FoodQuestTQ

The TQ stands for threat quotient

UNFAIR COMPETITION BY THE FEDERAL GOVERNMENT WITH SMALL BUSINESS: THE FOOD AND DRUG ADMINISTRATION VERSUS FOODQUESTTQ LLC

This paper presents a case study involving our small company, FoodQuestTQ LLC. At FoodQuestTQ we build computer automated risk management tools for the food industry. The case study details the actions of the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) as they: 1) took and used our small company's intellectual property without permission; 2) spent taxpayer dollars to duplicate FoodQuestTQ's commercial products, and; 3) attempted to force our small company out of business. The case study presented here raises pressing questions about FDA overreach under the Food Safety and Modernization Act of 2011, and the emerging pattern of unfair competition by the federal government with small businesses across America. The paper concludes with ten recommendations to limit unfair competition by the federal government with small businesses.

FoodQuestTQ Technical Paper No. 8

May 2013

This document contains the views of FoodQuestTQ LLC, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). The case study presented here contains a wealth of information on the internal workings of federal bureaucracies when confronted with their own wrongdoing. As such, it can serve as a valuable learning tool in the teaching of ethics and procurement and intellectual property integrity in institutions of higher education, the federal government and the private sector. Institutions of higher education, the federal government and private sector organizations desiring to use this case study for learning purposes are welcome to do so free of charge. Please contact Mr. Bruce Becker at 540-645-1050 for permission to reproduce this document.

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Forward by the Author

We are a small business that builds computer risk management software for the food industry. Since 2009, we have been working with the Food and Drug Administration (FDA) to strengthen the protection of America's food supply. Our ideas and trade secrets are based on a patent that looks at risk in a new way.

Since 2009, we have invested several million dollars of our own money and angel investor capital to produce our new risk management software. Last fall, we learned that the FDA, under a contract with Battelle Memorial Institute used our ideas, trade secrets and our patent to duplicate our products.

The FDA is continuing to try and force us out of business. When we try to sell our tools to the food industry they ask us, "Why should we buy your products when we can get the same thing from the FDA for free? Besides it's the FDA that inspects us and we'd be stupid not to use the tools that they have officially endorsed."

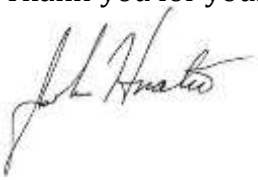
I am a 62 year old small business owner who has put his life savings into the start-up of our little company. I have had to lay off my employees. One of my business partners is a 70% disabled American veteran who risked everything he had to join our small company. All of us have now been forced onto the unemployment line as the result of unfair competition by the FDA.

The way the system works now the government can steal from small businesses with impunity. The only alternative left to a small business like FoodQuestTQ is to engage in a federal lawsuit that will cost millions of dollars and take years to settle. By that time a person like me will be dead and buried.

We need your support and would like to invite all of you to watch our You Tube presentation and sign our petition to strengthen the laws against unfair competition by the government against the millions of small businesses across America.

Please visit our You Tube link at: https://www.youtube.com/watch?v=xKHdJhGLQok and sign our petition. It only takes a minute to sign and it will help to keep the American dream of owning a small business alive.

Thank-you for your help,



John Hnatio
Small Business Owner
FoodQuestTQ LLC

Unfair Competition by the Federal Government with Small Business: The Food and Drug Administration versus FoodQuestTQ

Executive Summary

This report presents a case study of a small business, FoodQuestTQ LLC, which is being unfairly competed against by the Food and Drug Administration (FDA). The FDA is duplicating and publicly offering at no cost to the food industry similar products that were already being developed and commercially sold by the small company thus forcing it out of business. The report draws the following five major conclusions and ten recommendations based on a comprehensive analysis of the case study.

Conclusion	Recommendation(s)
C-1: Both the Department of Health and Human Services (HHS) and the FDA are suffering an unprecedented crisis in ethics.	R-1: Immediately require the legal counsels and all employees of HHS and FDA to re-new their oaths of government service to uphold the laws and Constitution of the United States.
	R-2: Conduct an immediate and independent review of ethical conduct and procurement integrity at both HHS and the FDA.
	R-3: Demand that the Office of Government Ethics (OGE) do its job in dealing with ethical breaches by federal agencies.
C-2: The Office of the National Ombudsman is powerless to prevent federal agencies from unfairly competing with small business.	R-4: Strengthen the powers of the National Ombudsman for Small Business to conduct investigations of federal agency wrongdoing and unfair government competition with small businesses.
C-3: Small businesses cannot rely on their government for help in preventing unfair competition by federal agencies.	R-5: Take the necessary steps to assure that officials in HHS and the FDA are responsive to the correspondence and inquiries of all American citizens, including the owners of small businesses.
C-4: The federal government can steal the intellectual property of small businesses with impunity.	R-6: Clarify and increase the penalties for government employees who steal the intellectual property of small businesses under Title 18, U.S.C.
	R-7: Establish an emergency hotline within the Office of the National Ombudsman for Small Business for small companies to anonymously report abuse by the federal government.
	R-8: Amend the Federal Activities Inventory (FAIR) Act [P.L. 105-270], to include specific requirements that each federal agency must conduct a "build-no build" determination based on the cost and commercial availability of the same or similar products by small business.
C-5: The federal government intentionally uses the law as a tactic to obfuscate simple realities to force small businesses into long and expensive litigation they cannot afford.	R-9: Create an independent arbiter to resolve intellectual property disputes involving small businesses as additional alternative to pursuing expensive and lengthy lawsuits in Federal District Court.
	R-10: Amend the Federal Activities Inventory (FAIR) Act [P.L. 105-270], to require that each federal agency conduct and document a "compete-no compete" determination with small business before initiating any acquisition or procurement action.

Figure 1: Summary of Conclusions and Recommendations

Timeline of Events

FoodQuestTQ is a small risk management and information technology company headquartered in Frederick, Maryland, that builds computer software for the food industry.

In the fall of 2012, FoodQuestTQ LLC learned that FDA was taking their ideas, business proprietary and trade secret information and infringing on their patent to duplicate FoodQuestTQ LLC's suite of commercial computer software products.

