John Hnatio

1-A

From: John Hnatio <jhnatio@thoughtquest.com>
Sent: Thursday, March 14, 2013 10:53 AM
To: 'Seeley, Ariel'
Cc: Elizabeth.Dickinson@fda.hhs.gov; mark.raza@fda.hhs.gov
Subject: RE: Response to your e-mail
Attachments: Comments on the NDA for Ariel 3-14-2013.pdf

Hi Ariel:

I have taken a few minutes this morning and reviewed the proposed NDA you sent over to me. Attached is a short note with our recommendations. We have clearly described the changes and they should be quick and easy to make. I know how busy you are and we are happy to make the changes for you if you can send along a soft copy in *Word*. I'll use *track changes* to make sure that you can see and approve everything.

I read your e-mail below and I still do not understand how you can make even a preliminary determination regarding infringement or violation of trade secret without seeing how the original invention was reduced to practice in the context of our tools. I am not attorney like you are and, under the circumstances, cannot afford to pay for one. I feel like an innocent man thrown in jail who must serve as his own lawyer because of the unfortunate circumstances here. I am a simple man and it is difficult for me to understand the complexities of the law like you do. Since I am at such a disadvantage here, I really need your help. All that I ask is that you be patient with me and explain things so that I can clearly understand them.

I do not understand how your e-mail answers my question. My question is: How will it be possible for you (the FDA) to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the FQTQ tools (reduction to practice for food) that were duplicated by the FDA? As I have explained to you before, our reduction to practice of the invention for food involves trade secrets that were stolen by the FDA Food Defense Team and others at the FDA. In the absence of having this information how can you possibly do a thorough and good faith review of the matter?

I am sincerely asking for your patience and understanding. I really need your help here as a wise, fair attorney of high integrity who obviously has a tremendous command of the law to just honestly answer my question in a clear and simple way that I can understand. I need your reassurance that we are all operating in good faith here. Thank-you for your hard work on this and all of us really appreciate your help. Best, j

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From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Thursday, March 14, 2013 9:31 AM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

We appreciate your willingness to share information about your patent, how it was reduced to practice in a suite of tools, and other business process information with us. However, the information you provided about your patent so far has been sufficient. We will contact you for additional information, if necessary, at a later date. Thus, at this time, we need to evaluate your claims by comparing your products to ours. To do so, we will need nonexclusive access to Food QuestTQ's

Food Defense Architect, Food DefenseTQ, Food Mapper, FREE tool, and FEAST. Again, we appreciate your willingness to work with and provide us with requested information in a timely manner.

Best,

Ariel

1-B

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

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From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Wednesday, March 13, 2013 4:17 PM
To: Seeley, Ariel
Subject: RE: Response to your e-mail

Hi Ariel:

Thank-you and I will look over the NDA.

Please be advised that the patent in question is a combination business process and data transformation patent.

In your e-mail you state "We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information."

Question

How then, will it be possible for you to make any type of good faith determination regarding matters of infringement on our patent in the absence of examining each of the 20 patent claims and the 101 objects of the invention that are integrally tied to those claims against the operation of the tools that were duplicated by the FDA.

Please advise. Thank-you. Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Wednesday, March 13, 2013 4:05 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr Hnatio:

Thank you for your email of March 2, 2013. I appreciate your willingness to work with me as I look into this matter. As you are most likely aware, dealing with the Food and Drug Administration (FDA), a federal agency, differs from dealing with private entities. Federal agencies must act according to a number of laws and regulations that govern their use of and

ability to protect information submitted or provided to them. I attach to this email a non-disclosure agreement (NDA) that meets FDA's legal requirements. FDA has signed the attached NDA to make this process more efficient.

Furthermore, I would like to clarify that, at this time, FDA is only requesting nonexclusive access to FoodQuestTQ LLC's (FQTQ) software tools that you claim FDA's software tools, the Food Defense Plan Builder, FREE-B, and FDA-iRisk, duplicate. Specifically, these tools are FQTQ's Food Defense Architect, Food DefenseTQ, Food Mapper, FREE Tool, and FEAST. Such access will allow FDA to evaluate the concerns raised by your previous communications. We are not requesting any additional information, such as information about your patent, how the patent was reduced to practice in a suite of tools, or other business process information. We ask that you do not send us such information at this time.

Please review the attached NDA and, if it is acceptable to you, send a signed copy to FDA with the FQTQ tools mentioned above by March 20, 2013, so that we can proceed with our evaluation. I look forward to hearing from you.

Best,

Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

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From: John Hnatio [mailto:jhnatio@thoughtquest.com]
Sent: Saturday, March 02, 2013 2:25 PM
To: Seeley, Ariel
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: Response to your e-mail

Hi Ariel.

We're looking forward to working with you.

It took a bit longer than I thought it would to get back to you because we just found out about another tool released by the FDA called ***iRisk*** that duplicates our ***Food Mapper*** tool.

Please find attached a short note I put together for you and a copy of a simple NDA for Ms. Dickinson to sign. Once we get the NDA in place we will be able to share whatever information we have with you so that we can work together to do a detailed cross-walk of our tools against the tools copied by the Food Defense Team and JIFSAN using our ideas.

In the meantime, I'm pulling together a cross walk of the 20 claims made in our patent and the associated 92 objects of the invention to help us do the crosswalk. I think your idea about doing a detailed look see of the FQTQ tools against the FDA duplications is right on target and will help us to resolve this very quickly.

Give me a call if you've got any questions on the attached materials. Look forward to meeting/working you. As soon as I hear back from you we will support you any way we can. Thanks and best, j

John Hnatio, EdD, PhD
Chief Science Officer
FoodQuestTQ LLC
4720 Hayward Road, Suite 102
Frederick, MD 21702
(O) 240.439.4476 x-11
(C) 301.606.9403

John Hnatio

1-C

From: John Hnatio <jhnatio@thoughtquest.com>
Sent: Friday, March 22, 2013 12:28 PM
To: 'Seeley, Ariel'
Subject: RE: Response to your e-mail

Ariel: Who would you recommend? Best, j

From: Seeley, Ariel [mailto:Ariel.Seeley@fda.hhs.gov]
Sent: Friday, March 22, 2013 12:21 PM
To: 'John Hnatio'
Cc: Dickinson, Elizabeth; Raza, Mark
Subject: RE: Response to your e-mail

Mr. Hnatio:

Thank you for your email of March 14, 2013 suggesting changes to the nondisclosure agreement (NDA). You will be contacted shortly by a colleague of mine within the Department of Health and Human Services' (HHS) Office of General Counsel, Dale Berkley, who is our intellectual property attorney. I have provided Mr. Berkley with all necessary background information and materials.

Going forward, please understand that Mr. Berkley and I are lawyers representing HHS/FDA and cannot provide you with legal advice. If you want legal advice on this matter, I recommend that you consult with an attorney. I understand that you have indicated this would not be financially feasible for you. There are various organizations that exist to provide free or low-cost legal services to people who cannot otherwise afford legal representation.

Best,
Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
301-796-8738

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Ariel

Ariel Seeley
Office of Chief Counsel, FDA
Food & Drug Division, OGC/HHS
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