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Patent Protection or Copyright for Nucleic Acid Sequences?

Biotechnology. For many, the mere mention of the word stirs up a thought of people in white lab coats working in underground bunkers trying to create superhuman mutant weapons, with beakers of green goo bubbling in the background. But, as often is the case, reality is far less sinister. Many scientists will tell you that working in a lab typically entails moving very small volumes of clear liquids from one tiny test tube to another and occasionally generating some smelly bacterial cultures. The work rarely involves the creation of super weapons or human clones and there are never any beakers of bubbling green goo.

There is one thing that is universally true about the biotechnology industry. It is full of brilliant people who constantly are innovating. Because of that, scientists and companies alike are always on the lookout for ways to protect what they create. As a patent attorney who practices in biotechnology, I'm often called on to protect engineered nucleic acid (DNA or RNA) sequences. By "engineered," I mean exactly what you expect: DNA or RNA sequences that have been created by scientists in a lab;

products of human ingenuity that require a lot of thought and have been created for a specific purpose. I do not mean DNA or RNA that exists in nature. This traditionally is done through the patent process, which takes several years to complete and requires a lot of time, money, and effort.

However, with the US Supreme Court ruling in *Association for Molecular Pathology v. Myriad Genetics, Inc.* [689 F.3d 1303, affirmed in part and reversed in part], obtaining patent protection for nucleic acid sequences has become challenging. This decision has called into question the validity and/or enforceability of numerous US patents, and has left some wondering if it is still possible to get patent protection for nucleic acid sequences.

Can Science Be Copyrighted?

This has caused people to revisit the concept of making copyright available as a form of intellectual property protection for nucleic acid sequences. Chris Holman, a professor at the University of Missouri-Kansas City Law School, has written extensively on this topic. His first piece was published in 2011 [Christopher M. Holman, "Copyright for Engineered DNA: An Idea Whose Time Has Come," *West Virginia Law Review*, Vol. 113, pp.699-738 (2011)] and earlier this year he penned a three-part

series covering this topic for *GQ Life Sciences*. [<https://www.gqlifesciences.com/blog/category/patent-landscape/>.] However, the idea of copyrighting DNA is not new. It was first discussed in 1982 in a law review article written by Professor Irving Kayton. [<http://www.compilerpress.ca/Competitiveness/Anno/Anno%20Kayton.htm>.]

Both Kayton and Holman make compelling cases in favor of expanding copyright to cover nucleic acid sequences. One of the points they raise is that it will not require a shift in the copyright paradigm; the proper avenue for protection already exists. Critics of this point assert that copyright was created to protect things such as books and music, not something purely functional like a nucleic acid; because of this, they argue that copyright is inappropriate for nucleic acids.

Copyright Extended to Software

But, we've heard that argument before—these same critics raised it when opposing the expansion of copyright to cover software. Software is copyrightable. It also is functional. It is a code read by a computer in order to produce some useful result. Holman and Kayton argue that nucleic acids operate similarly, just in a different medium. DNA, just as software, is a code. It is a series of As, Ts, Gs, and Cs, that is read by a cell in order to generate something useful. Both Professors conduct thorough comparisons, each concluding that there are enough similarities between software and nucleic acids to warrant copyright protection for nucleic acids.

Importantly, the expansion of copyright to include software was done without amending the Copyright Act to expressly state that software is copyrightable material. Even though the Act was amended

to include a definition for “computer programs,” software was never added to the list of examples of copyrightable material. Instead, Congress considered software to be a form of “literary work” falling within the scope of an “original work of authorship.” Because of that, there was no need to amend the Copyright Act to recite “software” [See Nimmer on Copyrights §§ 2.04(C)(1), 2.04(C)(2).] Because one can think of nucleic acids the same way as one thinks of software for purposes of copyright, the Copyright Act is broad enough already to include nucleic acids. They are “literary works” falling within “original works of authorship,” just as software, and are properly copyrightable.

Nonetheless, as of the date of this post, the US Copyright Office (Office) will not register a copyright in a nucleic acid sequence. As Kayton and Holman argue, this cannot be because the Copyright Act is insufficient or unable to cover nucleic acids. It is because the Office has determined that nucleic acids are not copyrightable.

There are many who disagree with the Office and the debate

is heating up. Holman himself recently helped a private company submit an application to the Office to register a copyright in an engineered nucleic acid sequence. The application was intended to “advance the conversation on the copyrightability of DNA.” [<https://www.gqlifesciences.com/copyright-for-engineered-dna-part-3/>.] Predictably, the Office refused the registration. In response, Holman submitted a petition to the Office arguing in favor of the copyrightability of nucleic acids, which similarly was rejected.

Holman presently is writing about this experience and intends to publish a “detailed response which...refutes the Office’s stated rationale for denying registration.” [Holman, *supra*.] He hopes to garner enough interest from the biotechnology community such that someone will challenge the Office’s position in court. As for the success of such a challenge, Holman states “frankly, I think the Copyright Office would have a hard time defending its position.” [*Id.*]

I agree. It is time for copyright to be expanded to cover engineered nucleic acid sequences.

Unfortunately, for now we have to wait and see if there is a willing challenger out there who will take on the Office and settle this dispute. Until then, keep filing your patent applications!

David Walker is a partner and co-chair of the Biotech Patent Practice group at Dorsey & Whitney LLP. He is an experienced patent attorney focused primarily on the biotechnology and pharmaceutical industries. He works extensively in Northern and Southern California, as well as in Colorado and New York. His clients range from pre-funded start-ups to publicly traded companies and governmental entities. Mr. Walker’s practice includes all aspects of patent prosecution and he has extensive experience in patent procurement; portfolio management; strategic analysis; due diligence investigations relating to venture capital, partnering and mergers and acquisitions; patent licensing and commercial contracting; and freedom-to-operate, patentability, infringement and non-infringement evaluations.

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