In October 2012, under extreme pressure to avoid direct competition with the FDA that would force them out of business, FoodQuestTQ offered the FDA a $1/yr. license for FDA employees to use their technology. FoodQuestTQ's reasoning was to offer the government their technology in the hope that the FDA would stop giving away duplicate products for free thus allowing the small company to continue to sell their products to the food industry. FDA officials did not respond the FoodQuestTQ LLC offer.

In January 2013, FoodQuestTQ requested that the FDA Chief Counsel conduct a good faith review of the matter. Instead, the FDA Chief Counsel mounted a legal defense of the FDA personnel who took the FoodQuestTQ owned intellectual property in the first place and duplicated the small company's products.

In March 2013, FoodQuestTQ filed a formal complaint with the National Ombudsman for Small Business to try and break the impasse. FoodQuestTQ's complaint was referred to the Office of the General Counsel in the Department of Health and Human Services (HHS).

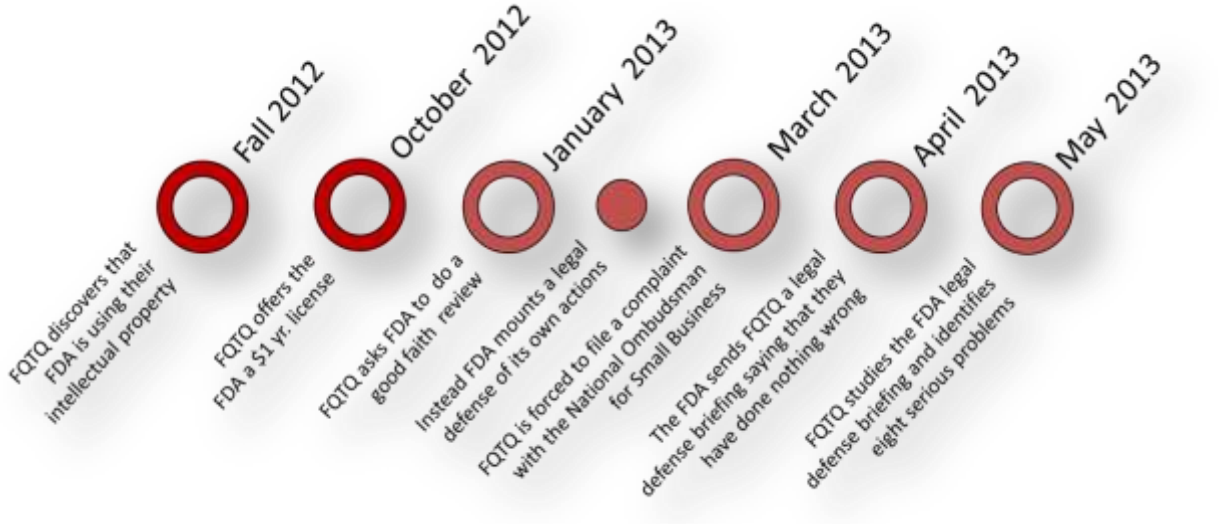


Figure 2: Timeline of Events

On April 26, 2013, FoodQuestTQ received a legal brief from the Office of General Counsel, HHS defending the actions of the FDA and their personnel as fully proper conduct that is allowable under the law.

As of May 2013, the FDA is still using FoodQuestTQ owned intellectual property without permission. The FDA continues to offer at no cost to the public food risk automated computer tools that are similar to the FoodQuestTQ applications. FoodQuestTQ is continuing their struggle to survive.

The Traditional Role of Small Business in the American Economy

Before the 1880's, thousands of small businesses handled virtually all of the production and distribution of goods and services in the American economy. It was in the middle of the nineteenth century that big businesses began to emerge in fields where new technologies permitted economies of scale in the production and/or distribution of goods. Many of these large companies arose from visionary small business entrepreneurs, people like Henry Ford and Thomas Edison. When large companies emerged, small business adjusted to remain the potent force in our economy that it remains today. By exploiting market niches, becoming intermediate suppliers of goods and services to larger firms and by constantly innovating, small businesses in America are still the mainstay of the modern American economy.[i]

Today, there are over 27.9 million small businesses, and 18,500 firms with 500 employees or more in the United States. Small firms accounted for 64 percent of the net new jobs created between 1993 and 2011 (or 11.8 million of the 18.5 million net new jobs). Since the latest recession, from mid-2009 to 2011, small firms, led by the larger ones in the category (20-499 employees), accounted for 67 percent of the net new jobs. Small businesses in the U.S. make up: 99.7 percent of U.S. employer firms; 64 percent of net new private-sector jobs; 49.2 percent of private-sector employment; 42.9 percent of private-sector payroll; 46 percent of private-sector output; 43 percent of high-tech employment; 98 percent of firms exporting goods, and; 33 percent of U.S. exporting value.[ii] Small businesses in America produce 13 to 14 times more patents per employee than do large firms.[iii] Small businesses' patents are twice as likely as those from the larger firms to be among the 1 percent most cited (that is; the most significant). Small businesses employ 39 percent of high-tech workers such as scientists; engineers; and information technology workers that generate the majority of innovations that come from U.S. companies.[iv]

The Growing Influence of the Federal Government

The Constitution of the United States places restrictions on the role of the federal government to a set of limited tasks with all other matters assigned to the states, local governments, and individual Americans. These tasks pertain mainly to protecting the security of the nation and ensuring "domestic tranquility," which means preserving public safety. Especially in the realm of domestic affairs, the founders intended very limited government interference in the daily lives of its citizens.[v]

Beginning with the administration of Franklin Roosevelt and the New Deal, the size of the federal government in the United States began to grow. Over the period from 1788 to 1952 eight cabinet departments were created. From 1953 to 2012, an additional eight federal cabinet departments have been established.[vi] Today, there are over 1,300 distinct organizations that comprise the federal government bureaucracy.[vii] Today, the U.S. government is the single largest employer of Americans.[viii] Fully two percent of America's working age population (2, 756,000 full time civilian workers) are directly on the federal payroll.[ix] But, the true influence of the federal government goes well beyond these large numbers to include a huge non-federal contractor workforce. Some estimates indicate that the true size of the federal government may be as high as 14.6 million employees.[x]

