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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of the General Counsel

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April 26, 2013

VIA FEDEX AND EMAIL

Dr. John Hnatio
FoodQuestTQ, LLC
4720 Hayward Road, Suite 104
Frederick, MD 21702
jhnatio@thoughtquest.com

Dear Dr. Hnatio:

We were asked to respond to your letter of April 1, 2013, to Secretary Sebelius.[1] As we describe below, the Food and Drug Administration (FDA) and other operational divisions within the Department of Health and Human Services (HHS), including their respective counsels' offices, have investigated your claims. These include serious allegations of patent and copyright infringement, misappropriation of allegedly confidential material, and various statutory violations.

Despite our best efforts to undertake a thorough investigation of your claims, you have refused to provide us with copies of the works that you allege the Agency has infringed. Consequently, we have done all that we can to evaluate the many allegations that you have made—set forth in multiple communications to disparate parties throughout the agency and indeed the government—with the evidence we have available. For the reasons set forth below and because we have found no supporting evidence for your allegations, we consider this matter closed.

Summary of Contacts and Communications

On January 9, 2013, FDA's Office of the Chief Counsel, which is also the Food and Drug Division of the HHS Office of General Counsel, received a letter dated December 19, 2012 from Senator Barbara Mikulski on your behalf, forwarding your letter of December 14, 2012.[2] In your December 14, 2012

[1] Exhibit 1: April 1, 2013 letter from John Hnatio to Secretary Sebelius.
[2] Exhibit 2: December 14, 2012 letter from John Hnatio to Sen. Mikulski, forwarded to FDA by Sen. Mikulski by letter dated December 19, 2012.

letter, you claimed that FDA took your patented technology (specifically, "Food Defense Architect") and used it to build an FDA software system. You also complained that you were unfairly excluded from the Agency's process for developing its food safety tools. In particular, you claimed that you were scheduled to participate in a FDA industry workshop and were disinvited because FDA did not want to endorse a specific company's product, and you complained that another company who produces similar products (Tyco Integrated Systems) was allowed to attend.

By letter dated January 28, 2013, Elizabeth Dickinson, FDA's Chief Counsel and HHS Associate General Counsel for the Food and Drug Division, responded to you stating that she was looking into your concerns and she asked for more information, including identification of the patents to which you referred in your December 14, 2012 letter, identification of the FDA software system you allege uses your ideas, and identification of the individuals with whom you were communicating at FDA about those patents.[3] On February 22, 2013, Ms. Dickinson sent you a second letter again requesting the information previously requested on January 28, 2013.[4]

On February 25, 2013, you emailed and faxed Ms. Dickinson's office a letter dated February 12, 2013, explaining that you had faxed this letter to the office previously on February 12, 2013.[5] In this letter you referenced the FDA Food Defense Plan Builder (FDPB), which you claim duplicates your "FoodDefenseTQ"/"Food Defense Architect" tool, and FDA FREE-B, which you claim duplicates your "FREE" and "FEAST" tools. You also referenced U.S. Patent No. 8,103,601 and claimed that FDA had infringed its claims.

On February 28, 2013, Ariel Seeley, an attorney in FDA's Office of Chief Counsel, responded to you by email, noting the allegations referenced above.[6] Ms. Seeley stated that "[i]n order for us to evaluate these claims, we would need to compare your products to ours. Accordingly, please provide us with copies of your Food DefenseTQ tool and the FREE and FEAST software tools, in whatever form you think would be convenient for this purpose."

On March 2, 2013, you emailed Ms. Seeley.[7] In this email you requested that FDA sign a non-disclosure agreement before you would share your software tools with FDA, and you included a draft agreement. You also added a new claim that FDA's iRISK tool "duplicates" your "Food Mapper" tool.

On March 8, 2013, you emailed Ms. Seeley.[8] In this email you sought a status update and also added new claims that the FDA Food Protection Plan "duplicates" your "CSM Method" and that the FDA Food Defense Mitigation Strategies Database "duplicates" your "POISON," "FoodDefenseTQ," "Food Safety Architect," "Food Defense Architect," and "Food Mapper" tools.

