Patent Docs Author Testifies at Genetic Diagnostic Testing Hearing

Patent Docs author Dr. Kevin Noonan (at right) gave the following testimony at today's USPTO hearing on genetic diagnostic testing:

I want to thank the organizers for inviting me to testify today.

This study by the PTO is important because it should give the Office the opportunity to determine whether there is any evidence that "patents are the problem" with regard to patient access to genetic diagnostic testing. It has become fashionable in some quarters (mostly the medical and legal academies) and in some industries to question the value of patenting in promoting innovation. Those that do so analogize patents to a tax on innovation and even contend that patenting can retard innovation. Judges and even some Justices have proposed that there needs to be a balance between patenting; like a judicial Goldilocks, there is abroad the idea that we need just the right amount of patenting, and that steps, like the "second opinion" exemption we are discussing today are ways to achieve that golden mean.

These ideas are current under circumstances where there is little evidence that patents are responsible for preventing patients from enjoying the benefits of the new genetic technology. There is also little evidence that current genetic diagnostic test providers are beset by rampant error in the test results they provide. It isn't as if no one has looked for these effects, but in every case the reports and studies are forced to begrudgingly admit that there is no apparent effect of patents on either access or quality, even while remaining steadfast that there *could* be or *might* be in the future. This includes many academic studies as well as official U.S. government agencies including the Department of Health and Human Services SACGHS report. I know of no study showing that limitations on patient access are not the consequence of behaviors and policies of private and government insurers, payors and providers rather than patents. After all, in America, the one right patients *don't* have when it comes to medical treatment or diagnosis is an economic one. Healthcare in this country depends on what each individual patient can afford, or if they have benefits through their employer, what their employer provides. If an insurer won't pay for a genetic diagnostic test, it doesn't mean the test is too expensive -- it means the insurer has decided that it, and its insureds, can wait until the price comes down. The patent system didn't create this situation and weakening patenting won't solve it.

So we are left again with a discussion of what might be done with patents, that supporters contend will facilitate patient access and diagnostic reassurance even in view of a dearth of evidence that patents are the problem. I propose that if we are willing to do that, we would be remiss if we didn't consider all of the consequences of such actions and to inquire whether patient access or test quality would improve or not (particularly if our efforts are not taken in parallel with reforms in other areas of healthcare system).

It is unlikely that the future will resemble the past, but it would also be a mistake to ignore the past. And the record of the past 30 years is that biotechnology has been an extraordinarily fruitful and successful industry. This is remarkable, if you remember that the industry is only about 30 years old. As Judge Rader noted in his "additional views" in the *Classen* case, and Judge Moore in her concurring opinion in the *Myriad* case, biotechnology has prospered in large part because it was supported by the U.S. patent

system. And the reasons for that outcome are two-fold: technology transfer from university research under the Bayh-Dole Act, and investment in the technology because of the existence of patent protection.

As an example of the importance of university tech transfer, since the passage of the Bayh-Dole Act, 6,000 new companies were founded on university inventions, more than 4,000 new products came on the market (including 153 new drugs, vaccines, or medical devices), at least 279,000 new jobs were created just in the period between 1996 and 2007, and over $457 billion was added to the country's gross national product.

Universities and research institutes have performed the basic scientific research, and the potential to protect the practical applications of that research through patenting have provided the incentives (and the economic benefits to those universities and research institutes) for companies to commercialize them. This partnership has propelled the U.S. to the forefront of biomedicine, providing biologic drugs and diagnostic methods for important and previously intractable diseases.

These foundations of success may be negatively influenced by proposals that permit unfettered (and uncompensated) "second opinion" testing. This is because of another reality: while the Human Genome Project created the largest amount of scientific information in the shortest time in human history, in many ways it was what Bob Weinberg of MIT has called "the race to the beginning of the road." The next 50-100 years will be consumed with a much more difficult task -- understanding how this genetic information interacts with environmental factors to cause disease. And in doing this we will be faced with another reality: there will be very little "low hanging fruit" of unrecognized single-gene genetic mutations associated with human disease. Most common diseases like cancer and diabetes involve genetic and other changes in multiple genes, unlike Myriad's BRCA test and other existing genetic tests.

In other words, complexity will be the rule. And when something is complex, it is harder to reverse engineer. *That* reality produces the danger of proposals to weaken patent protection for genetic diagnostic testing. I haven't picked up a pipette in 25 years, but even I can envision ways for a company to produce a genetic diagnostic test for a multivariate disease that can be protected without patenting. Simply identify the genetic variants from the 6-12 genes involved and put diagnostic sequences on a gene chip along with probes for 10,000 other genes. Encrypt each chip so that the diagnostic patterns -- the diagnostically informative positions -- cannot be identified without the encryption key, and then provide the public with the test. No patents, no problem -- and no disclosure and no end to the ability to charge whatever a provider wants, limited only by the time it takes for someone to independently make the same discovery.