The activities of today's federal bureaucracy are as diverse as the growing size of the central government itself and extend to literally every aspect of an American citizen's life from birth until long after death. The federal government regulates the activities of industry, provides goods and services ranging from the development of computer software, to the design and construction of nuclear weapons and other military systems, to the development of new drugs, to the management of healthcare, the social security retirement system, burial services and a list of other activities too numerous to list. To support these varied activities of the federal government, the average American citizen will spend more in taxes in 2013 than they will spend on food, clothing, and housing combined.[xi]

The Case Study

FoodQuestTQ LLC is just one of the millions of small businesses in America trying to build a better mousetrap. The idea to create FoodQuestTQ had its beginnings over a decade ago when one of the company's founders was conducting his doctoral research. The subject of his research focused on the simple but powerful notion that preventing bad things before they happen is preferable to picking up the pieces after a disaster occurs. In June 2007, the United States Patent and Trademark Office (USPTO) granted him a pending patent for his ideas. In July 2012, the final patent was issued by USPTO.[xii]

With the events of 9-11 a matter of continuing concern to the nation, the company took their new ideas across the federal government. They tried to convince the federal bureaucracy that the new patent represented a revolutionary weapon in the war against terrorism by focusing in a scientific way on prevention before the fact rather than response after the damage has already been done. Federal agencies including the Departments of Defense, Homeland Security, Energy, Justice (including the Federal Bureau of Investigation), Agriculture, Health and Human Services (including the Food and Drug Administration) and others had no interest in his ideas.[xiii]

In October 2009, after being soundly rebuffed by the federal government, the inventor of the patent decided to start his own company. The new company would work directly with industry, versus the federal government, to help companies better manage the complex safety and security risks. Over the next two and half years, he invested everything he owned, borrowed $2.8 million dollars and built a suite of computer automated risk management tools to protect the food supply. He closely coordinated his work with the U.S.

Department of Agriculture and the Food and Drug Administration.[xiv] He did this to obtain inputs on the information needed by the federal government to perform their regulatory oversight of the food industry to include as part of the automated risk management tools his small business was building for the food industry.

In July of 2012, after a decade of development, FoodQuestTQ was finally ready to launch their small business by offering for commercial sale a suite of the most advanced software tools ever developed to manage the risks associated with the safety of the food supply. But this is when the unexpected began to happen.

Over the ensuing weeks FoodQuestTQ sales fell far short of even the most conservative projections. The lack of sales was at odds with prior detailed pre-launch market research indicating strong food industry demand for preventive risk management tools.[xv] Months earlier, on January 4, 2011, President Obama signed into law the Food Safety Modernization Act [Public Law 111-353]. According to the Food and Drug Administration itself, The Food Safety Modernization Act (FSMA), "… aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it."[xvi]

In September 2012, FoodQuestTQ LLC became aware that the Food and Drug Administration was building their own computer automated tool under a multi-million dollar contract with Battelle Memorial Institute to help the food industry build food defense plans. It quickly became clear that the FDA took FoodQuestTQ's intellectual property and trade secrets to duplicate a FoodQuestTQ computer software tool developed for the same purpose. The duplication of FoodQuestTQ's computer software for building food defense plans by the FDA was subsequently confirmed by several food companies during FoodQuestTQ marketing presentations.[xvii]

Never expecting that the government would go into direct competition with them FoodQuestTQ was caught completely by surprise. FoodQuestTQ then conducted a comprehensive review of the entire FDA government website. The review disclosed that the FDA, unbeknownst to FoodQuestTQ, had stolen FoodQuestTQ's patented ideas, the trade secrets they developed as they reduced their patented ideas to practice and other business confidential information to develop their agency strategy for food protection and duplicate FoodQuestTQ's entire suite of food risk management tools.[xviii]

In late October 2012, under intense pressure to avoid direct competition with the FDA that would put them out of business, FoodQuestTQ offered the FDA a $1/yr. license for their employees to use FoodQuestTQ's technology. FoodQuestTQ's Board of Directors, which includes several of the major investors in the business, hoped that such an arrangement would allow the company to stay in business. FoodQuestTQ' s reasoning was to offer the government their technology in the hope that the FDA would stop giving away duplicate products for free thus allowing the small company to continue to sell their products to the food industry. But the FDA never responded to FoodQuestTQ offer.[xix]

By December 2012, with sales failing to meet projections for FoodQuestTQ LLC's suite of food risk management tools, the company was forced to lay off all of their employees including the two founders of the company. Without pay, FoodQuestTQ LLC principals continued to try and keep their small business alive.

On December 6, 2012, FoodQuestTQ published an article on a vulnerability assessment tool being developed and marketed by the FDA to the food industry under an $114,801,090 dollar Agency line item in the FY 2012 budget.[xx] The FoodQuestTQ article presented a critical technical appraisal of the FDA assessment tool called C.A.R.V.E.R. plus Shock.[xxi] The FoodQuestTQ article received significant attention by the FDA Food Defense Team and was opened and/or distributed both inside and outside of the Agency at least 40 times.[xxii]

A few days later, on December 12, 2012, FoodQuestTQ was unexpectedly disinvited from an industry workshop being held by the FDA. The purpose of the FDA workshop was to solicit industry inputs on the new FDA computer automated tool for building food defense plans. FoodQuestTQ's participation in the workshop was scheduled weeks beforehand and included a demonstration of the company's own commercial food defense planning tool.

The FDA later stated that they prohibited FoodQuestTQ participation in the workshop for two reasons. First, that participation in the workshop was strictly limited to food processors. The second reason was that FDA did not want to give the appearance of the Agency endorsing FoodQuestTQ's commercial product.[xxiii]

But the official sign in sheet for the attendees at the December 12, 2012, FDA sponsored workshop includes the names of several companies who are not food processors.[xxiv] One of these companies was a direct competitor of FoodQuestTQ that sells food risk computer automated software to the food industry.[xxv] The FDA has publicly endorsed this company's products.[xxvi]

