UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

United States of America	: Civil Action No. 1:08 CV 354
ex rel. Michael Daugherty,	:
	: District Judge S. Arthur Spiegel
Plaintiff-Relator,	:
	: Magistrate Judge Karen L. Litkovitz
v.	:
	:
Bostwick Laboratories	:
	:
and	: · · · · · · · · · · · · · · · · · · ·
	:
David Bostwick	:
	:
Defendants.	:

PROTECTIVE ORDER

It is ordered that the following terms and provisions will govern the production and use of certain documents, information, and evidence ("Produced Material") to be produced by the Parties (Defendant Bostwick Laboratories, Defendant David Bostwick, and Relator are referred to herein collectively as the "Parties") or any third party in connection with the above-captioned action (each, a "Producing Person"):

1. "Confidential Information" is that Produced Material which the Parties reasonably believe in good faith constitutes either (a) personal health or personal financial information of individuals, or personal information contained in an employee's personnel file; and/or (b) trade secrets or other confidential research, development or commercial information subject to confidential treatment under Rule 26(c)(1)(G), Fed. R. Civ. P.

Pursuant to the HIPAA Privacy Rule, a covered entity such as Bostwick Laboratories is permitted to disclose protected health information in the course of a judicial proceeding if certain "satisfactory assurances" are received. This Protective Order hereby provides Bostwick Laboratories or any other covered entity compelled to produce documents in this litigation with the requisite satisfactory assurances under HIPAA. *See* 45 C.F.R. § 164.512(e)(1)(iv). In accordance with the HIPAA Privacy Rule, this Protective Order allows for the disclosure and receipt of a patient's protected health information, in the possession of a covered entity, for the limited purpose of this litigation, including at depositions, hearings, or other judicial proceedings in this litigation. In accordance with the HIPAA Privacy Rule, this Protective Order specifically prohibits the Parties from using or disclosing the protected health information for any purpose other than this litigation for which such information was requested. 45 C.F.R. §164.512(e)(1)(v)(A). Also in accordance with the HIPAA Privacy Rule, the protected health information disclosed to any persons listed in Paragraphs 5 and 6 of this Protective Order, including all copies made, shall be destroyed at the conclusion of this litigation. 45 C.F.R. § 164.512(e)(1)(v)(B).

This Protective Order also permits and authorizes the Parties to disclose individually identifying health, personal and financial information of nonparty patients during discovery in this case. The Court further finds that it is not possible to identify and contact all nonparty patients whose names or other personal, identifying information may be produced and that removal or deletion of all such information is not practical or feasible. Therefore, the Court hereby authorizes and ORDERS, to the extent a court order is necessary under state law, that the Parties are permitted to disclose individually identifying health, personal, and financial information, records and data regarding

nonparty patients during discovery in this case, including information otherwise privileged or confidential under state law.

2. "Confidential – Attorneys' Eyes Only Information" is that Produced Material which is so designated by the Producing Person, which designation may be used only for the following types of Confidential Information that is dated after July 1, 2011:

(1) Sensitive confidential business or financial information and records, reflecting pricing agreements or pricing proposals dated after July 1, 2011, which were offered to actual or potential customers or obtained from suppliers, distributors, or private payors; and

(2) Competitive business information, including non-public financial or marketing analyses or comparisons of competitors' products or services and strategic planning.

3. All documents containing Confidential Information or Confidential – Attorneys' Eyes Only Information shall be clearly labeled as either "Confidential Information" or "Confidential – Attorneys' Eyes Only Information" by the Producing Person. To the extent that only portions of a document contain Confidential – Attorneys' Eyes Only Information, the Producing Person shall clearly identify the portions that do not contain information subject to the Attorneys' Eyes Only designation. Electronic information may be designated by labeling the disk or other media containing the designated information as "Confidential Information" or "Confidential – Attorneys' Eyes Only Information."

