

Dr. Dale D. Berkley
Office of the General Counsel
Public Health Division
Room 2B-50, NIM Bldg. 31
31 Center Drive, MSC 2111
Bethesda, Maryland 20892-2111



March 28, 2013

Dear Dr. Berkley:

We have received your letter of March 27, 2013.

In your letter, you refer to my March 22nd e-mail to Ms. Zahirieh of the Office of the National Ombudsman for Small Business. In your letter you take exception to our concerns that the FDA did not and never intended to conduct a good faith review of our concerns. But, in fact, it was for this reason that we were forced to turn to the National Ombudsman for Small Business for help.

I am very surprised to hear that you do not understand why Ms. Seeley's e-mail is so threatening. Please let me explain.

I too was a civil servant. On my first day of government service I took an oath to uphold the Constitution and the laws of the United States. There were many times during my 30 year career with the government that this oath was sorely tested. In the face of serious wrongdoing in my own agency and at serious risk to my own well-being, I held fast to my oath. When my agency was guilty of wrongdoing my loyalty was always guided by my oath to uphold the Constitution and the laws of the United States first- certainly not the defense of my colleagues in the agency who engaged in the misconduct in the first place.

Please keep in mind that it was Ms. Seeley's own decision to turn this matter into an adversary legal defense of her colleagues on the FDA Food Defense Team instead of an impartial and objective fact finding mission to determine the truth. We certainly do not want to hurt Ms. Seeley. But her e-mail is, in fact, very clear. To the FDA, this matter is not about finding the truth. Rather, it is about mounting a legal defense for the FDA's own unconscionable actions in this matter. Based on your letter and your defense of Ms. Seeley's misguided actions, this now appears to be your motivation as well.

We also want thank you very much for your concern about the need for us to hire legal assistance to defend us against your investigation of this matter. But, if you intend to conduct a fair and impartial good faith review of this matter, then why do we have to pay money that we desperately need to feed our families to pay for an expensive legal defense? At this time, all of us in FoodQuestTQ have been forced into unemployment by the actions taken against us by the FDA. We simply cannot afford the expense of engaging in a legal battle with the government.

The non-disclosure agreement (NDA) you sent to us, still does not contain several important recommendations that we have already provided to the FDA legal counsel. Among the most important changes that must be made to the draft NDA involve the “Purpose” of the agreement.

As we have said from the very beginning, this matter involves three inextricably intertwined issues that arise from the FQTQ complaint to the FDA that must be considered if there is to be any true good faith review of this matter, namely:

1. FQTQ allegations of unlawful FDA competition with FQTQ under statutes and governmental procedures including, but not limited to, the FAIR Act and OMB-Circular A-76, respectively;
2. The alleged FDA theft of ideas, trade secrets and proprietary information from Thought Quest LLC, FoodQuestTQ LLC and Projectioneering LLC, and;
3. Projectioneering LLC and FQTQ proof that FDA has infringed on Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

The reason for these changes is because the FDA legal counsel has repeatedly attempted to pigeon hole the FQTQ complaint against the FDA as solely and exclusively a matter of patent infringement. This is not the case. Our complaint to the National Ombudsman for Small Business goes well beyond the single isolated issue of patent infringement to include violations of the FAIR Act, the theft of our ideas, trade secrets and intellectual property, the duplication of our products and unlawful government competition against FoodQuestTQ. Thus, the NDA must clearly reflect that your good faith review will encompass all aspects of the formal complaint we have filed with the National Ombudsman for Small Business.

The NDA must also reflect a fair and reasonable quid pro quo in the sharing of information between FQTQ and Department of Health and Human Services and the FDA. If FQTQ provides you with information regarding their tools then the FDA should share information with FQTQ regarding each of the FDA tools under suspicion for further evidence of theft of our ideas, trade secrets and intellectual property and infringement on the Projectioneering LLC owned patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2.

Several weeks ago, we suggested such a quid-pro-quo but the FDA counsel declined. We requested that the FDA provide us with an in-depth demonstration of the tools they duplicated and the opportunity for us to ask further questions. Thereafter, FoodQuestTQ would provide the FDA with a complete demonstration of our tools that would demonstrate the specific ideas, trade secrets and intellectual property that was stolen from us. Both presentations would be done via webinar and recorded for independent review by the National Ombudsman for Small Business, the office of Inspector General, the Department of Justice and others who may become involved in this matter. We now extend this same offer to you. Such demonstrations will quickly and conclusively demonstrate the truth of this matter as part of the official record.

The provisions at 48 C.F.R. §227.7004 relate to the resolution of patent infringement claims on the part of the offended party. The information you request is not germane to the conduct of a good faith fact finding mission by either the FDA or the Department of Health and Human Services under the administrative law provisions at 48 C.F.R. §227.7002 and 48 C.F.R. §227.7004. As you are well aware, we are not yet at the resolution phase of this process.

At this juncture, you have a copy of our USPTO granted patent: The Complexity Systems Management Method, Patent No.: US 8,103,601 B2 and a detailed list of the specific ideas, trade secrets and intellectual property that were stolen from us by the FDA that I have provided to the National Ombudsman for Small Business. I understand that this information has already been provided to you by the National Ombudsman. On prior occasions, we have also offered FDA counsel a detailed technical crosswalk of how our patent was reduced to practice for our food applications. But the offer was declined.

Again, thank you very much for your letter. I can be reached at 240-439-4476 x-11 if you have any questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Hnatio". The signature is written in a cursive style with a large initial "J" and "H".

John Hnatio
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cc: Ms. Elahe Zahirieh, NOSB
Ms. Ariel Seeley, FDA Counsel