Letter(s)	Date(s)	Response		Comments
		Yes	No	
Secretary Kathleen Sebellius, HHS	4-1-2013		X	FoodQuestTQ LLC requests to meet with Secretary Sebellius to resolve the matter; no response
	4-19-2013		X	Secretary Sebellius has the office of General Counsel to reply with April 26, 2013 HHS legal defense brief stating that there has been no wrongdoing; no response to FoodQuestTQ' s request to meet
	5-1-2013		X	FoodQuestTQ LLC requests to meet with Secretary Sebellius to resolve the matter; no response
DASGAPA Nancy Gunderson, HHS	4-20-2013		X	Request for Ms. Gunderson to hand-carry FoodQuestTQ correspondence and speak directly with Secretary Sebellius
Commissioner Margaret Hamburg, FDA	4-22-2013		X	FoodQuestTQ LLC requests to meet with Commissioner Hamburg to resolve the matter; no response
Chief Counsel Elizabeth Dickinson, FDA	2-12-2013 3-16-2013		X	Numerous correspondence and e-mails with Ms. Dickinson and her legal staff; no response to FoodQuestTQ requests to meet with Ms. Dickinson to resolve the matter
Director, Office of Government Ethics, William Straub	4-20-2013		X	FoodQuestTQ letter informs Director Straub that there is a crisis in ethics at HHS and FDA and requests that he review the matter; Mr. Straub never responds

Figure 3: Summary of Executive Branch Communications in FoodQuestTQ Matter

Over the ensuing weeks FoodQuestTQ wrote letters to the Secretary Sebelius, Department of Health and Human Services (HHS); the Office of the General Counsel, HHS; Commissioner Hamburg at the FDA, the FDA Office of Chief Counsel; the FDA Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability, Ms. Nancy Gunderson, and the Director of the Office of Government Ethics, Mr. William Straub.

As depicted in Figure 3, above, in all cases, FoodQuestTQ pleas for a meeting to resolve the issues were rebuffed while the situation was allowed to escalate. Instead of conducting a fair and impartial review to resolve the matter, the Office of the Chief Counsel FDA, followed in short order by the Office of the General Counsel, HHS, took the lead and mounted a legal defense of the two agencies and the FDA personnel who were guilty of the wrongdoing in the first place.[xxvii]

Faced with this impasse, FoodQuestTQ LLC had no option but to file a complaint with the Office of the National Ombudsman for Small Business of the Small Business Administration. In their complaint, FoodQuestTQ LLC reiterated their concerns that the FDA was unfairly competing against FoodQuestTQ LLC by publicly offering at no cost to the food industry the same or similar products that were already being commercially sold by FoodQuestTQ LLC thus forcing the small company out of business. [xxviii]

Following FoodQuestTQ's complaint to the National Ombudsman the entire matter was then elevated to the Office of the General Counsel, Department of Health and Human Services (HHS), for review. HHS legal counsel, like FDA counsel, continued to defend the Agency's actions rather than conduct a fair and impartial review of the matter.

On April 26, 2013, FoodQuestTQ LLC received a legal brief from the Office of General Counsel HHS defending the actions of the FDA and their personnel as fully proper conduct that is allowable under the law.[xxix] A copy of this document appears at Appendix 1.

An analysis of the HHS legal defense brief highlights eight of the most egregious concerns raised by the FDA report. The next sections of this paper review in more detail each of the eight concerns that arise from a comprehensive review of the HHS legal defense brief. A summary of the concerns raised by the HHS legal defense brief of the FDA appears as Figure 4, below.

Concern 1: The HHS Legal Defense Brief is fundamentally flawed by a conflict of interest

The case study demonstrates that Office of the FDA Chief Counsel and the HHS Office of General Counsel engaged in a conflict of interest in their handling of the FoodQuestTQ matter. The HHS legal defense brief is tainted by feelings of personal animus toward the FoodQuestTQ LLC, the loyalty of government counsel to HHS and the FDA organization and his desire to protect his government friends and colleagues. Thus, at the outset, the HHS legal defense brief is fundamentally flawed.

Concern 2: The HHS Legal Defense Brief raises the potential of obstruction of justice

The manner by which HHS conducted their inquiry into this matter goes beyond the serious conflict of interest that has occurred in this case to include possible obstruction of

justice. The HHS legal defense brief suggests that the FDA employees questioned during the inquiry were not truthful. The HHS legal defense brief also demonstrates that the Office

Issue of Concern	Descriptive Summary
1. The HHS legal defense brief is fundamentally flawed by a conflict of interest.	The HHS legal defense brief is tainted by the conflict of interest created when HHS counsel allowed his feelings of personal animus toward FoodQuestTQ LLC, loyalty to his own organization and the desire to protect his FDA friends and colleagues to cloud an objective and impartial inquiry into the FoodQuestTQ matter.
2. The HHS legal defense brief raises the potential of obstruction of justice.	The HHS legal defense brief suggests that the FDA employees questioned during the inquiry were not truthful.
	The Office of General Counsel HHS used means and methods to conduct their inquiry into the FoodQuestTQ matter that have befouled future attempts to achieve a fair and impartial resolution of this case.
3. The HHS legal defense brief intentionally obfuscates simple realities.	The reality of the FoodQuestTQ LLC matter is very simple. The small company is being forced out of business by the FDA's duplication of the company's commercial line of food risk management tools.
4. The HHS legal defense brief misinterprets federal procurement law.	The HHS characterizations of the FAIR Act, the implementing provisions OMB Circular A-76, and the FARs misinterpret federal procurement law and implementing policy as it relates to the FoodQuestTQ matter and the involvement of Battelle Memorial Institute.
5. The HHS legal defense brief misportrays the intellectual property issues involved in this case.	The FDA legal defense brief does not address the twenty-five specific FoodQuestTQ proprietary ideas that are being used without permission in the tools being given to the food industry at no cost by the FDA.
	The HHS legal defense brief misportrays both the process and data transformation aspects of the patent by focusing on only one of 20 integrally tied claims granted by USPTO under the patent.
6. The HHS legal defense brief contains false accusations that FoodQuestTQ failed to cooperate.	FoodQuestTQ officials repeatedly asked to meet with federal officials in order to resolve the matter. FoodQuestTQ's repeated requests to meet with both HHS and FDA officials were repeatedly rebuffed.
7. There are serious omissions of material significance that remain unaddressed in the HHS legal defense brief.	The HHS legal defense brief is silent on several points of material significance in the FoodQuestTQ matter such as the twenty-five specific FoodQuestTQ owned proprietary ideas being used by the FDA without permission, procurement integrity and the involvement of Battelle Memorial Institute and other FDA contractors in this matter, FDA endorsement of FoodQuestTQ's commercial competitors and the FDA role in "blacklisting" FoodQuestTQ.
8. There is a crisis in ethical conduct at HHS and the FDA.	HHS and FDA officials have placed their loyalty to their organizations, even if it means defending their own wrongdoing, ahead of their sacred oaths to uphold the Constitution and laws of the United States.