On March 11, 2013, you emailed Ms. Seeley asking her to contact you. Ms. Seeley emailed you back the same day indicating that she would get back to you later in the week.[9]

On March 13, 2013 you emailed Ms. Seeley, repeating your claims, adding another FDA tool you suggest

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[3] Exhibit 3: January 28, 2013 letter from Elizabeth Dickinson to John Hnatio.
[4] Exhibit 4: February 22, 2013 letter from Elizabeth Dickinson to John Hnatio.
[5] Exhibit 5: February 25, 2013 email from John Hnatio to Mark Raza, attaching February 12, 2012 fax from John Hnatio to Elizabeth Dickinson.
[6] Exhibit 6: February 28, 2013 email from Ariel Seeley to John Hnatio.
[7] Exhibit 7: March 2, 2013 email from John Hnatio to Ariel Seeley.
[8] Exhibit 8: March 8, 2013 email from John Hnatio to Ariel Seeley.
[9] Exhibit 9: March 11, 2013 12:06 PM email from John Hnatio to Ariel Seeley; March 11, 2013 12:22 PM email from Ariel Seeley to John Hnatio.

may copy some of your technology (FDA EMS), and seeking a status update.[10] In this email you also referenced the FAIR Act and OMB Circular A-76.

Later in the day on March 13, 2013, Ms. Seeley emailed you, and attached a revised non-disclosure agreement signed by Ms. Dickinson on behalf of FDA and repeated, for clarity, that FDA was only requesting nonexclusive access to the tools that you claim were infringed in order to evaluate your concerns.[11]

Later the same day, you responded to Ms. Seeley, questioning why FDA was only requesting nonexclusive access to your software tools that were at issue.[12]

On March 14, 2013, Ms. Seeley emailed you, explaining that the information you had already provided about your patent was sufficient for the time being, and that her request was limited to the tools at issue because she needed to evaluate your claims (which appeared to be largely based on a claim of copyright infringement) by comparing your products to FDA's products.[13]

Later on March 14, 2013, you emailed Ms. Seeley with requested changes to the non-disclosure agreement.[14] You also repeated your earlier questions and noted that you could not afford legal counsel.

On March 22, 2013, Ms. Seeley emailed you and introduced me, an intellectual property attorney in the HHS Office of General Counsel. She indicated that I had been provided with background information and materials.[15] In response to your repeated questions and your statement that you could not afford legal counsel, Ms. Seeley recommended that you consult with an attorney and noted that there are organizations that provide free or low-cost legal services to people who cannot otherwise afford legal representation.

On March 27, 2013, I emailed you, stating that I needed to compare FDA's tools to your tools to evaluate your claims of "duplication," that I needed a copy of your tools to do this, and I included a revised copy of the non-disclosure agreement accepting some, but not all, of your changes.[16] I also listed information that we would need to evaluate your patent infringement claim.

On March 28, 2013, you responded and, ignoring the fact that you have made serious accusations of patent and copyright infringement against this Agency, complained that we had "turned this matter into an adversary legal defense."[17] Furthermore, after insisting that you could not provide us with copies of the works that we allegedly infringed without a non-disclosure agreement, you rejected the latest version of the revised non-disclosure agreement apparently because you were unhappy with a statement of its "purpose." In this letter, you expressed your expectation that FDA must provide you with certain information about FDA's tools in exchange for receiving access to your tools to evaluate your claims of "duplication."

At this point we reached an impasse. Attorneys in the Office of General Counsel had repeatedly explained that we needed access to your tools to evaluate whether FDA's tools in fact have any similarity to them, but you refused to provide access to those tools without receiving a contractual commitment to

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[10] Exhibit 10: March 13, 2013 11:36 AM email from John Hnatio to Ariel Seeley.
[11] Exhibit 11: March 13, 2013 4:05 PM email from Ariel Seeley to John Hnatio.
[12] Exhibit 12: March 13, 2013 4:17 PM email from John Hnatio to Ariel Seeley.
[13] Exhibit 12: March 14, 2013 9:31 AM email from Ariel Seeley to John Hnatio.
[14] Exhibit 12: March 14, 2013 10:53 AM email from John Hnatio to Ariel Seeley.
[15] Exhibit 13: March 22, 2013 email from Ariel Seeley to John Hnatio.
[16] Exhibit 14: March 27, 2013 email from Dale Berkley to John Hnatio.
[17] Exhibit 15: March 28, 2013 email from John Hnatio to Dale Berkley.

an unspecified disclosure of FDA information. This was an unreasonable request and not something that FDA was prepared to do. FDA was willing to sign a standard non-disclosure agreement for the limited purpose of receiving and reviewing your software tools in response to your allegations. However, every reasonable version of the agreement was rejected by you based on some minor pretense. Thus, we have conducted an investigation of your complaints using the limited information you did provide, and in this letter we summarize the results of that investigation.

