DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
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March 27, 2013
VIA EMAIL

Dr. John Hnatio
Chief Science Officer
FoodQuestTQ
4720 Hayward Drive
Suite 104
Frederick, MD 21702

Re: FDA's Food Defense Team

Dear Dr. Hnatio:

With respect to your email of March 22, 2013 to Ms. Zahirieh on which I was copied, I take exception to your characterization of Ms. Seeley's recent email to you as "threatening," and your suggestion that our agency does not intend to investigate your allegations of "wrongdoing." Neither of your statements is true or the least bit accurate.

Ms. Seeley's email merely introduced me as the intellectual property attorney who will be helping with the analysis of your allegations. Her email properly suggested that you obtain competent legal counsel, in view of your earlier communication to us that you are unrepresented, with respect to an area of the law that is highly technical.

In your letter of February 12, 2013 to Ms. Dickinson, you claimed that FDA duplicated your Food DefenseTQ tool and took elements of your FREE and FEAST computer software tools and incorporated them into FDA tools.

In order to evaluate this claim I will need to compare the FDA tools with each of your company's tools for any similarities. However, we do not have a copy of your company's tools, and you indicated in a previous communication that you were willing to provide them to us for this purpose under a Non-Disclosure Agreement ("NDA").

Ms. Seeley's March 13, 2013 email contained an executed copy of the NDA, which was modified consistent with our standard practices. You proposed in your March 14, 2013 response that certain changes be made to the NDA. I accepted some of your changes as follows: (1) I revised the "Purpose" of the NDA, (2) I revised the definition of "Confidential Information" to account for its intended relationship to the "Exempted Information," and (3) I revised the definition of "Exempted Information."

Please find an executed copy of the NDA, which has been modified to accommodate some of your suggestions. In return, please forward a copy of the tools that are the subject of your complaint directly to me, along with a description of those parts of the FDA tools that you believe incorporate subject matter from your tools.

With respect to your claim of infringement of U.S. Patent No. 8,103,601, the regulations at 48 C.F.R. § 227.7004 describe the information necessary to evaluate a claim of this kind. In particular we need, as applicable, the following:

1. A detailed identification of the accused article or process, and an element by element comparison of the representative claims with the accused article or process. If available, this identification should include documentation and drawings to illustrate the accused article or process in suitable detail to enable verification of the infringement comparison;
2. Names and addresses of all past and present licenses under the patent, and copies of all license agreements and releases involving the patent;
3. A brief description of all litigation in which the patent has been or is now involved, and the present status thereof;
4. A list of all persons to whom notices of infringement have been sent, including all departments and agencies of the Government, and a statement of the ultimate disposition of each; and
5. A list of all Government contracts under which the inventor, patent owner, or anyone in privity with him performed work relating to the patented subject matter.

If you have any questions or wish to discuss this further, please contact me at (301) 496-6043, of at Berkleyd@od.nih.gov.

Sincerely,

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

Attachment: Executed NDA