April 21, 2015

CONSTRUCTIVE NOTICE

IF THIS AFFIDAVIT IS NOT PROPERLY REBUTTED WITH A COUNTER-AFFIDAVIT WITHIN FORTY FIVE (45) DAYS FROM THE DATE OF ITS MAILING, ALL PARAGRAPHS NOT DENIED SHALL BE CONFESSED AFFIRMED, BY SUCH DEFAULT, AND SHALL BE ACCEPTED AS DISPOSITIVE, CONCLUSIVE FACTS, BY THE FOOD AND DRUG ADMINISTRATION (FDA). WHEREIN THE COMMISSIONER, CONTRACTORS AND SUB-CONTRACTORS WITH THE AGENCY OF GOVERNMENT OR ANY PROPERLY DELEGATED AUTHORITY HAVE BEEN GIVEN NOTICE AND HAD THE OPPORTUNITY AND “FAILED TO PLEAD.” ALL COUNTER-AFFIDAVITS MUST BE SIGNED WITH THE VALID LEGAL NAME OF THE RESPONDENT. FICTITIOUS OR INCOMPLETE NAMES OF RESPONDENTS, OR THOSE NOT CONTAINING COMPLETE LEGAL FIRST, MIDDLE, AND LAST NAMES, EMPLOYEE NUMBER, AND PHOTOCOPY OF DRIVER’S LICENSE, SHALL NOT CONSTITUTE A VALID RESPONSE BECAUSE IT IS CONSIDERED NOT PROPERLY AUTHENTICATED.

Affiant: John Hnatio

This Affidavit and all attached documents have been made a part of the Public Record and will be used for evidence in the administrative and judicial proceedings at law, or equity regarding this case. ALL of these documents must be maintained in Claimant’s Administrative File. This affidavit and exhibits shall be posted on the John Galt Program of Investigative Studies web site at (<http://jgpis.org/>) for further public notice and to provide the Food and Drug Administration (FDA) the opportunity to rebut each of the forty-three (43) claims appearing below.

Affidavit of Truth

1. From 2002 through the summer of 2006, JOHN HNATIO conducted a program of doctoral research at The George Washington University.
2. On October 28th, 2003, JOHN HNATIO applied to the United States Patents and Trademarks Office (USPTO) for a patent (Application No. US 10/694,024) based on his doctoral research. [EXHIBIT]
3. The United States issues patents through the USPTO which is valid in the United States and its territories.
4. The Food and Drug Administration (FDA) is an agency of the United States and subject to statutes, codes and patent laws under the jurisdiction of the United States.
5. The FDA is headquartered in Silver Springs, Maryland, in the United States of America, and is subject to the Uniform Commercial Code for a remedy in commerce.
6. In August 2006, JOHN HNATIO’s doctoral dissertation was published by The George Washington University and registered as copyrighted material. [EXHIBIT]
7. On June 12, 2007, JOHN HNATIO submitted a USPTO Patent Application No. US 11/808,580 claiming preference to his 2003 invention disclosure. [EXHIBIT]
8. In November 2007, the FDA issued their “National Food Protection Plan.” [EXHIBIT]
9. The “National Food Protection Plan,” contains written expressions of ideas contained in JOHN HNATIO’s doctoral dissertation. [EXHIBIT]
10. The “National Food Protection Plan,” contains ideas as described in HNATIO’s 2003 patent application and his then pending July 2007 USPTO patent. (<http://www.fda.gov/Food/GuidanceRegulation/FoodProtectionPlan2007/ucm132565.htm>) [EXHIBIT]
11. Over the period 2006 to 2012, FDA officials received a series of proprietary briefings from John Hnatio concerning the development of food risk management tools based on his doctoral dissertation.
12. These briefing materials contained trade secrets that Hnatio developed as he reduced his inventions to practice.
13. The briefings were marked as containing proprietary information. [EXHIBIT]
14. The use of trade secrets developed to reduce patented inventions to practice by another party can represent patent infringement.
15. On March 25, 2009, JOHN HNATIO submitted a proprietary unsolicited proposal to the FDA Joint Institute for Food Safety and Nutrition (JIFSAN) (Dr. Julianna Ruzzante) and the Center for Food Safety and Applied Nutrition (CFSAN) (Dr. Robert Buchanan) for the co-development of HNATIO’s patented food risk software.
16. The unsolicited proposal contained trade secret information HNATIO developed as he reduced his inventions to practice and was marked proprietary. [EXHIBIT]
17. The unsolicited proposal was rejected by JIFSAN and CIFSAN.
18. Title 18 USC §1905 prohibits government employees from revealing business confidential information provided to them by a private sector entity that relates to trade secrets, processes, operations, style of work, or apparatus. [EXHIBIT]