At various times during and after the communications described above, you contacted others about your claims, including the Small Business Administration (SBA)[18], the Secretary of the Department of Health and Human Services[19], the President of the United States[20], and the FDA Ombudsman[21]. Because your March 19, 2013 email to the SBA contained the most detailed statement of your allegations, this response focuses primarily on your allegations as described in that email.[22]

FDA's Food Defense Documents and Tools

In May 2007, the Secretary of HHS and the Commissioner of FDA charged FDA to develop a comprehensive food protection plan to keep the nation's food supply safe from both unintentional and deliberate hazards and counter them before they do harm. In response, FDA developed and released the FDA Food Protection Plan in November 2007. The plan addresses both food safety and food defense for domestic and imported products. The plan operates through integrated strategies that: focus on risks over a products life cycle from production to consumption; target resources to achieve maximum risk reduction; address both unintentional and deliberate contamination; and use science and modern technology systems. The Food Protection Plan is available for free on FDA's website.[23]

In February 2011, FDA began development of the Food Defense Plan Builder through a contract with Battelle Memorial Institute. FDA planned for this tool to combine its other food defense tools (then under development, at various stages of completion) into one user-friendly program that food companies could use to develop food defense plans specific to their operations, drawing on other FDA preexisting sources of information and guidance. The Food Defense Plan Builder has not yet been released on the FDA website.

In March 2011, FDA released the FDA Mitigations Database to the public. This tool is a database that provides a range of preventive measures that companies may choose to better protect their facility, personnel, and operations. Safety measures in the database are specific to individual categories that impact every step of the food production and distribution process. The database is available for free on FDA's website.[24] The development of FDA's Mitigation Strategies Database began in 2006.

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[18] Exhibit 16: March 16, 2013 email from John Hnatio to Elizabeth Dickinson, CCing Elahe Zahirieh, Office of the SBA Ombudsman; March 19, 2013 10:38 AM email from John Hnatio to Elahe Zahirieh; March 19, 2013 4:05 PM email from John Hnatio to Elahe Zahirieh; March 22, 2013 email from John Hnatio to Elahe Zahirieh; April 15, 2013 letter from John Hnatio to Yolanda Swift.

[19] Exhibit 1: April 1, 2013 letter from John Hnatio to Kathleen Sebelius, Secretary of the Department of Health and Human Services; Exhibit 17: April 19, 2013 letter from John Hnatio to Kathleen Sebelius (with cover letter dated April 20 to Nancy Gunderson).

[20] Exhibit 18: April 1, 2013 letter from John Hnatio to Barack Obama, President of the United States.

[21] Exhibit 19: April 18, 2013 email from John Hnatio to Laurie Lenkel, FDA Ombudsman.

[22] Specifically, this response focuses on the email attachment in Exhibits 16 with the file name "Summary report for Ms. Dickinson" and document title "SBA Ombudsman Case No. 1303150001." This document will be cited in this letter as "Exhibit 16: SBA Ombudsman Case No. 1303150001."

[23] Exhibit 20: print out of http://www.fda.gov/Food/GuidanceRegulation/FoodProtectionPlan2007/default.htm

[24] Exhibit 21: print out of http://www.accessdata.fda.gov/scripts/fooddefensemitigationstrategies/

In July 2011, FDA publicly released its FREE-B tool.[25] The tool is available for free on FDA's website.[26] The tool is a compilation of scenarios based on intentional and unintentional food contamination events, and was designed with the intention of assisting government regulatory and public health agencies in assessing existing food emergency response plans, protocols and procedures that may be in place, or may be in the process of revising or developing. FDA developed FREE-B in cooperation with the Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS). Development of FREE-B began in 2007.