Interrogatory answers or other responses to written discovery and information contained therein may be designated by means of a statement at the conclusion of each

answer specifying the "Confidential Information" or "Confidential – Attorneys' Eyes Only Information" contained therein or by other means that clearly indicate what portion of the answer or information is to be designated and by labeling the front of any set of interrogatory answers or other responses to written discovery indicating that it contains either "Confidential Information" or "Confidential – Attorneys' Eyes Only Information."

4. Testimony at a deposition or hearing concerning Confidential Information or Confidential – Attorneys' Eyes Only Information may be designated as subject to this Protective Order by an appropriate statement at the time of the giving of such testimony or in writing within thirty (30) days after receipt of each volume of such transcript. Until such time period expires, the portion of any such transcript shall be treated as Confidential Information or Confidential – Attorneys' Eyes Only Information unless otherwise specified in writing or on the record at the hearing or deposition. All copies of portions of transcripts that contain material designated as Confidential Information or Confidential - Attorneys' Eyes Only Information shall be marked prominently "Subject to Protective Order" on the cover thereof. No testimony shall be deemed subject to this Protective Order unless specifically designated as such. Either Party's designation of testimony as Confidential Information or Confidential – Attorneys' Eyes Only Information shall be limited to only that part of the testimony that it in good faith and reasonably believes is protected by federal or state law or is otherwise confidential and/or proprietary. To the extent deposition testimony is designated as subject to this Protective Order, attendance during that portion of the deposition shall be limited to those individuals authorized to access such information under Paragraph 5 or Paragraph 6, as applicable.

5. Confidential Information may not be disclosed by any person to anyone

other than:

- a. The Court;
- b. The Parties, including their current or former officers, directors, agents, employees, and consultants;
- c. Counsel of record and associated counsel and employees or agents of counsel of record or associated counsel;
- d. Court reporters, stenographers, or video operators at depositions, court, or arbitral proceedings at which Confidential Information is disclosed;
- e. Discovery consultants, processors and vendors, and outside document copying services;
- f. Document coding or computerization services, demonstrative exhibit vendors and jury consultants;
- g. Associated personnel of any person within the above subcategories (a) through (f) for whom access to Confidential Information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing testimony in this action, and principals and employees of the firm with which consultants or experts are associated;
- h. Deponents and other persons who may provide testimony in this matter and their counsel, if any;
- i. Any person who authored, received, or who otherwise has already been provided access to the Confidential Information in the ordinary course of business;
- j. Independent experts and consultants retained by counsel of record to assist them in connection with this action; and
- k. Such other persons as the Parties may mutually agree upon in writing.

6. Confidential – Attorneys' Eyes Only Information may not be disclosed by

any person to anyone other than:

- a. The Court;
- b. Counsel and Bostwick Laboratories' in-house counsel directly managing the litigation;
- c. Counsel of record and associated counsel and employees or agents of counsel of record or associated counsel;
- d. Court reporters, stenographers, or video operators at depositions, court, or arbitral proceedings at which Confidential Attorneys Eyes Only Information is disclosed;
- e. Discovery consultants, processors and vendors, and outside document copying services;
- f. Document coding or computerization services, demonstrative exhibit vendors and jury consultants;
- g. Associated personnel of any person within the above subcategories

 (a) through (f) for whom access to Confidential Attorneys' Eyes
 Only Information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing testimony in this action, and principals and employees of the firm with which consultants or experts are associated;
- h. Deponents who have created or received, in the scope of their employment, the Confidential – Attorneys' Eyes Only Information that may provide testimony in this matter and their counsel, if any;
- i. Any person known to have created or received, in the scope of their employment, the Confidential – Attorneys' Eyes Only Information outside of the discovery process in the Matter; and
- j. Independent experts and consultants retained by counsel of record to assist them in connection with this action; and
- k. Such other persons as the Parties may mutually agree upon in writing.