Figure 4: Summary of Concerns arising from the HHS Legal Defense Brief of FDA

of General Counsel HHS used means and methods to conduct their inquiry into the FoodQuestTQ matter that may have befouled future attempts to achieve a fair and impartial resolution of this case. These issues raise the serious specter of potential obstruction of justice by both HHS and the FDA in their handling of the FoodQuestTQ LLC matter.

Concern 3: The HHS Legal Defense Brief intentionally obfuscates simple realities

The HHS legal defense brief gives the erroneous impression that the FoodQuestTQ matter is so steeped in legal complexity that it defies a prompt and fair resolution. The facts of the FoodQuestTQ matter are very simple and can be easily understood by lawyer and layman alike. Namely, the FDA is unfairly competing against FoodQuestTQ LLC by publicly offering, at no cost to the food industry, similar products that were already being commercially sold by FoodQuestTQ LLC thereby forcing the small company out of business.

Concern 4: The HHS Legal Defense Brief misinterprets federal procurement law

The HHS characterizations of the Federal Activities Inventory (FAIR) Act [P.L. 105-270], the implementing provisions of Office of Management and Budget (OMB) Circular A-76, and the Federal Acquisition Regulations (FAR) as set forth in the HHS legal defense brief misinterpret federal procurement law and implementing policy in the FoodQuestTQ matter.

Among the key provisions of the FAIR Act is the requirement for the heads of federal agencies to identify "inherently governmental functions." According to the Act, inherently government function means: "a function that is so intimately related to the public interest as to require performance by Federal Government employees." Other important provisions of the FAIR Act require "Realistic and Fair Cost Comparisons" before the heads of federal agencies can enter into contracts.[xxx]

In the FoodQuestTQ LLC case, the FDA entered into a contract with Battelle Memorial Institute to help them develop and publicly market at no cost to the food industry computer risk management software products that were already commercially available at a fraction of the cost. The procurement action itself demonstrates that the FDA itself does not consider these types of activity to be inherently governmental in nature. Thus, it follows that the FDA did not conduct the due diligence required under the FAIR Act in their procurement dealings with Battelle Memorial Institute. If the FDA had done so, they would have surely discovered that the same or better capability to build computer automated food risk management tools was widely available from the private sector at dramatically reduced cost to the taxpayer.

Because of the FDA's own failure to conduct adequate due diligence as required by the FAIR Act (whether it was the result of negligence or intentional contract fraud) the FDA placed itself in the position of unfairly competing with FoodQuestTQ LLC and publicly offering, at no cost to the food industry, the same or similar products that were already being commercially sold by FoodQuestTQ LLC.

In similar fashion, the HHS legal defense brief mischaracterizes the provisions and intent of Office of Management and Budget (OMB) Circular A-76. OMB Circular A-76 mirrors the requirement of the FAIR Act requiring the conduct of realistic and fair cost comparisons.[xxxi] Thus, the FDA did not, or intentionally chose not to, conduct the due diligence required under OMB Circular A-76 in their procurement dealings with Battelle Memorial Institute. If the FDA had done so, they would have discovered that the capability to build computer automated food risk management tools of the same or superior quality was already available from the private sector at a fraction of the cost to the taxpayer of building or re-building the same or similar tools by the government.

Again, the HHS legal defense mischaracterizes federal procurement law and how it is implemented under the Federal Acquisition Regulations (FAR). The guiding principles of the FARs dictate that the federal government will maximize the use of commercial products and services. The FAR assigns the responsibility to maintain awareness of the capabilities of the commercial marketplace to the federal government.[xxxii] The FAR further dictates that the federal government must conduct the people's business with integrity, fairness, and openness. An essential consideration in every aspect of the FARs system is maintaining the public's trust.[xxxiii] In the case of FoodQuestTQ, the FDA violated the public trust by entering into a contract with Battelle Memorial Institute without conducting the due diligence required under the FAIR Act, OMB Circular A-76 and the FARs.[xxxiv]

The above are offered only as representative examples of the gross misinterpretation of federal acquisition law in the HHS legal defense brief. There exist numerous other instances in the HHS legal defense brief that fail to identify applicable provisions of the FARs in the FoodQuestTQ matter or seriously mischaracterize the federal procurement process as set forth under federal statute and the FARs.

Concern 5: The HHS Legal Defense Brief misportrays the intellectual property issues in this case

The intellectual property issues involved in the FoodQuestTQ matter are simple and can be easily understood by lawyer and layman alike. In the matter of FoodQuestTQ, the FDA is using FoodQuestTQ owned intellectual property in violation of federal law to duplicate computer software tools similar to the computer software tools being sold commercially by FoodQuestTQ LLC to the food industry.[xxxv] It is noted that the Office of General Counsel HHS was provided with the list of the twenty-five specific FoodQuestTQ owned ideas that are being used by the FDA without permission.[xxxvi]

The HHS legal defense brief raises the secondary, but still critical, issue of potential patent infringement by the FDA in the FoodQuestTQ LLC matter. The FoodQuestTQ LLC owned intellectual property shared with the FDA is, in fact, based on a patent.[xxxvii]

The patent used by FoodQuestTQ LLC does two things. First, the patent sets forth a new process for thinking about the management of risk. In the jargon of a patent attorney this is known as a "process." Second, the patent sets forth a specific way to mathematically translate data so that it can be used in support of the new way of thinking about the management of risk. In the legal jargon of a patent attorney it is what is called a "process and data transformation" patent. The business confidential information shared by

FoodQuestTQ with the FDA included both the thinking process, i.e., "process" as well as, the "data transformation" aspects of the patent as physically embodied, i.e., "reduced to practice" by FoodQuestTQ LLC in their food risk management tools.