We note that, as discussed below, FDA's Food Defense Team's first contact with you occurred when you emailed Don Kautter and Jody Menikheim to introduce yourself on December 23, 2011, and the team's first and only in-person meeting with you occurred on February 2, 2012.

On October 4, 2012, FDA publicly released its "iRisk" tool.[27] The tool is available for free online.[28] FDA-iRisk is a web based system that can be used to compare and rank (1) estimated risks from multiple microbial or chemical food safety hazards and (2) estimated effectiveness of various changes to specific steps of a food's farm-to-table pathway. FDA began developing FDA-iRisk in 2006.

Facts and Allegations

You claim that your first contact with FDA was in a meeting with Drs. Juliana Ruzante, Robert Buchanan, and Leanne Jackson at the Joint Institute of Safety and Nutrition (JIFSAN). You claim that during this meeting you submitted a "detailed proposal describing the patent, scientific breakthroughs, technology tools, and business plans for creating a safer food supply."[29] JIFSAN is partially supported through a collaborative agreement between FDA's Centers for Food Safety and Nutrition and Veterinary Medicine and the University of Maryland at College Park; however, FDA and JIFSAN are separate entities. No one from FDA attended or has records of this meeting. Dr. Leanne Jackson is an FDA employee, but she was not present at this meeting, nor did she have any other interaction with you or your companies in 2009. Drs. Ruzante and Buchanan of JIFSAN do recall attending this meeting; however, they recall that your company did not share detailed information during the meeting. Instead, according to Dr. Buchanan, your company requested a meeting with JIFSAN, shared a general prospectus for a project you wanted to pursue, and explored the possibility of working collaboratively with JIFSAN. JIFSAN indicates that it declined your offer and did not establish any formal or financial relationship with your company after this meeting. JIFSAN has no written materials from this meeting and, to the best of our knowledge, shared no information from this meeting with FDA.

You claim that in 2010 you "closely coordinated the results of [a] simulation [you conducted for a private company] and the methodology [you] used with Dr. Reginald Bennet [sic] and other officials at the FDA in order to prompt the development of specific laboratory and field tests that would detect the deadly agent."[30] Dr. Bennett is an FDA employee. Dr. Bennett has no knowledge of you or of ThoughtQuest LLC, and no memory or documentation of this alleged interaction.

You claim that "in June 2011, Mr. Menikheim, a senior member of the FDA food defense team, and his food defense staff were given a comprehensive briefing and demonstration of the entire suite of ThoughtQuest LLC software tools that were being commercially sold or under development for

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[25] Exhibit 22: Press Release July 20, 2011, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm263213.htm.
[26] Exhibit 23: print out of http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295902.htm.
[27] Exhibit 24: Fact sheet: FDA-iRisk, food safety modeling tool, http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM316705.pdf.
[28] Exhibit 25: print out of https://irisk.foodrisk.org/.
[29] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 3.
[30] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 4-5.

commercial sale. The presentation included a demonstration of the Food Response and Emergency Evaluation (FREE) tool and the Food Event Analysis and Evaluation (FEAST) tools. Over the coming months, the company maintained close contact with Mr. Menkheim [sic] to give him periodic updates on their progress."[31] FDA has no record of such a briefing and Mr. Menikheim has no memory of such a briefing, or of contact following up on such a briefing. In fact, the first record of your contact with FDA's Food Defense Team that we are aware of occurred six months later, as documented in an email you sent to FDA on December 23, 2011.

On December 23, 2011, you emailed Don Kautter and Jody Menikheim to introduce yourself, your company, and your tools, and to request a meeting to share the tools with and obtain guidance from FDA.[32] In that email you stated, "Don & Jody: We received you [sic] names from Jenny Scott who suggested that we contact you." Jenny Scott is an FDA employee. Ms. Scott recalls stopping by your company's booth at a conference and being shown a demonstration of your company's work. Because your company's work was relevant to an area covered by others at FDA, Ms. Scott referred your company to FDA's Food Defense Team, specifically to Mr. Kautter and Mr. Menikheim. You attached three documents to your December 23, 2011 email. In the email and its attachments, you describe your product "FoodProtectionTQ" as consisting of six tools (POISON, Food Mapper, FoodDefenseTQ, FoodSafetyTQ, FEAST, and FREE), each of which you described only in general terms. FDA's Food Defense Team has no record of interaction with you or your companies prior to this email.

