EDITORIAL

DNA patents revisited

A bipartisan proposal to modify restraints in patent law was debated before the United States Senate Judiciary Committee this month. Immediately following the third hearing last week, leading scientists called for a study of the relevant issues by the U.S. National Academies of Sciences, Engineering, and Medicine, prior to the draft legislation moving forward (www.patenteligibility.com). This study should be initiated soon, with a short timeline, to ensure that appropriate information and analysis can inform the legislative processes that will substantially affect how the benefits of science and innovation are delivered to society.

Patents balance providing incentives to take the financial risks necessary to convert an invention into useful products with the benefits of sharing information to drive other useful inventions. Since the advent of DNA sequencing and gene identification methods, patenting human genes has been controversial. A notable example involves patents for the genes *BRCA1* and *BRCA2*, variations in which modulate risks for breast and ovarian cancer. These patents supported increased costs and hence, limited accessibility, for diagnostic tests for cancer patients and their families. In 2013, the U.S. Supreme Court ruled that these patents were invalid (*Association for Molecular Pathology* v. *Myriad Genetics*). The Myriad decision shifted the landscape not only for gene patents but also for patents on other "products of nature." The current bill is directed toward clarifying the concepts and language underlying the issues involved in patenting products of nature. It is essential that these issues be examined thoroughly and thoughtfully prior to enshrining language in law that could easily have unintended consequences.

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To avoid overly restricting research, there are certain exclusions from patentability, namely for abstract ideas, natural laws, and products of nature. However, for products of nature, exceptions have been made for identifying and isolating substances whose properties differ substantially from the source from which they were obtained. For more than a century, natural products, such as adrenaline, have been deemed patentable in their purified forms because of the enhancement of their activities through purification. Natural products have been quite important as drugs or in driving drug discovery, such as the immunosuppressive compounds cyclosporine and tacrolimus (FK506), which enabled solid organ transplantation.

Isolation of natural substances also enables "composition of matter" patents. These are valuable because they cover the material regardless of its use or the processes in which they are components. The Myriad patents involved the composition of matter of the *BRCA1/2* genes. The Supreme Court ruled that these substances were not eligible as exceptions from the product of nature exclusion because isolation of the *BRCA* genes from their chromosomal environment did not transform their character sufficiently. Moreover, the item of value was information in the gene sequences rather than the materials themselves. However, the language in the Court opinions was subject to different interpretations. Some have interpreted them as applying only to the patenting of genes, whereas others suggested that they change the scope of natural products that can be patented.

Because of the great importance of these somewhat esoteric issues for facilitating the generation of new diagnostics and drugs and for advancing basic research, it is crucial that appropriate steps be taken to guide modification of existing patent law. At this point, case law based on particular court rulings is controlling the evolution of these patent rulings. However, a more intentional approach implemented through legislation has the potential to address these issues in a more comprehensive manner. This task should be informed by a thorough process that the National Academies can effectuate—bringing together stakeholders including academic scientists, industry leaders, patent experts, and patient advocates. Striking the right balance with language that clearly conveys the intended interpretations should strengthen patent protection, bolster science, and improve societal well-being.

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