In a patent or patent application, the "claims" collectively define, in technical terms, the extent of the protection conferred by a patent. The patent in the FoodQuestTQ matter grants a total of twenty "claims" that when integrally tied together cover both the "process and data transformation" aspects of the patent. The dual "process and data transformation" nature of the patent in the FoodQuestTQ LLC matter has already been contextually upheld through the *"patent teachings"* of the inventor by prior USPTO rulings.[xxxviii]

In the legal jargon of a patent attorney an "object of an invention" is a characteristic that is used to support the claims made in an invention. In the FoodQuestTQ case, there are one hundred and one "objects of the invention" that are also integrally tied to the twenty claims granted by United States Patent and Trademarks Office (USPTO) under the patent. It is noted that FoodQuestTQ offered both the Office of General Counsel HHS and the Office of Chief Counsel FDA a detailed technical crosswalk of the 20 patent claims and the one hundred and one objects of the invention that demonstrates gross infringement on the patent in the FoodQuestTQ LLC matter.[xxxix] Both the Office of the FDA Chief Counsel and the Office of General Counsel, HHS rebuffed the FoodQuestTQ offers.[xl]

The HHS legal defense brief misportrays both the nature and scope of the patent in the FoodQuestTQ matter by focusing on only one of the twenty "claims" granted by USPTO under the patent. FoodQuestTQ concludes that this is an intentional omission of material fact since the author of the HHS legal defense brief is a trained patent attorney and a senior federal official representing the government in this matter. This gives still further rise to the specter of potential obstruction of justice in this matter.

Also, a comparison of the twenty "claims" and supporting one hundred and one "objects of the invention" with the FDA Food Defense Plan and the various computer tools developed by the FDA clearly demonstrate gross infringement on the patent in the FoodQuestTQ LLC matter. It is noted that both the Office of the Chief Counsel FDA and the Office of General Counsel HHS rebuffed FoodQuestTQ offers to allow government counsel to review this material as part of the HHS inquiry into this matter.[xli] This gives still further rise to the specter of potential obstruction of justice in this matter.

Finally, the patent involved in the FoodQuestTQ matter was originally filed on June 12, 2007. The final patent issued on January 24, 2012.[xlii] The pending patent in the FoodQuestTQ matter was widely published and has been publicly available for over five years. A review of the FDA's guiding policy document for the future protection of the nation's food supply, i.e., the FDA Food Protection Plan, which was put into development in 2007, demonstrates gross infringement on the patent.[xliii] Thus, it follows that FDA's initial infringement of the patent well-preceded FoodQuestTQ LLC's discovery of FDA's illicit activities in the fall of 2012.

Concern 6: The HHS Legal Defense Brief contains false accusations that FoodQuestTQ refused to cooperate

The record of correspondence in the FoodQuestTQ matter is replete with requests by FoodQuestTQ officials to meet with government officials in order to resolve this matter. In every case, FoodQuestTQ's repeated offers to meet with federal officials to resolve the matter were rebuffed.[xliv] The unfounded accusations contained in the HHS legal defense brief further demonstrate that the document is tainted by an actual conflict of interest and, as such, fundamentally flawed.

The HHS legal defense brief states that FoodQuestTQ acted in an unreasonable fashion by requesting the opportunity to more fully understand the scope of activities and the technical details of the tools being built by the FDA in return for providing full proprietary access by the government to FoodQuestTQ's commercial food risk management product offerings. Taking full account of the situation, however, the FoodQuestTQ call for FDA transparency by requesting a quid-pro-quo in the sharing of information was not at all unreasonable given the fact that the FDA, by this time, was already mounting a legal defense of the Agency's own actions in this case. The HHS legal defense brief itself confirms that both the Office of Chief Counsel FDA and the Office of General Counsel HHS were mounting a legal defense of the FDA's actions in the FoodQuestTQ LLC matter that included the withholding of information rather than engaging in a fair, impartial and transparent inquiry into the matter.

Concern 7: There are serious omissions of material significance that remain unaddressed in the HHS legal defense brief

The HHS legal defense brief is silent on several points of material significance that are highly relevant to the FoodQuestTQ matter. Both individually and collectively these omissions give further rise to the specter of potential obstruction of justice in the handling of this matter by HHS and FDA.

On December 6, 2012, FoodQuestTQ published an article on a vulnerability assessment tool[xlv] being developed and marketed by the FDA to the food industry under an $114,801,090 dollar Agency line item in the FY 2012 budget.[xlvi] The FoodQuestTQ article presented a critical technical appraisal of the FDA assessment tool. The FoodQuestTQ article received significant attention by the FDA Food Defense Team and was opened and/or distributed both inside and outside of the Agency at least 40 times.[xlvii]

A few days later, on December 12, 2012, FoodQuestTQ was unexpectedly disinvited from an industry workshop being held by the FDA. The purpose of the FDA workshop was to solicit industry inputs on a new FDA computer automated food defense planning tool. FoodQuestTQ's participation in the workshop was scheduled weeks beforehand and included a demonstration of the company's own commercial food defense planning tool.[xlviii]

The HHS legal defense brief states that FDA prohibited FoodQuestTQ participation in the workshop for two reasons. First, that participation in the workshop was strictly limited to food processors.[xlix] The second reason was that FDA did not want to give the appearance of the Agency endorsing FoodQuestTQ's commercial product.[l] In the matter of FoodQuestTQ this situation raises questions the answers to which may drive at other motivations of the FDA in excluding the participation of FoodQuestTQ in the workshop.

For example, did the FDA exclude FoodQuestTQ participation in the workshop because of the critical article written by FoodQuestTQ that raised questions about the Agency's $114,801,090 million line item? Or, was FoodQuestTQ excluded because FDA personnel feared that the small company might disrupt the workshop when they discovered that the FDA was using their intellectual property without permission to duplicate their commercial products? The HHS legal defense brief remains silent on these significant issues.

The official sign in sheet for the attendees at the December 12, 2012, FDA sponsored workshop includes the names of several companies who are not food processors.[li] One of these companies is a direct competitor of FoodQuestTQ that sells food risk computer automated software to the food industry. The FDA has publicly endorsed this company's products.[lii] These issues raise very serious questions regarding HHS and FDA implementation of the Ethics in Government Act of 1978 [Title 5, U.S.C.] and applicable sections of the FARs as they relate to procurement integrity. The HHS legal defense brief also remains silent on these significant issues.