On January 11, 2012 you emailed Mr. Kautter and Mr. Menikheim, following up on your December 23, 2011 request for a meeting.[33] On January 17, 2012 you emailed Mr. Menikheim, referring to a phone call you received from him and stating "thank-you for your guidance on how best to proceed... look forward to the possibility of talking with you."[34] On January 23, 2012 you emailed Mr. Menikheim again seeking a meeting date.[35] On January 24, 2012, Mr. Menikheim emailed you, agreeing to the requested meeting but stating that FDA would not be able to provide you with any guidance.[36] After emails agreeing on February 2, 2012 as the meeting date,[37] you emailed Mr. Menikheim on February 1, 2012 attaching a slide show for the upcoming meeting.[38] The slide show describes the same six tools as the documents you provided the FDA Food Defense Team in your December 23, 2011 email. The slide show contains different information from the December 2011 documents, but the descriptions of your tools in the slide show were general and high-level in nature and did not include specific questions or items, and merely included references to broad subject matter categories, like "emergency drills" and "loss of power."

According to your email of February 1, 2012, you planned to quickly review the power point slides and demonstrate your tools.[39] On February 2, 2012, Mr. Menikheim and other members of the FDA Food Defense Team, specifically Julia Guenther and Mike Dixon, met with you, Dave Park, and Bart Michelson from your company, and Bill Wright from MRI Global (a company you described as doing certain work related to your tools). Mr. Menikheim's recollection of the meeting is that you gave an overview of your tools using the slides you sent on February 1, 2012, and then the group moved to the

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[31] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 5.
[32] Exhibit 26: December 23, 2011 email from John Hnatio to Donald Kautter and Jody Menikheim, with attachments "Briefing Book: Executive Summary," "Briefing Book: The Need," "Briefing Book: The Solution" all dated December 2011.
[33] Exhibit 26: January 11, 2012 email from John Hnatio to Don Kautter and Jody Menikheim.
[34] Exhibit 27: January 17, 2012 email from John Hnatio to Jody Menikheim.
[35] Exhibit 27: January 23, 2012 email from John Hnatio to Jody Menikheim.
[36] Exhibit 27: January 24, 2012 9:22 AM email from Jody Menikheim to John Hnatio.
[37] Exhibit 27: January 24, 2012 2:05 PM email from John Hnatio to Jody Menikheim; January 26, 2012 email from Jody Menikheim to John Hnatio.
[38] Exhibit 27: February 1, 2012 email from John Hnatio to Jody Menikheim, with attachment "FDA Briefing Book: Food DefenseTQ" dated February 2012.
[39] Exhibit 27: February 1, 2012 email from John Hnatio to Jody Menikheim, with attachment "FDA Briefing Book: Food DefenseTQ" dated February 2012.

Center for Food Safety and Nutrition (CFSAN) café so that you could briefly demonstrate the tools using a public Wi-Fi network on your laptop. The entire meeting took approximately one hour. The only materials you provided for FDA to keep were the slides you sent on February 1, 2012.

FDA did not share these documents outside of the agency, did not share these documents with its contractors working on the Food Defense Plan Builder, and did not use these documents to duplicate or copy your tools. Any material that you may have displayed in the CFSAN café beyond the February 1, 2012 slides was eyes-only, and we have no evidence that whatever may have been briefly displayed was incorporated into an FDA product.

Based on a review of the February 1, 2012 slides, the "Food DefenseTQ" software described in those slides apparently implements the methods described in U.S. Patent No. 8,103,601.[40] The slides describe an algorithm that purports to account for the degree of vulnerability of a "target," the potential worst case consequences of an adverse food safety event, and factors that could mitigate the consequences of an adverse event. The objective is apparently to determine a probability of occurrence of any particular adverse event.