But in such a world the partnership between universities and business that fueled the biotechnology revolution is broken, because universities cannot -- and should not -- fail to disclose the results of their research. While not everything that university research has produced over the past 30 years has been patented, it has been disclosed (whether patented or not). And support for some of that research has been provided by investors and companies translating that technology from the lab bench to the clinic, and the basis for that support will be diminished if not extinguished if genetic diagnostic methods lose the ability to be fully protected.

While such a scenario could also arise under present law, there is little incentive for it to do so, since the public can eat its cake and have it too -- basic university research can proceed as it always has, being directed to science instead of technology. Important technologies have resulted from such basic research, from Cohen and Boyer's identification of restriction enzymes to Fire and Mello's siRNA; these inventions were arose unexpectedly from basic scientific research based on new biological discoveries. Such discoveries don't always have clinically or commercially useful applications, but where they do they can be protected by patenting. If that is changed, investment behavior may change, and it may not take a dramatic change in the scope of patent protection to change the incentives that exist today. Permitting "second opinion" genetic diagnostic testing for some applications of biotechnology may be enough to make patenting less attractive compared with the effort necessary to protect genetic diagnostic methods by non-disclosure.

If there were no alternatives to legislating some sort of exemption from patent infringement liability for "second opinion" genetic diagnostic tests, then perhaps public policy concerns would tip the scales in favor of some form of the legislation as has been proposed. But there are at least the following possible ways to prevent this outcome in the patent arena (and I'm sure many unexplored ways in the insurance and general healthcare space).

First, we can recognize that under Federal Circuit case law and PTO practice the written description and enablement requirements have limited the scope of medical and genetic diagnostic claims over the past decade or so -- it is unlikely that a broad claim to detecting *any* mutation associated with a particular gene for a particular disease would be granted or enforced today. So the specter of broad, overarching claims that inhibit all research on genetic mutations in a particular gene associated with a particular disease is and has been a strawman in the debate.

Second, other robust patent principles -- such as patent exhaustion -- can be employed to the problem if it arises. The Supreme Court has extended patent exhaustion principles to method claims in the *Quanta* case. Here, for example, an individual could be given the right to a "second opinion" test provide that she can show that she has obtained the first test from the patent holder or her licensee.

Third, as we heard from MPEG LA there are ways to avoid "patent thickets" even if they were to arise -- and the possibility for them to arise is low, if only because many underlying gene patents will expire. The telecommunication industry has used standard setting and other means to avoid patent thickets, and the biotechnology industry can as well.

Fourth, in egregious circumstances, the U.S. government can exercise "march-in" rights to encourage non-exclusive commercialization (although this option should be exercised sparingly).

Under any scenario in which second opinion genetic diagnostic testing is performed, a critical requirement must be that the lab that provides such a second opinion be at least as competent and provide at least as accurate a diagnosis as the patent holder or her licensee or an important reason for even considering unrecompensed second opinion testing will be unfulfilled. One of the aspects of genetic diagnostic methodology is that implementing it with actual patient samples isn't as simple as performing an experiment in a lab -- providing the required quality control is one of the things patent

protection funds, so that the public gets the benefits of genetic testing in the first place. Permitting any genetic testing without such safeguards would be irresponsible.

Finally, in addition to upsetting the settled expectations of a highly successful industry, any action to carve out an exemption from patent infringement liability for "second opinion" genetic diagnostic testing would amount to a taking that would need recompense. Any legislation or policy change that would permit such second opinion testing -- which would amount to a compulsory license -- would need to take the public cost into account. The same impetus underlying some of these proposals -- the coming age of personalize medicine and widespread genetic diagnostic testing -- will multiply and exacerbate the cost of any policy that permits someone other than the patentee from performing a patented genetic diagnostic test, and it is disingenuous not to consider the cost. We will also need to factor in the cost to the economy in general if loss of patent protection leads to job losses in states like Massachusetts and California that have a disproportionately large number of biotech companies.

In addition, these costs must be balanced with impending patent expiry, since any benefit to the public will be short lived in many cases and, if the result is unpatented but undisclosed genetic tests, any such benefit will likely be overwhelmed by increased costs from such unpatented tests.

These considerations, in my mind, make any proposal for permitting "second opinion" genetic diagnostic testing to be unnecessary, premature and ill-advised, and I urge the Office to include these reservations in its report to Congress.

Thank you.