The "blacklisting" of FoodQuestTQ by HHS and FDA employees in the food industry is another issue of serious concern. In the FoodQuestTQ matter, the company reports that key business partnerships are being terminated and product sales are continuing to decline as the result of HHS and FDA actions in this matter.[liii] The HHS legal defense brief is silent of the issue of FDA blacklisting in the matter of FoodQuestTQ. The HHS legal defense brief is also silent on the FDA endorsement of the commercial food risk computer automated products by direct FoodQuestTQ commercial competitors and the impact that this is having on FoodQuestTQ's sales.

Concern 8: There is a crisis in ethical conduct at HHS and the FDA

On the first day of government service each federal employee swears a sacred oath to uphold the Constitution and the laws of the United States. In the matter of FoodQuestTQ and the government, the clause, *"I will well and faithfully discharge the duties of the office on which I am about to enter. So help me God,"* is especially operative.[liv]

In the handling of the FoodQuestTQ matter, the Office of General Counsel, HHS and the Office of Chief Counsel FDA chose to mount a legal defense of their own wrongful actions in lieu of conducting a fair, impartial and transparent inquiry into the matter. HHS and FDA personnel from the lowest to the highest levels are the unfortunate victims of their own misplaced loyalties. They have placed the defense of their own Agency's wrongdoing ahead of their sacred oaths to uphold the Constitution and the laws of the United States.

Report Conclusions and Recommendations

Conclusion 1: Both the Department of Health and Human Services (HHS) and the FDA are suffering an unprecedented crisis in ethics.

The analysis of the case study demonstrates that both HHS and FDA employees are placing their loyalty to their own positions and organizations, even if it means defending their own wrongdoing, ahead of their sacred oaths as public servants to uphold the laws and Constitution of the United States.

Conclusion 2: The Office of the National Ombudsman is powerless to prevent federal agencies from unfairly competing with small business.

The National Ombudsman for Small Business currently has no authority to stop federal agencies from competing with and forcing small companies out of business.

Conclusion 3: Small businesses cannot rely on their government for help in preventing unfair competition by federal agencies.

Small businesses in America have nowhere to turn for help if they become the victims of unfair government competition. For example, the case study is replete with unanswered pleas for help written to HHS, FDA and other federal officials.

Conclusion 4: The federal government can steal the intellectual property of small businesses with impunity.

Small businesses, confronted with the government theft of their intellectual property, cannot afford the expensive and lengthy legal battles required to undertake and settle lawsuits, respectively. As the case study demonstrates, the HHS and FDA are fully aware of this fact and use it to take advantage of small companies forcing them out of business.

Conclusion 5: The federal government intentionally uses the law as a tactic to obfuscate simple realities to force small businesses into long and expensive litigation they cannot afford.

The case study demonstrates that both HHS and FDA attorneys purposely created the erroneous impression that the FoodQuestTQ matter was so seriously steeped in legal complexity that it defied a prompt and fair resolution when, in fact, the issues involved in the case study are simple and easily understood by lawyer and layman alike. The case study also shows that the obfuscation of simple realities is a tactic used by the government to leave small businesses with no alternative but to pursue long and expensive litigation that the government knows that they cannot afford.

The report makes the following ten recommendations to prevent unfair competition by the federal government with small businesses.

Recommendation 1: Immediately require the legal counsels and all employees of HHS and FDA to re-new their oaths of government service.

The case study demonstrates that Office of the FDA Chief Counsel and the HHS Office of General Counsel and other employees engaged in a serious conflict of interest in their handling of this matter. The implementation of this recommendation should include specific training on how to deal with possible conflicts of interest that may arise between an employee's loyalty to his or her own organization, their knowledge of wrongdoing within the organization, and their sacred responsibility to uphold the laws and Constitution of the United States.

Recommendation 2: Conduct an immediate and independent review of ethical conduct and procurement integrity at both HHS and the FDA.

The case study demonstrates that FDA is not following the basic requirements of the FAIR Act, OMB Circular A-76 and the Federal Acquisition Regulations that are essential to

maintain procurement integrity. The implementation of this recommendation should include an independent review of the integrity of both the HHS and FDA procurement and acquisition system and the FDA practice of "blacklisting" of small companies.

Recommendation 3: Demand that the Office of Government Ethics (OGE) do its job in dealing with ethical breaches by federal agencies.

The case study demonstrates that FoodQuestTQ sought help to deal with serious ethical breaches by contacting the United States Office of Government Ethics (OGE). The small company requested that OGE conduct a policy oversight review of both HHS and FDA procurement practices. The company was told by OGE that this was not their job. To implement this recommendation, the Office of Government Ethics should be directed to do their job of assuring that their own ethics policies are being fully implemented by all federal agencies.

Recommendation 4: Strengthen the powers of the National Ombudsman for Small Business to conduct investigations of federal agency wrongdoing and unfair government competition with small businesses.

The case study demonstrates that the National Ombudsman for Small Business, Small Business Administration, does not currently have the authority to investigate unfair competition by federal agencies with small business. The implementation of this recommendation should include the amendment of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) [P.L. 104-121 as amended by P.L. 110-28] to grant the National Ombudsman the authority to investigate reports and recommend redress in cases of unfair competition by federal agencies with small businesses.

Recommendation 5: Take the necessary steps to assure that officials in HHS and the FDA are responsive to the correspondence and inquiries of all American citizens including the owners of small businesses.

The case study demonstrates that government civil servants are adversarial and not responsive to citizen's concerns. Civil servants are the employees of the American people who pay their salaries. The concerns of all Americans, including small businesses, should be addressed with respect by all employees of the federal government. The implementation of this recommendation should include awareness and training for all federal employees making it clear that they work for the people.

Recommendation 6: Clarify and increase the penalties for government employees who steal the intellectual property of small businesses under Title 18, U.S.C.

The case study demonstrates that FDA employees were familiar with FoodQuestTQ owned intellectual property provided to them pursuant to the provisions of Title 18 U.S.C. The case study also shows that these same FDA employees, under a contract with Battelle Memorial Institute, knowingly duplicated tools similar to those already being commercially sold by the small business. The implementation of this recommendation should include increased penalties for the misuse of business confidential information by government employees and more robust procurement integrity training and awareness programs, especially for HHS and the FDA employees.