There is no evidence that any analysis of the kind described in the slides or in U.S. Patent No. 8,103,601 was used to develop the FDA products like FDA's FDPB. While FDA's FDPB is obviously the subject of careful consideration of the potential vulnerabilities that an organization might face from any number of threats, its core is essentially a well-organized checklist of questions and issues that an organization should address to minimize threats. The methods claimed in the patent, on the other hand, offer one very distinct and purportedly sophisticated technique for determining the probability that certain adverse scenarios or events would occur, and there is no suggestion from anything in the record that determining such probability in this way was a part of the FDA process for developing its FDPB tool.

Between July 25, 2012, and September 25, 2012, you exchanged emails and phone calls with Mr. Menikheim.[41] In these communications you requested another meeting with FDA to demonstrate your tools and seek guidance from FDA, and Mr. Menikheim agreed to a webinar on October 2, 2012. You claim that in mid-September 2012, your company learned that "FDA had been working with Battelle Memorial Institute to build their own food defense tool to compete directly with the FoodQuestTQ LLC's existing Food DefenseTQ product. This situation prompted [you] to call Mr. Menkheim [sic] to express [your] concerns that FDA was developing a product that already existed."[42] You also claim that in late September 2012, you had another phone call with Mr. Menikheim in which you "asked him specifically about the nature and purpose of an upcoming FDA sponsored workshop on FDA's new food defense plan builder tool scheduled to be held on December 12, 2012."[43]

Mr. Menikheim does not recall either of these alleged calls, and FDA has no records relating or referring to such calls. To the contrary, in your emails in September 2012, you did not express concern about FDA's Food Defense Plan Builder and proceeded to work on scheduling another meeting with FDA to

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[40] Exhibit 27: February 1, 2012 email from John Hnatio to Jody Menikheim, with attachment "FDA Briefing Book: Food DefenseTQ" dated February 2012.

[41] Exhibit 28: July 25, 2012 5:16 PM email from John Hnatio to Jody Menikheim; July 25, 2012 5:42 PM email from Jody Menikheim to John Hnatio; August 10, 2012 email from John Hnatio to Jody Menikheim; August 20, 2012 email from John Hnatio to Jody Menikheim; August 21, 2012 email from Jody Menikheim to John Hnatio; August 22, 2012 7:57 AM email from John Hnatio to Jody Menikheim; August 22, 2012 11:30 AM email from Jody Menikheim to John Hnatio; September 6, 2012 email from John Hnatio to Jody Menikheim; September 25, 2012 1:54 PM email from John Hnatio to Jody Menikheim; September 25, 2012 4:50 PM email from Jody Menikheim to John Hnatio; September 25, 2012 5:05 PM email from John Hnatio to Jody Menikheim; September 25, 2012 5:12 PM email from Jody Menikheim to John Hnatio.

[42] Exhibit 16: SBA Ombudsman Case No. 1303150001, pp. 5-6.

[43] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 6.

demonstrate your company's products. On October 1, 2012, you emailed Mr. Menikheim and Ms. Jackson and attached a short, outline-format description of the software tools you intended to demonstrate at the next day's webinar ("Food Defense Architect," "Food DefenseTQ," "Food Mapper," "Poison," " FEAST," and "FREE Tool").[44]

You held a webinar for Mr. Menikheim and other members of the FDA Food Defense Team, specifically Julia Guenther, Michael Dixon, Wendy Buckler, and Jon Woody, on October 2, 2012 to demonstrate your software tools.[45] The only material you provided for FDA to keep was the short outline sent to FDA on October 1, 2012. You claim that in addition to presenting your tools, you raised concerns that FDA was building a food defense planner tool that would compete with FTQTQ's Food DefenseTQ and Food Architect products during the webinar; and thus, you offered FDA a license to use your companies' technology for $1 /year.[46] According to those at FDA who attended the meeting, the webinar included an update on the status of your tools, and you asked Mr. Menikheim if FDA was developing a food defense plan tool. Mr. Menikheim informed you that FDA was in the process of developing a tool (the FDPB) that would combine all of FDA's existing food defense tools into one tool. You did offer FDA a S 1 /year license of your technology to FDA, but Mr. Menikheim said that he was not in a position to accept such an offer.