(<https://www.law.cornell.edu/uscode/text/18/1905> )

1. In April 2011, the FDA released their “Food Defense Mitigation Strategies Database,” food risk management tool that accomplishes the same purposes as HNATIO’s prior developed risk management software. [EXHIBIT] (<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm248125.htm>)
2. In June 2011, the FDA released their “Food Response Emergency Exercise Bundled or FREE-B,” food risk management tool that accomplishes the same purposes as HNATIO’s prior developed risk management software. [EXHIBIT]
3. On January 24, 2012, USPTO Patent No. US 8103601 B2 issued based on Application No. US 11/808,580 with Affiant listed as inventor. [EXHIBIT]
4. On May 16, 2012, The FDA executed a Military Interdepartmental Purchase Request (MIPR) from the Department of Defense Chemical Warfare/Chemical and Biological Defense Information Analysis Center (CBIAC) to fund a directed pass through subcontract to Valbrae Technologies. [EXHIBIT]
5. Valbrae Technologies was granted a non-competitive FDA subcontract to produce FDA’s “Food Defense Plan Builder” tool that accomplishes the same purposes as JOHN HNATIO’s prior developed risk management software. [EXHIBIT]
6. On October 2, 2012, Mr. Jody Menikheim, head of FDA’s Food Defense Team, stated that their “Food Defense Plan Builder,” tool accomplished the same purpose as JOHN HNATIO’s prior developed risk management software but was not as sophisticated. [EXHIBIT]
7. On October 2, 2012, JOHN HNATIO offered Mr. Menikheim and the FDA a $1.00 per year license for FDA employees to use HNATIO’s suite of computer tools if the FDA stopped competing directly with HNATIO. The FDA never responded to the offer. [EXHIBIT]
8. In October 2012, the FDA released their “iRisk,” food risk management tool that accomplishes the same purpose as HNATIO’s prior developed risk management software. [EXHIBIT] (<http://blogs.fda.gov/fdavoice/index.php/tag/fda-irisk/> )
9. The FDA did not follow 5 C.F.R. Part 2635 when it publicly endorsed the brand name and products of Tyco Integrated Security Systems.
10. The FDA allowed an FDA official to appear in an on-line marketing video produced by Tyco Integrated Systems. [EXHIBIT] (http://www.foodmanufacturing.com/videos/2013/04/food-defense-strategy-part-1-assess)
11. Tyco Integrated Security Systems is a direct competitor of JOHN HNATIO.
12. On December 12, 2012, the FDA held a food industry meeting at the Headquarters of the Grocery Manufacturer’s Association (GMA) in Washington, D.C., to obtain inputs on their new “Food Defense Plan Builder,” software tool.
13. JOHN HNATIO was prohibited by the FDA from attending this meeting. [EXHIBIT]
14. FDA’s claim that no one but food processors would be allowed to attend the meeting in order to avoid unfair competition was later proven false. (EXHIBIT]
15. On May 18, 2013, the FDA released their “Food Defense Plan Builder,” food risk management tool that accomplishes by FDA’s own admission the same purposes as JOHN HNATIO’s prior developed risk management software. [EXHIBIT]
16. The FDA, placed their food risk management tools that contain the trade secrets developed by JOHN HNATIO on the World Wide Web thereby publicly releasing Affiants trade secrets to multiple corporations acting in commerce. [EXHIBIT]
17. U.S. Government employees and their contractors used JOHN HNATIO’s trade secrets in the performance of their official U.S. Government work.
18. U.S. Government employees and their contractors gained from the use of JOHN HNATIO’s trade secrets.
19. These gains took the form of offers of FDA employment, awards, bonuses, promotions and other forms of individual recognition for developing software tools that accomplish by the FDA’s own admission the same purposes as JOHN HNATIO’s prior developed risk management software. [EXHIBIT]
20. U.S. Government employees engaged in a conflict of interest by failing to recuse themselves from investigating JOHN HNATIO’s allegations of fraud, waste and abuse that were being made directly against them.
21. 5 C.F.R. Part 2635, Subpart A, General Provisions, specifically requires employees of the U.S. Government to avoid appearances of, and never engage in, actual conflicts of interest. The Code of Ethics for Government Service (P.L. 96-303) states that such allegations should be referred to the Office of Inspector General for an independent investigation. [EXHIBIT]
22. U.S. Government employees engaged in the obstruction of justice by entering into an actual conflict of interest to conduct an investigation of their own alleged misconduct. [EXHBIT]
23. The Code of Ethics for Government Service (P.L. 96-303) states that such allegations should be referred to the Office of Inspector General for an independent investigation. [EXHIBIT]
24. FDA spoliated evidence to avoid the public release of evidence under Title 5 U.S.C. §552 (the Freedom of Information Act). (EXHIBIT)
25. Affiant incorporates by reference a comprehensive report of investigation that includes a computer library of documentary evidence supporting each of individual statements of truth as set forth in paragraphs one (1) through nineteen (42), above. The report dated November 28, 2014, entitled, “The Case of FoodQuestTQ” and exhibits can be directly accessed on the World Wide Web at <http://www.jpgis.org>