Conclusion	Recommendation(s)
C-1: Both the Department of Health and Human Services (HHS) and the FDA are suffering an unprecedented crisis in ethics.	R-1: Immediately require the legal counsels and all employees of HHS and FDA to re-new their oaths of government service to uphold the laws and Constitution of the United States.
	R-2: Conduct an immediate and independent review of ethical conduct and procurement integrity at both HHS and the FDA.
	R-3: Demand that the Office of Government Ethics (OGE) do its job in dealing with ethical breaches by federal agencies.
C-2: The Office of the National Ombudsman is powerless to prevent federal agencies from unfairly competing with small business.	R-4: Strengthen the powers of the National Ombudsman for Small Business to conduct investigations of federal agency wrongdoing and unfair government competition with small businesses.
C-3: Small businesses cannot rely on their government for help in preventing unfair competition by federal agencies.	R-5: Take the necessary steps to assure that officials in HHS and the FDA are responsive to the correspondence and inquiries of all American citizens, including the owners of small businesses.
C-4: The federal government can steal the intellectual property of small businesses with impunity.	R-6: Clarify and increase the penalties for government employees who steal the intellectual property of small businesses under Title 18, U.S.C.
	R-7: Establish an emergency hotline within the Office of the National Ombudsman for Small Business for small companies to anonymously report abuse by the federal government.
	R-8: Amend the Federal Activities Inventory (FAIR) Act [P.L. 105-270], to include specific requirements that each federal agency must conduct a "build-no build" determination based on the cost and commercial availability of the same or similar products by small business.
C-5: The federal government intentionally uses the law as a tactic to obfuscate simple realities to force small businesses into long and expensive litigation they cannot afford.	R-9: Create an independent arbiter to resolve intellectual property disputes involving small businesses as additional alternative to pursuing expensive and lengthy lawsuits in Federal District Court.
	R-10: Amend the Federal Activities Inventory (FAIR) Act [P.L. 105-270], to require that each federal agency conduct and document a "compete-no compete" determination with small business before initiating any acquisition or procurement action.

Figure 5: Summary of Conclusions and Recommendations

Recommendation 7: Establish an emergency hotline within the Office of the National Ombudsman for Small Business for small companies to anonymously report abuse by the federal government.

The case study demonstrates that government agencies can take reprisals against small businesses that raise questions about unfair treatment. The fear of being "blacklisted" within their industries (especially government regulated industries) as a "non-team player" or the fear of losing future government contracts creates a powerful disincentive for reporting abuse. Establishing an anonymous hotline where small businesses do not have to fear reprisal from federal agencies is one additional step that can be taken to prevent unfair government competition with the private sector.

R-8: Amend the Federal Activities Inventory (FAIR) Act [P.L. 105-270], to include specific requirements that each federal agency must conduct a "build-no build" determination based on the cost and commercial availability of the same or similar products by small business.

The case study demonstrates that federal agencies are not conducting "realistic and fair" cost comparisons when they decide to build their own products "in house" for activities that are not "inherently government functions." The FAIR Act should be amended to require that all federal agencies must conduct and document a "build-no build" determination whenever they decide to build their own products "in house" for activities that are not "inherently government functions."

R-9: Create an independent arbiter to resolve intellectual property disputes involving small businesses as additional alternative to pursuing expensive and lengthy lawsuits in Federal District Court.

Small businesses cannot afford long and expensive legal battles with the government. The implementation of this recommendation should include the amendment of 28 U.S.C. 1498- Patent and copyright cases, to establish an alternate dispute resolution (ADR) process for small businesses who believe they have had their intellectual property stolen by a federal agency.

R-10: Amend the Federal Activities Inventory (FAIR) Act [P.L. 105-270], to require that each federal agency conduct and document a "compete-no compete" determination with small business before initiating any acquisition or procurement action.

The case study demonstrates that federal agencies are competing directly with small businesses forcing them out of business. The FAIR Act should be amended to require that all federal agencies must conduct and document a "compete-no compete" determination to certify that they are not competing with small business.

End Notes

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[xxiv] Note: These documents are maintained by the Grocery Manufacturers Association (GMA). Attendees can also be verified by multiple industry participants attending the FDA workshop.

[xxv] Ibid.

[xxvi] Note: The FDA has publicly endorsed the products of one of FoodQuestTQ LLC's industry competitors. See: http://www.foodmanufacturing.com/videos/2013/04/food-defense-strategy-part-1-assess

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[xli] Ibid.

[xlii] Hnatio, J.H. (January 2012) Complexity Systems Management Method, Patent No.: US 8,103,601 B2. Date of Issue: January 24, 2012. United States Patent and Trademark Office, Washington, DC Read more at: http://www.patentgenius.com/patent/8103601.html

[xliii] FoodQuestTQ LLC (March 9, 2013). HHS-FDA Patent Crosswalk.

[xliv] Note: FoodQuestTQ wrote two letters to the FDA Chief Counsel, one letter to Commissioner Hamburg and three letters to Secretary Sebelius requesting the opportunity to meet and resolve the matter. The government never responded to these requests.

[xlv] Hnatio, John H. (December 6, 2012). Bringing C.A.R.V.E.R. into the 21st century, FoodQuestTQ, LLC, Frederick: Maryland, as retrieved from the world Wide Web on May 7, 2013 at: http://www.nfpcportal.com/MemberResources/Blog/tabid/176/Article/3034/bringing-carver-into-the-21st-century.aspx

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[li] Note: These documents are maintained by the Grocery Manufacturers Association (GMA). Attendees can also be verified by multiple industry participants attending the FDA workshop.
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Appendix 1: HHS Legal Defense Brief, April 26, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
Room 2B-50, NIH Bldg. 31
31 Center Dr., MSC 2111
Bethesda, Maryland 20892-2111
(301) 496-6043
Fax (301) 402-1034

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

[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

[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

[25] Exhibit 22: Press Release July 20, 2011, http://www.fda.gov/ForConsumers/ConsumerUpdates/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.fda.gov/irisk.aspx
[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. 130315000I, 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 Goenther, 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 $ 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."[48] 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 Architect™ 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. 130315001, 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.

Report Distribution

1. The President
2. Administrator, Small Business Administration
3. The Director, Office of Management and Budget
4. Comptroller General, General Accounting Office
5. The Director, Office of Government Ethics
6. The Secretary, Department of Health and Human Services
7. The Commissioner, Food and Drug Administration
8. All Federal Offices of Small and Disadvantaged Business Utilization
9. The Senate Committee on Entrepreneurship and Small Business
10. The House Committee on Small Business