served DJO with any discovery requests under the Federal Rules of Civil Procedure and has never sought a Rule 26(f) conference. Instead, the Relator has decided to try to circumvent the Federal Rules of Civil Procedure by seeking expedited discovery in advance of a Rule 26(f) conference through a Rule 45 subpoena directed to the government for production of all documents produced by DJO pursuant to subpoenas issued by government.[2]

ARGUMENT

I. RELATOR HAS NOT DEMONSTRATED GOOD CAUSE TO JUSTIFY ONE-SIDED DISCOVERY

Pursuant to Rule 26(d)(1), Relator is prohibited from seeking any discovery– including the issuance of a Rule 45 subpoena – until after a Rule 26(f) conference, unless the parties stipulate to such discovery or the Court otherwise orders discovery. *See* Fed. R. Civ. P. 26(d)(1). One purpose of a Rule 26(f) conference is to allow the parties to try to agree upon an orderly discovery process and schedule, and thereby avoid discovery disputes like the current one. Seeking discovery in advance of a Rule 26(f) conference is an exception to the rule. "In order for a party to obtain expedited discovery before the Rule 26(f) conference, it must show good cause." *Combat Zone, Inc. v. Does 1-84*, No. 12-30085-MAP, 2013 WL 1092132 at *6 (D. Mass. Feb. 20, 2013) (citing Fed. R. Civ. P. 26(b)(1)), *Magistrate's Report and Recommendation adopted without objection*, 2013 WL 1092458 (D. Mass. Mar. 14, 2013).

[2] It is unclear why the Relator refuses to proceed in the normal course under the Federal Rules of Civil Procedure. DJO has advised the Relator that if he desires to obtain relevant documents DJO produced to the government pursuant to the subpoenas, he should simply serve DJO with an appropriate Rule 34 Request for Production of Documents, and DJO will respond accordingly. Relator has refused to do so and instead is attempting to obtain the documents pursuant to a Rule 45 subpoena.

Relator has not established "good cause" for avoiding these rules. Indeed, the only explanation Relator offers for his effort to avoid application of the discovery rules is a conclusory one-sentence statement that "Rule 26 proceedings are unnecessary at this time given that defendants have already produced the documents to the Government." Relator's Motion at 2. Simply stating this fact is in no way a justification or explanation as to why the discovery rules should not apply here – and the Relator's failure to make any threshold showing of "good cause" alone requires denial of Relator's Motion. *St. Louis Group, Inc. v. Metals & Additives Corp., Inc.*, 275 F.R.D. 236, 240 (S.D. Tex. 2011) (the burden of establishing good cause for expedited discovery prior to the Rule 26(f) conference is on the party seeking the discovery).[3]

A. The "Good Cause" Analysis

Putting aside Relator's failure to establish *any* need for discovery outside the normal procedures, an analysis of the "good cause" standard further demonstrates why Relator's Motion should be denied. Courts evaluating motions for expedited discovery pursuant to Rule 26(d)(1) have applied two standards to analyze whether good cause exists: (1) a four-part inquiry that is similar to a preliminary injunction standard, *see Notaro v. Koch*, 95 F.R.D. 403, 405 (S.D.N.Y. 1982); and (2) a "reasonableness" standard that assesses the reasonableness of the request in light of all the circumstances. *See Momenta Phama., Inc. v. Teva Phama. Indus., Ltd.*, 765 F. Supp. 2d 87, 88-89 (D. Mass. 2011) (citing cases). The First Circuit has not addressed the proper standard to determine whether "good cause" exists to justify discovery of the sort contemplated by Relator. *See Combat Zone*, 2013 WL 1092132 at *6. However, a majority of district courts – including at least one in this district – have applied the "reasonableness" standard. *See St. Louis Group*, 275 F.R.D. at 239; *McMann v. Doe*, 460 F. Supp. 2d 259, 265 (D. Mass. 2006).

[3] Of course, it may be impossible for the Relator to proffer any credible argument for expedited discovery in a case that is already eight years old.

Relator's Motion falls far short of satisfying the good cause standard regardless of the test employed.