7. Any Party who wishes to use Confidential Information or Confidential – Attorneys' Eyes Only Information in any affidavit, brief, memorandum or other paper to be filed with the Court in this litigation must first move for leave to file such material under seal. Any sealed information shall be filed with the Clerk of Court in an envelope marked "DOCUMENTS UNDER SEAL PURSUANT TO ORDER OF COURT DATED

______2013" pursuant to Local Rule 79.3. The filing of documents under seal shall be without prejudice to the Parties' rights under Section 12 of this Protective Order.

8. Prior to disclosing Confidential Information or Confidential – Attorneys' Eyes Only Information to those individuals authorized in Paragraphs 5(e)-(j) and 6(e)-(j) above, the Parties shall obtain a signed agreement in the form of Exhibit A hereto from the party to whom the Confidential Information or Confidential – Attorneys' Eyes Only Information is to be disclosed. Such agreement shall be retained by counsel throughout the course of the action, including any appeals.

9. Confidential Information and Confidential – Attorneys' Eyes Only Information may be used by the Parties solely for the prosecution or defense of the claims in this action and shall not be used for any other purpose, including without limitation any business, commercial, competitive, or personal purpose, and shall not be disclosed except as provided in this Protective Order.

10. Confidential Information and Confidential – Attorneys' Eyes Only Information shall be stored under the direct control of counsel, who shall use its best efforts to prevent any disclosure thereof except in accordance with the terms of this Protective Order. At the conclusion of this case, all Confidential Information and Confidential – Attorneys' Eyes Only Information, and all copies thereof shall be

destroyed or returned to the Producing Person.

11. Restrictions and obligations set forth herein relating to Confidential Information and Confidential – Attorneys' Eyes Only Information shall not apply to any Produced Material which: (a) is already public knowledge or becomes public knowledge through disclosure in open court; or (b) the Producing Person agrees, or the Court rules, has become public knowledge other than as a result of disclosure by the party receiving the Confidential Information and Confidential – Attorneys' Eyes Only Information.

12. In the event that any Party believes that any Confidential Information and Confidential - Attorneys' Eyes Only Information does not contain protected health information, or is not confidential or proprietary and, therefore, should not be subject to this Protective Order, the Party shall state the grounds for the objection in writing and serve it on the Producing Person. The objecting Party shall thereafter try to resolve such disputes in good faith on an informal basis with the Producing Person. In the event the dispute cannot be resolved informally within fourteen (14) days after the Producing Person's receipt of the notice, the Producing Person may file an appropriate application with the Court requesting that the designated Produced Material be treated as subject to the Protective Order. The Party making the designation shall have the burden of proving that the material should be treated as designated. During the pendency of any motion to reclassify Produced Materials that have been designated as "Subject to Protective Order," the Parties shall adhere to the previously designated classification. However, if no motion is filed within fourteen (14) days of the receipt of the notice of objection, the designated Produced Material shall no longer be treated as "Subject to Protective Order." All costs of such a challenge, including but not limited to attorneys' fees, shall be borne by the

Party that incurred said cost, unless the Court otherwise orders.

13. This Protective Order is without prejudice to the right of any Party or nonparty to argue that certain information designated as Confidential Information or Confidential – Attorneys' Eyes Only Information: (a) should not be subject to this Protective Order; (b) is not relevant to any issue in this case; or (c) otherwise should not be admitted as evidence in the case. By entering into this stipulation, neither Party concedes that any information produced in this litigation does in fact contain protected health information, confidential information or proprietary information.

14. The inadvertent disclosure of unmarked Produced Material that the Producing Person believes should have been designated as Confidential Information or Confidential – Attorneys' Eyes Only Information shall not be deemed to be a waiver or impairment of the Party's or Producing Person's right to make designations under this Protective Order going forward, either as to the specific material in question or as to any other materials relating thereto or to the same or related subject matter. On the other hand, no person shall be subject to any penalty or sanction for any otherwise appropriate use of any material before they have been designated pursuant to this Protective Order. This provision shall be governed by, and this Protective Order is entered pursuant to, Federal Rule of Evidence 502. To the extent that the terms of this provision conflict with Rule 502, that Rule shall control as to any inadvertent disclosure of privileged information.