John Hnatio contends that the following laws apply to the matter *John Hnatio versus the Food and Drug Administration*:

1. Federal procurement fraud: *18 U.S. Code § 1031 - Major fraud against the United States;* Competition in Contracting Act (CICA) of 1984 (*41 U.S.C. 253*); Federal Acquisition Regulations as codified at (*Title 48, Chapter 1 of the United States Code of Federal Regulations*).
2. Conspiracy to defraud United States (*18 U.S. Code § 371*).
3. The violation of procurement integrity law. *5 C.F.R. Part 2635* applies.
4. Violation of the Code of Ethics for Government Service, as part of a purposeful scheme to defraud. *P. L. 96-303*, July 3, 1980, applies.
5. Violation of Sherman Antitrust law as part of a purposeful scheme to defraud. *Title 15 U.S.C. §§ 1-7* and *Title 18 U.S. Code § 1031* apply.
6. Mail and wire fraud as codified at *18 U.S.C. §§ 1341 and 1343.*
7. Title 5 USC § 552, Freedom of Information Act.
8. Title 17 USC, copyright law of the United States.
9. The Federal Records Act of 1950 (FRA; 44 U.S.C. Chapters 21, 29, 31, and 33) as amended.
10. The misappropriation intellectual property. *18 U.S.C. § 654: US Code - Section 654: Officer or employee of United States converting property of another, 18 U.S.C. § 641: US Code - Section 641: Public money, property or records,* and *18 U.S. Code § 1832 - Theft of trade secrets*; *Article I, clause 8, of the United States Constitution*: the “patent and copyright” clause, and; *Amendment V of the United States Constitution*: the “takings” clause apply*.*

Damages: John Hnatio is seeking damages of 183 million dollars as independently estimated by a firm specializing in the market valuation of technology. These damages arise from the fact that Hnatio was not able to sell his food risk management software to the food industry due to the public release of the trade secrets developed as HNATIO reduced his inventions to practice.

Severability: If one or more provisions of this Agreement shall be held to be invalid or unenforceable for any reason, the remaining provisions shall continue to be valid and enforceable. If a qualified court finds one or more provisions of this Agreement is invalid or unenforceable, but that by limiting such provision(s) it would become valid or enforceable, such provision(s) shall be deemed to be written, construed, and enforced as so limited. In the event that such a finding and limitation causes damages or hardship to either Party, the Agreement shall be amended in a lawful manner to make all Parties whole.

Waiver of Contractual Right: The failure of either Party to enforce one or more provisions of this Agreement shall not be construed as a waiver or limitation of that Party’s right to subsequently enforce and compel strict compliance with every provision of this Agreement. Secured Party shall not be deemed to have waived rights under this Agreement unless such waiver is given in writing and signed by Secured Party. No delay or omission on the part of Secured Party in exercising a right shall operate as a waiver of such right or any other right. A waiver by Secure Party of a provision of this Agreement shall not prejudice or constitute a waiver of the Secured Party’s right otherwise to demand strict compliance with that provision or any other provision of this Agreement. No prior waiver by Secured Party, nor any course of dealing between Secured Party and Debtor shall constitute a waiver of Secured Party’s rights or of Debtor’s obligation under this Agreement as to future transactions. Whenever the consent of the Secured Party is required under this Agreement, the granting of such consent by Secured Party in one instance shall not constitute consent over the whole.

Ambiguities and Interpretation: Each Party acknowledges receipt of this Agreement and has had the opportunity to have counsel review it, and that any rule of construction claiming ambiguities are to be resolved against the drafting Party, shall not apply in the interpretation of this Agreement or its amendments.

Authority to Represent: A signer of this Agreement on behalf of a legal entity certified that he has the authority to sign this Agreement and that this transaction has been duly authorized by such entity.

Gender: All references within this Agreement to a specific gender, include the other.

John Hnatio “Without Prejudice.” All Rights Reserved UCC.

John Hnatio

County of: Frederick

State of: Maryland

Notary Signature