On November 15, 2012, Warren Stone of the Grocery Manufacturers Association (GMA) emailed members of its Food Defense Committee and other interested industry professionals to invite them to a focus group meeting to test FDA's Food Defense Plan Builder.[47] This email stated the purpose of the meeting: "To ensure that the tool is user-friendly and in line with industry needs, FDA is seeking feedback from industry members in this upcoming focus group." Bruce Becker, an employee of your company FoodQuestTQ, was on the CC list for this email.

Between November 16, 2012 and November 27, 2012, you repeatedly emailed Colin Barthel, an employee of Batelle Memorial Institute listed as a contact in Warren Stone's November 15, 2012 email.[48] In these emails you asked to speak with Mr. Barthel "to give [Mr. Barthel] a short pre-demo of what we will be presenting to the industry at the meeting on a webinar," referencing your "Food Defense Architect."[49] On November 27, 2012, Mr. Barthel responded by email and informed you that he could not speak about this project without written permission from FDA, and that the GMA meeting "is a focus group feedback session."[50] As far as we are aware, this is the only contact you and your companies had with the contractors assisting in the development of FDA's Food Defense Plan Builder tool.

After your correspondence with Mr. Barthel, Mr. Menikheim became aware that you intended to give a presentation of your own tools to the focus group. Mr. Menikheim was concerned that it would be an inappropriate use of the focus group if you were allowed to use that time to give a presentation of your own tools. Mr. Menikheim spoke with Mr. Stone of GMA and asked that you be uninvited from participating in the focus group.

On December 11, 2012, you emailed Mr. Menikheim "to touch base before the session tomorrow,"

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[44] Exhibit 29: October 1, 2012 email from John Hnatio to Jody Menikheim and LeeAnne Jackson, with attachment titled "Food Defense ArchitectTM Specifications."

[45] Exhibit 30: October 2, 2012 1:14 PM email from John Hnatio to Jody Menikheim; October 2, 2012 1:16 PM email from Jody Menikheim to John Hnatio.

[46] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 6.

[47] Exhibit 31: November 15, 2012 email from Warren Stone to GMA-FoodDefenseInfo@lists.gmaonline.org.

[48] Exhibit 32: November 16, 2012 email from John Hnatio to Colin Barthel; November 20, 2012 10:35 AM email from John Hnatio to Colin Barthel; November 20, 2012 3:49 PM email from John Hnatio to Colin Barthel; November 27, 2012 email from John Hnatio to Colin Barthel.

[49] Exhibit 32: November 16, 2012 email from John Hnatio to Colin Barthel.

[50] Exhibit 32: November 27, 2012 email from Colin Barthel to John Hnatio.

attaching a document titled "Managing Food Defense Risk" dated December 2012.[51] Later in the day after your email on December 11, 2012, Mr. Menikheim emailed Mr. Stone and asked when you would be presenting to the group, and stated "I just want to make sure that ThoughtQuest will not be attending our focus group."[52] Mr. Stone responded that you would be presenting at 4:30 pm, which was the time the FDA focus group was scheduled to end.[53] Mr. Menikheim reiterated that he did not want you participating in or attending the FDA focus group, but that "I do not have any issue with Bruce or anyone from ThoughtQuest presenting to your group before or after our focus group."[54] Mr. Stone responded, "Sorry about the mix up too. I'll take care of it."[55] FDA does not have any record of how Mr. Stone or GMA communicated this message to you. According to your letter to the SBA, you presented your tools to the focus group after FDA left the building.[56]

Your Claims

First, for a copyright infringement claim to lie, the infringer must have had access to the work that is infringed, and the infringing work must be found to be substantially similar to the infringed work. You have provided no evidence that FDA or its contractors had access to any of the works allegedly infringed. Because you have refused to provide us with copies of the allegedly infringed work, there is no way for us to determine whether the agency's works are substantially similar to yours.

Second, with respect to your claims of infringement of U.S. Patent No. 8,103,601, in order to infringe a patent the infringer must practice each and every step of the patent claim. Claim 10 of the patent is representative.[57]

In order to infringe Claim 10, one must practice four highly complex and specific steps, which we paraphrase for simplicity here:

(a) Defining fundamental elements which control a complex adaptive system.
(b) Assigning a plurality of sets of initial values.
(c) Determining which of a set of features are directly related to the fundamental elements for each of the initial conditions
(d) Measuring an effect of each one of the sets of initial conditions of each respective one of said developed plurality of scenarios on said ones of said plurality of features most directly related to said fundamental elements to generate sets of data functionally related to the likelihood of a particular occurrence in said complex adaptive system.