15. A Producing Person must take reasonable steps to prevent inadvertent disclosure of material subject to claims of protection under the attorney-client privilege, work product doctrine, and/or other doctrines or privileges of nondisclosure ("Privileged

Material"). Even with reasonable preventative measures, production of documents may result in inadvertent disclosure of Privileged Material. If a Producing Person learns of an inadvertent disclosure, the Producing Person may notify in writing the Receiving Party that the production was inadvertent and demand the return of the Privileged Material. On such demand, the Receiving Party must promptly return, sequester or destroy all copies of the identified Privileged Material to the Producing Person and may not further disclose or use the information contained in the Privileged Material for any purpose, other than in connection with the service or filing of a motion seeking a ruling of the Court as to whether the Privileged Material is protected by privilege and should be returned to the Producing Person. If the Receiving Party seeks to challenge the claimed privileged status of any Privileged Material, it shall use reasonable efforts in presenting such a motion to preserve the confidentiality of the Privileged Material, including filing the Privileged Material in a sealed envelope and seeking review in camera. If the Court determines that the Privileged Material is privileged and that the disclosure of the Privileged Material was inadvertent, as set forth in Federal Rule of Evidence 502(b), the Receiving Party may not utilize the Privileged Material in the litigation or disclose it to any third-party. As set forth in Federal Rules of Evidence 502(d) and (e), this Protective Order constitutes the entry of an Order by this Court that the inadvertent disclosure of Privileged Material by any Party in connection with this matter, will not constitute in any respect a waiver in any other federal or state proceeding, regardless of whether a finding of waiver is sought by a Party or non-party in that proceeding.

16. This Protective Order may be amended only by Order of the Court.

17. Notwithstanding any of the non-disclosure obligations set forth in the Protective Order, such obligations shall not extend to any Material required to be produced by an appropriate subpoena, court order, a regulatory agency, or otherwise by law. To the extent that the information subpoenaed includes protected health information, the Parties understand that disclosure of protected health information must comply with the HIPAA Privacy Rule and state law. Should a Party or its counsel be served with a subpoena or other notice seeking disclosure or production of Confidential Information or Confidential – Attorneys' Eyes Only Information, including protected health information, that Party shall give notice to counsel for the other Party promptly and in writing, sufficiently in advance of the requested production date to allow the counsel for the Party or such other interested person or entity an opportunity to object to the requested production.

18. Nothing herein shall affect the right of a Producing Person to use or in any way to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own information. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the Producing Person the information becomes public knowledge.

18. Any allegations regarding violation of this Protective Order shall be submitted to the Court for adjudication.

SUBJECT TO FURTHER ORDER OF THE COURT

Date: 7/11/13

S. Arthur Spiegel

United States Senior District Judge

/s/

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/s/

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EXHIBIT A

AGREEMENT REGARDING PROTECTIVE ORDER

, residing at	
	;
states that he or she is employed by	
and has read the Protective Order entered into by the parties to the action entitl	ed
UNITED STATES OF AMERICA ex rel. MICHAEL DAUGHERTY v. BOS	TWICK
LABORATORIES AND DAVID BOSTWICK, Civil Action No. 1:08-cv-354	, and
agrees that he or she will not disclose any Confidential Information or Confide	ential –
Attorneys' Eyes Only Information (as defined in said Protective Order) except	in
accordance with the terms of said Order, or the terms of any Order modifying	it of which
he or she has noticealso states that	t he or she
agrees to submit to the personal jurisdiction of the Southern District of Ohio, v	vith respect
to any proceeding relating to enforcement of said Protective Order.	
Dated:	

_____[Signature]