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Senate Subcommittee Hearing of Patent Eligibility Wrap Up – Now What?

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In my first post on the Subcommittee Hearings held last week, I noted the absence of many witnesses from the life science industry, as opposed to groups such as IPO, AIPLA, BIO, ACLU and PhMA. The third and final panel, held yesterday, remedied this absence and then some. This panel included Laurie Hill (Genentech), Gonzalo Merino (Regeneron), Sean George (Invitae), Peter O'Neill (Cleveland Clinics Innovations), David Spetzler (Caris Life Sciences), Corey Salsberg (Novartis) and Robert Deberadine (Johnson and Johnson). The witnesses were rushed, and the written testimony that was submitted provides more thorough accounts of their positions.

Chairman Tillus opened this hearing by summarizing some of his takeaways from the previous hearings, agreeing that the current judge-made law of patent eligibility is a "complete mess", and that the draft definitions of utility and the amendments to s. 112 (f) as proposed need further work. He also recognized the need for an enhanced experimental use exception to infringement. He criticized the ACLU for advancing a "false narrative" that an individual's genes would be patent eligible, were the draft bill to become law. He said that he was hopeful that a revised final bill would be sent to the Judiciary Committee and come up for vote in the Senate.

Apart from the general uncertainty about the effect of the proposed amendments to s. 112(f) (one witness suggested dropping them out of the draft bill at this time), there was a nearly a consensus among the witnesses, both from the info-tech and life sciences areas, on the need to amend section 101. As stated by Dr. Spetzler:

“Any invention relying even in part upon the relationship between a gene and disease, or a gene and treatment benefit, may be characterized as an unpatentable ‘natural law.’ And any invention relying even in part upon analyzing large amount of molecular data may be characterized as an unpatentable ‘abstract idea.’” He described the use of “machine learning algorithms” to select therapies when alternative ones are available, and to detect the origin of tumors based on molecular analysis, so as to better choose from treatment options, but stated that “the systems and methods we have developed to inform treatment decisions may be alleged to be unpatentable natural laws, abstract ideas or both.”

Laurie Hill came close to generally explaining the need for a patent system that protects inventions that “harness natural processes” to create treatments that are “deliberately close to nature”. She noted that there is a lot of uncertainty with respect to the PE of inventions based on in vivo systems, presumably including correlations occurring in vivo. When she was asked if it would be sufficient to craft a PE bill limited to diagnostic tests, she replied that PE difficulties would remain for certain drugs, cells and organisms – presumable derived from natural sources — and for inventions based on AI and bioinformatics.

Peter O’Neill, Director of the Cleveland Clinic Innovations, agreed with Ms. Hill that individual genes should not be PE and told the story of his office’s failed attempts to protect a “If A, then B” diagnostic assay based on the MPO biomarker, even when the claim was simply directed to determination of the level of the biomarker (“A”), without drawing a diagnostic conclusion. He stated that this level of uncertainty about patent protection for any invention that was evaluated by his office would be likely to cause his office to discontinue commercial development of the invention. (Luckily, the Cleveland Heart Lab was established and successful before the final judgments that the patents were invalid as natural phenomena.)

A number of the witnesses agreed both that patent eligibility is colliding with the need to advance personalized medicine and that bioinformatics (“big information”) and conventional methods of treatment and diagnostic techniques are beginning to merge. The last witness, Robert Deberardine, summarized some of the major discussion points, namely, the predictability is essential to investment decisions, that the PTO should be given more deference by the courts in developing examination standards in this area, that transparency in R&D is provided by the present system and that the dangers posed by patent thickets in the life sciences are largely fiction, since additional patent protection is justified for many drugs, given their lengthy development periods.

This post only scratches the surface of the testimony, oral and written, in the Part III hearing. I apologize for witnesses I failed to mention, but I hope I captured the tenor of the discussion. Now here is some of my Wednesday morning testimony. After listening to almost all of the testimony, I am beginning to worry about the judicial response to the proposed definition of “useful”: “specific practical utility in any field of technology through human intervention.” In other words, would this language change the fate of claims to isolated genes or to diagnostic methods that do not also recite a treatment step?

It can certainly be argued that it would not change the outcome in Myriad. In that decision, the Supreme Court held that breaking bonds to isolate a human gene from

the genome was not enough human intervention to yield other than a patent-ineligible natural product. In Ariosa, the steps necessary to confirm the presence of cffDNA in maternal serum were held to be insufficient human intervention to elevate the claims to other than the patent-ineligible observation of a natural product, even though the discovery was of great diagnostic importance.

This holding would probably not trouble the witnesses at this hearing, since they almost all agreed that human genes should not be patentable. However, how much human intervention is enough to render an invention or discovery patent-eligible, even if it has specific, practical utility in medicine, e.g., it is the discovery of an in vivo correlation that provides the basis for an important diagnostic test, a la Cleveland Clinic or Athena. How will the PTAB or the courts interpret “human intervention”?

They have already arguably repeatedly held that the human intervention required to carry out a “basic” diagnostic assay –sampling, measuring, comparing and concluding, is not sufficient to cause the claim to be other than an impermissible attempt to claim a natural phenomenon. In fact, they have stated that even ground-breaking and medically important discoveries are not patentable without additional steps that are “inventive”. We can hope that the steps required to carry out a typical diagnostic assay will be found by the courts or the Board to meet the requirement for human intervention, even if they are conventional but, if they find insufficient human intervention, we are right back at square one in the PE conundrum. Would adding “any” before human intervention alleviate my fears? Oh, but then isolated human genes would be patent-eligible again.