There is no evidence that FDA personnel or their contractors practiced even one of these steps, let alone all of them, as would be required for a claim of patent infringement.

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[51] Exhibit 33: December 11, 2012 4:41 PM email from John Hnatio to Jody Menikheim.
[52] Exhibit 34: December 11, 2012 6:31 PM email from Jody Menikheim to Warren Stone.
[53] Exhibit 34: December 11, 2012 7:06 PM email from Warren Stone to Jody Menikheim.
[54] Exhibit 34: December 11, 2012 9:33 PM email from Jody Menikheim to Warren Stone.
[55] Exhibit 34: December 11, 2012 9:53 PM email from Warren Stone to Jody Menikheim.
[56] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 8.
[57] Claim 10. A method of increasing the likelihood of behavior of a complex adaptive system, comprising the steps: defining fundamental elements which control the functioning of the complex adaptive system; assigning a plurality of sets of initial values at a respective plurality of times to a plurality of features of the complex adaptive system; determining which ones of said plurality of features of the complex adaptive system are most directly related to said fundamental elements for each of said plurality of sets of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system; measuring an effect of each one of said plurality of sets of initial conditions of each respective one of said developed plurality of scenarios on said ones of said plurality of features most directly related to said fundamental elements to generate sets of data functionally related to the likelihood of a particular occurrence in said complex adaptive system.

Third, you allege that "the government is precluded under the FAIR Act from competing with the private sector whenever the same or better products can be procured from industry."[58] This is not what the FAIR Act does. Rather, the FAIR Act requires the head of each executive agency to 'submit to the Director of the Office of Management and Budget a list of activities performed by Federal Government sources for the executive agency that, in the judgment of the executive agency, are not inherently governmental functions.' Pub. L. No. 105-270, sec. 2. Based on our understanding of the complaint FoodQuestTC LLC has filed with the Office of Small Business Advocacy, FoodQuest's allegations do not appear to implicate the FAIR Act because, *inter alia*, there is no indication that your complaint takes issue with any inventory submitted by the FDA under the FAIR Act.

Similarly, you allege that "FDA actions in this case raise questions regarding the Agency's compliance with OMB Circular A-76 [because] this document (and other statutes) specifically restrict government agencies and federally funded research and development organizations such as Battelle Memorial Institute from directly competing with the private sector."[59] This too is incorrect. Even if your complaint were correct in alleging that the FDA has violated OMB Circular A-76, Section 5(g) of the Circular states that "Noncompliance with this Circular shall not be interpreted to create a substantive or procedural basis to challenge agency action or inaction, except as stated in Attachments A and B." OMB Circular A-76, Sec. 5(g)(May 29, 2003). Attachment A permits a challenge by an interested party within 30 days of publication in the Federal Register of the list of activities required under the FAIR Act noted above, while Attachment B permits a protest by a directly interested party when the Agency conducts a standard competition under Circular A-76. Because the FDA has not conducted such a competition for the services you have described, the Circular does not create any right or benefit enforceable at law by FoodQuestTC LLC against the United States or the FDA.

In spite of your unwillingness to cooperate, and your insistence on sending additional letters to different recipients rather than working with the counsel assigned to evaluate your claims, we have done our best to investigate your allegations, as much as we can understand them. We have uncovered no evidence that FDA or its contractors took or used any trade secrets that you might own. We have uncovered no evidence that FDA or its contractors infringed your patent or copyrighted works. We have uncovered no evidence that FDA or its contractors violated any statute in its dealings with you or your company. In light of the information that we have reviewed and in light of your failure to cooperate with our requests for necessary information to further evaluate your claims, we consider this matter closed.

Sincerely,

Dale D. Berkley, Ph.D., J.D.
HHS IP Counsel

Attachment: Exhibits

[58] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 10.
[59] Exhibit 16: SBA Ombudsman Case No. 1303150001, p. 10.