June 27, 2014

Dear Deputy Commissioner Hirschfeld:

I write to comment on the *Myriad* guidelines, following up on my comments at the BIO meeting on June 25, 2014. My comments go to the PTO's overall approach to drafting guidelines and not to the details of what has been drafted. I respectfully ask you to consider a different approach altogether – one that will create a "win-win" situation for the PTO and its users.

I applaud your efforts to harmonize past Supreme Court case law and attempt to uncover an approach that will do so *and* respond to the PTO's many examiners' questions. However, that is an impossible task, as I think you are coming to realize. It also may take you beyond the PTO's authority by extending *Myriad* beyond its holding. Let me suggest an option.

As the Solicitor of Patents and Trademarks between 1994 and 1999, I was faced with similar issues in both biotechnology and software areas. After going through the exercise you are going through now and listening to PTO's users, we determined the PTO should push back on certain decisions that limited inventors' protection for their inventions, included *Benson*, *Flook,* and *Funk Bros*.

Obviously, the Supreme Court holdings had to be followed, just as the holding in *Myriad* must be followed. But dicta that was not needed to support the holdings did not. In fact, dicta should not be followed by the PTO. That should be good news to you, as I know the PTO's interest is in providing protection for new, nonobvious inventions disclosed to you for patenting. By limiting the prior cases to their actual holdings, we were able to issue the original utility and written description guidelines in the biotech area and the original computer-implemented inventions guidelines in the software area and instruct examiners accordlingly. Those guidelines were applauded, and the examiners were able to apply them. Of course, there will always be difficult fact patterns to address. In patent law, there's no way to avoid that, but broader stroke guidelines with follow up training helps.

Addressing the *Myriad* case, the actual holding is that isolated DNA, if it is the same as naturally occurring DNA, is not patent eligible. Period. Thus, the PTO cannot issue patents to such DNA molecules just because the DNA is isolated. Please seriously consider limiting the guidelines to that holding. That would be a service to biotechnology and to the PTO.

However, if you are compelled to go further, i.e., to other types of naturally occurring molecules and substances that have been isolated but maintain their naturally occurring form, then instruct examiners such isolated molecules or substances are not patent eligible, but again do not go further. If the molecule or substance is changed in any way – structurally or functionally – then clearly it does not fall under the actual *Myriad* holding. Extending *Myriad* as you are contemplating doing would be a mistake you should resist making.

As a final comment, in preparing the guidelines, if you are attempting to answer a difficult question, such as the ones you suggested at BIO, then I entreat you to answer that question in favor of patent eligibility. If there are those encouraging you to do otherwise, ask whether they are users of the patent

system or are they those wanting to use others' inventions at no cost. If the latter is the case, then ask whether the PTO should be guided by those who do not contribute to our patent system.

Your task is not easy. I understand that. But taking a different approach to the Myriad guidelines will lighten that task.

Thank you for your consideration of my comments and others. If you would like to discuss the above, please do not hesitate to contact me.

Best regards,

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