Morton in Cell & Gene: Protecting Intellectual Property In The Genomics Revolution

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PRACTICES Intellectual Property, Healthcare and Life Sciences, Patents, Life Sciences

Haynes Boone Partner Jeff Morton authored an article for *Cell & Gene* discussing the ongoing revolution in genomics, which do not fall neatly into discrete forms of IP protection.

Read an excerpt below.

We are in the midst of a revolution in the field of genomics. Twenty-plus years on from the so-called "completion" of the Human Genome Project in 2003, we are now witnessing significant advances in genomics that will have long-lasting implications in myriad disciplines, including medicine, agriculture, and biotechnology. Scientific progress has moved from a predominant focus on discrete linear nucleotide sequences to an appreciation of the beautiful complexity of the implications of these sequences such as: three-dimensional protein structures and the importance of protein-protein folding; the role of post-translation modifications such as glycosylation; and the previously undervalued importance of non-coding nucleotide sequences, such as introns.

In medicine, advances in personalized medicine, pharmacogenomics, and CRISPR-Cas9 gene editing are now moving from theory to practice. In agriculture, genomics is playing a central role in advances in sustainable agriculture, such as the development of crops that are pest and disease resistant. In the biotechnology industry, genomics is increasingly merging with artificial intelligence (AI) to foster innovations such as next-generation sequencing and improvements in related data analysis, fostered by AI advancements.

This article will look at the role that various forms of intellectual property (IP) protection have played and will continue to play in protecting key innovations in genomics.

Patents
Traditionally, utility patents have been the go-to IP tool for protecting life sciences-related innovations. In exchange for a full disclosure of the invention, the patent owner can — through a granted patent — obtain a monopoly that effectively excludes others from carrying out the same invention for a period of 20 years.1 In the life sciences arena, a period of exclusivity can be the difference between being a market leader and an unfunded company. While patent protection continues to be a hallmark of an IP protection strategy for genomics-related inventions, there are a number of legal issues that impact the utility of a pure patent protection strategy.

Patentable Subject Matter
The United States and other leading jurisdictions limit the scope of life sciences-related subject matter that can and cannot be patented. In the United States, the identification of key genomic sequences — for example, isolated human genes associated with breast cancer — when naturally occurring, cannot be patented.2 Further, and also relevant to recent advances in genomics, diagnostic methods that are viewed as merely describing a natural correlation between a biomarker and a disease state are considered to constitute unpatentable subject matter and are thus patent

ineligible.3 The increasing role of AI in genomics-related inventions adds to subject matter issues as AI-relevant algorithms, in isolation, are also typically viewed as unpatentable subject matter.

Disclosure Requirements

The classic *quid pro quo* under patent law is that in exchange for a full disclosure of the invention by the inventor, the state will grant a patent monopoly for a defined period of time. The disclosure requirement is treated seriously by the United States Patent Office and relevant courts — and an inventor cannot "hide" key aspects of their invention while simultaneously applying for related patent protection.4 These disclosure issues become very challenging when there are aspects of an invention that are — by their very nature — difficult or impossible to patent. In such an instance, an inventor needs to consider whether disclosure of the full invention, which may include unpatentable subject matter, is worth the price of obtaining patent protection on other aspects of the same invention. For example, an invention centered around building a novel gene target panel on a gene chip device, which is likely patentable per se, could be commercially compromised if the efficacy of the panel requires disclosure of AI-generated algorithms that are unlikely to be patentable in isolation. A prospective patent applicant may ultimately decide that unfettered disclosure of the AI-related algorithms could be devastating for a business to the point that the patent protection strategy is scaled back or not sought at all.

To read the full article on *Cell & Gene*, click here.