Under the more liberal "reasonableness" test, the factors courts consider include: the purpose of the discovery; the need for the discovery to prevent irreparable harm; the plaintiff's likelihood of success on the merits; the burden of discovery on the defendant; and the degree of prematurity. *Momenta,* 765 F. Supp. 2d at 89 (quoting *McMann,* 460 F. Supp. 2d at 265).[4]

Relator's Motion does not specify any purpose for seeking to employ discovery procedures outside the normal discovery process. More importantly, Relator does not offer any reason why he believes he is entitled to discovery prior to commencement of the formal discovery process in this case. For example, Relator does not – and could not credibly – contend there is any risk of irreparable harm that requires discovery prior to a Rule 26(f) conference. *See Momenta,* 765 F. Supp. 2d at 89 (holding that Rule 26(d)(1) expedited discovery was not warranted because there was no risk of irreparable harm and no preliminary injunction motion pending). Because the documents already have been produced to the government, there is no risk that the documents will be destroyed or otherwise will not be available from defendants during the normal discovery period. Nor does the Relator assert any other need for the requested discovery outside the discovery process, such as the need to determine the identity of "John Doe" parties. *See Combat Zone,* 2013 WL 1092132 at *6 (noting that courts routinely permit discovery pursuant to Rule 26(d)(1) for the purpose of discovering the identity of a John Doe defendant) (citing cases); *2815 Grand Realty Corp. v. Goose Creek Energy, Inc.*, 656 F. Supp. 2d

[4] Plainly, the Relator cannot satisfy the more stringent preliminary injunction standard, which analyzes whether the party seeking discovery has shown: (1) irreparable injury; (2) some probability of success on the merits; (3) some connection between the requested discovery and the avoidance of irreparable harm; and (4) some evidence that the injury that will result without expedited discovery is greater than the injury the party would suffer if expedited discovery were available. *See Edgenet, Inc. v. Home Depot USA, Inc.*, 259 F.R.D. 385, 386 (E.D. Wis. 2009).
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707, 723 (E.D. Ky. 2009) (denying motion for expedited discovery because there was no claim that evidence would be destroyed, no request for preliminary injunction, and no challenge to the court's jurisdiction that would need to be resolved through early discovery).

B. Production Would Unfairly Prejudice DJO and Third Parties

Permitting the requested discovery would also unfairly prejudice DJO in several ways. For example, if Relator is permitted to seek DJO's documents directly from the government – rather than from DJO in the normal course of discovery – DJO will not have any opportunity to object to the production of particular documents that are not relevant to the allegations in Relator's Second Amended Complaint. Unlike discovery requests in civil litigation which are at least limited to matters relevant to the claims or defenses in a case, subpoenas issued by the government investigating criminal offenses are not limited in any similar way. This concern is particularly relevant here because the government's subpoenas and requests for documentation from DJO were broader than Relator's allegations, and thus DJO produced documents to the government that are irrelevant to Relator's allegations.

In addition to the prejudice to DJO, the government and other third parties would be prejudiced by Relator's attempted discovery because the documents sought would reveal third parties who are or have been subjects of an on-going government investigation. The "Touhy" regulations cited by the Relator provide that the government should not make disclosures in a demand for documents where the documents "would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired." 28 C.F.R. § 16.26(b)(5).

In contrast, the Relator will suffer no prejudice if he followed the normal discovery process. If he simply served DJO with a proper Request for Production of Documents in the normal course of discovery, he would receive in due course the relevant documents that DJO has produced to the government.

Furthermore, if Relator is permitted to do an end-run around the discovery rules and obtain DJO's documents from the government, Relator will not be subject to any restrictions on the further use or disclosure of that information. This is a troublesome circumstance to the extent that the documents DJO produced to the government include any reference to protected patient health information and other confidential information. In the ordinary course, DJO would have the opportunity during discovery to designate documents as confidential pursuant to a valid protective order entered by the Court. In the absence of any "good cause", DJO should not be denied the protections that otherwise would be available to it during in a traditional discovery process.

CONCLUSION

In short, "[e]xpedited discovery is not the norm" and is neither justified nor permitted unless the party seeking discovery outside the formal discovery period has satisfied the "good cause" standard. *St. Louis Group.*, 275 F.R.D. at 242 (request for Rule 26(d)(1) discovery denied because the parties seeking the discovery "have not presented the Court with a compelling reason to deviate from the normal course of discovery by ordering one-sided discovery"). The expedited discovery would also unfairly prejudice DJO, the government and third parties.

The Relator's Motion should be denied.

Dated: April 4, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document will be sent through the Court's ECF system to counsel of record for all parties registered on the Court's ECF filing and service system, and by U.S. First Class Mail on this date to those who are indicated on the Notice of Electronic filing as not registered on the ECF system

Dated: April 4, 2013

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/s/ *Andrew C. Bernasconi*