From: rosanne kosson
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To: Eligibility2019
Subject: Comments on the 101 guidelines published in the Federal Register on Jan. 7, 2019, Revised Patent Subject Matter Eligibility Guidance

I am a biotech examiner at the PTO and am writing to you following a training session that we had on yet another revised version of the 101 guidelines. Those of us in biotech (examiners, attorneys and their clients) having been living with 101 guidelines for a long time now that seem excessive and prohibitive, relative to the Supreme Court decisions on which they are based. OPLA went wild and overdid it. Now that we are in a new era, and have a PTO Director who listens, tries to fix problems and is responsible to the businesses that we serve, in contrast to the former Director (whose deer-in-the-headlights appearances in hearings before two different House Subcommittees were memorable), we should get back to working under the patent laws, rather than under political correctness or under the logic of certain political groups, that we cannot have biotech patents, because Obamacare is already too expensive, and biotech patents make Obamacare even more expensive. It is time to stop mixing apples and oranges, as some have said. And the long-term costs of denying patents to the pharmaceutical industry, and other biotech industries, one of the strengths of the U.S. economy, are devastating to our economic future, particularly in the global economy. Further, if we deny the exclusive rights of patent protection, we are in a much weaker position to complain about IP theft and unauthorized use.

One of the big problems in biotech cases, for example, in the natural products/natural medicine cases (compositions comprising plant and/or animal extracts and/or microorganisms), is that we are forced to reject, under 101, compositions comprising, i.a., multiple extracts and/or multiple microorganisms. The composition is not naturally occurring. The plants, animals and microorganisms, as extracts or otherwise, do not occur naturally together. The case law that OPLA uses for such a rejection is a Supreme Court decision from 1948, Funk Brothers Seed Co. v. Kalo Inoculant Co. (333 US 127), in which the patent to Kalo Inoculant was invalidated for not being inventive. It was considered not inventive to combine six strains of *Rhizobia* (nitrogen-fixing bacteria) into one product, based on the natural properties of each strain. This Supreme Court decision talks about how the invention was not inventive. The patent was not invalidated for being drawn to a product of nature. The PTO appears to have missed this distinction, which is not all that subtle, in the unbridled fervor to find 101 case law in biotech cases. It would be most helpful if we could remove this part of the guidelines and indicate to patent applicants that this sort of rejection will no longer be made. Certainly, the biotech industry would be most grateful, as would I, as I have trouble writing rejections that seem unwarranted. This correction is the most significant one needed in the OPLA guidelines for biotech.

Some biotech patent attorneys have pointed out that cases decided prior to 1952 were decided under different statutes. The 1946 act contained a combined single provision from which 101 and 102 were not separated until the 1952 patent act. Therefore when citing to those cases, whose blended analysis was appropriate under the 1946 patent act, one should be extremely careful in determining the extent to which those decisions reflect a 101 or 102/103 analysis under the 1952 act. OPLA seems to have missed this point.

Moreover, the Board (PTAB) uses a different standard than OPLA and does not seem to bother with the OPLA guidelines. The Board's standard for making a 101 natural product rejection is that the examiner must demonstrate that the claimed product that is rejected does exist in nature. The examiner has this burden. The problem of course is that, if OPLA tell us that we have to do a lot of time-consuming work to write rejections that the Board will reverse, patent examination becomes extremely slow and inefficient. It also provides bad customer service, which we are meant to be all about.

Fortunately, the newly revised Section 101 guidelines discuss that if a natural phenomenon or law of nature has one or more practical applications, it is patent eligible. See pp. 13-20 of the 27-page document entitled 2019 Revised Patent Subject Matter Eligibility Guidance (https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-28282.pdf). The claims to the natural medicine compositions mentioned above typically recite the functional properties and intended uses of these compositions, e.g., that they treat pain, inflammation, infections or one or more specific diseases (e.g., cardiovascular diseases, diabetes, neurodegenerative disease, certain types of cancers). Thus, the revised guidelines will help in biotech cases and could be expanded to discuss rejections that will no longer be made in biotech cases.

I hope that these comments will be given to Director Iancu and his staff, for making some needed changes to the biotech 101 guidelines that are long overdue. Certainly after the Myriad Genetics decision, everyone understands that simply isolating a natural product is no longer enough for patentability. But the PTO's 101 guidelines should mirror the Supreme Court's decisions and not broaden the scope, if you will pardon the expression.

Thank you for considering these comments. These comments were written in my personal not professional capacity, and I do not speak on behalf of the USPTO or a group of USPTO employees.