CELL & GENE THERAPY INSIGHTS

EXPERT INSIGHT

An alternative to patents: can DNA be protected by copyright and design right law?

Beatriz San Martin & Heidi Hurdle

Historically, applications of technology that use DNA have been protected through the patent system. Many of the techniques for isolating and manipulating DNA are now considered to be routine and it has become more difficult to rely on the patent system for protection, particularly in light of recent decisions from the US Supreme Court. This is making it increasingly challenging for diagnostic and biotech companies to obtain investment as they increasingly rely on trade secrets for protection. Other types of intellectual property rights, such as copyright and design right, and the role they may play in protecting DNA have not typically been considered or asserted by owners of technology that use, manipulate or design DNA. In this article, we consider the extent to which DNA sequences and what they code may be protected by UK copyright and design right.

Submitted: Apr 21 2017 ▶ **Published**: Oct 19 2017

WHAT CAN BE PROTECTED AS A PATENT?

In the European Union, there has been some harmonization of patent law including through the European Patent Convention (to which all EU Member States are signatories) and the Biotech Directive [1]. Whilst the simple discovery of the sequence or partial sequence of a gene is excluded from patentability, if the DNA sequence is isolated from the human body or otherwise produced by means of a technical process, then it may constitute patentable subject matter, even if that chemical sequence is identical (other than perhaps at the ends) to what is found in nature [2]. The logic being that a DNA sequence in its natural environment (as opposed to, for example, synthetically derived DNA) is considered a discovery, and for public policy and morality reasons should not be entitled, on its own, to protection that could result in market

monopolies. Once a technical process or application is included, then it is no longer excluded from being patentable subject matter so long as it meets all other patentability criteria (it is new, involves an inventive step and is capable of industrial applicability).

Until recently, it was relatively straightforward to patent inventions concerning DNA sequences in the USA. In June 2013, the US Supreme Court held that merely isolated DNA sequences per se cannot be patented because DNA is a 'product of nature' though DNA manipulated in a lab (such as cDNAs) is eligible to be patented because DNA sequences altered by humans are not found in nature [3]. Since then, there has been a further US Supreme Court decision which has raised the bar even higher for enabling anything that may be considered to be a product of nature or an abstract idea to be patent eligible [4]. The current test appears to be that, for something to be patentable, besides meeting the usual patentability criteria, it must also disclose something that is significantly different from what is already found in nature. As such, synthetic DNA is not captured by this test. The US Patent Office has provided some guidance as to what may be patentable in the biotech field [5] but, it is the authors' understanding from discussions with US patent lawyers, that their application by different patent examiners is inconsistent and unreliable. Further, it is unclear what the courts will now accept as being patentable.

The current position in the US affects global patent strategy for many biotech businesses. We are aware from discussions with biotech companies and other legal professionals that it appears that a significant number are choosing to keep certain aspects of their technology as trade secrets rather than attempt the arduous process of seeking patent protection (given the uncertainty over what might be patentable). Even though patent protection might be possible in Europe, if they were to seek such protection, it would eventually be in the public domain (as is the case with all patents) and third parties would be able to compete in those regions where protection is either not sought or not possible to register. This is coupled with ever-increasing challenges for biotech businesses in finding something that they can protect through the patent system in circumstances where the relevant DNA sequences are already in the public domain and the processes for their isolation and then their use are already well understood. Although there can still be plenty of scope to identify patentable subject matter in this arena, this comes at a time when there is an explosion of new opportunities to synthesize bespoke sequences at a relatively low cost and to mix-and-match different known DNA elements into plasmids and vectors.

BACKGROUND TO UK COPYRIGHT AND DESIGN RIGHT LAW IN THE UK

Copyright

Copyright law was originally introduced in the UK to protect the printing trade against the unauthorized copying of books. Ever since then, it has developed to keep pace with the introduction of new technologies. In recent years, a great focus has been given to the application of copyright law to new media (e.g., on the internet and through various

DOI: 10.18609/cgti.2017.062

digital devices) and there have been numerous references to the Court of Justice of the European Union to determine the extent to which certain acts amount to copyright infringement (such as hyperlinking and framing content).

Copyright is not a monopoly right, but instead makes copying an infringement. It subsists in original works automatically without the need for any formality, such as registration or the deposit of instruments. Originality means that the author must have created the work through his own skill, judgment and individual effort and that it is not copied from other works [6]. Copyright does not protect ideas, but the expression of them. Protection can last for a significant amount of time: the length of protection for literary works being the life of the author plus 70 years. UK copyright law is primarily set out in the Copyright Designs and Patents Act 1988 (CDPA), which has been amended by various pieces of subsequent legislation, in particular the Copyright Directive [7]. Given the extent of the amendments to the CDPA over nearly 30 years, it is ripe for a complete overhaul. Indeed, at a seminar on developments in copyright law in early 2017, a respected UK judge had this to say in respect of the current legislation: "To call the result a patchwork quilt would be an insult to the art of quilting: [8].

Design right (unregistered designs)

Besides covering the scope of UK copyright protection, the CDPA created a new right for unregistered designs (referred to in the CDPA and this article as 'design right'), to replace copyright protection for industrial designs. The CDPA places strict limitations on the type of designs that will attract design right protection and the scope of protection for industrial designs under this design right is much narrower than was previously the situation before the CDPA. Like copyright, design right arises automatically but only lasts for a maximum of 15 years and in many cases (when the design is exploited) it will expire after 10 years. In the last 5 years of its existence, licences of right are available to third parties.

There are also other forms of protection for designs: namely (i) UK registered designs; (ii) Community registered designs; and (iii) Community unregistered design right. Their consideration is beyond the scope of this article.

Overlap between copyright & design right law

There is some potential overlap between the subsistence of copyright and design right. To avoid the situation where there is dual protection, one of the provisions of the CDPA [9] provides that it is not an infringement of any copyright in a design document or model for anything other than an artistic work or a typeface, to make an article to the design or to copy an article made to the design. In other words, in such a situation only design right applies.

This provision is potentially relevant to the form of protection for DNA sequences as is discussed below.

COPYRIGHT IN DNA: SUBSISTENCE

DNA sequences found in nature

As copyright subsists in original works, the key question is whether

a DNA sequence is a 'literary work' and whether it is 'original'. The CDPA defines a literary work as any work 'which is written, spoken or sung' and gives specific examples of 'a table or compilation' and 'a computer program' [10].

Whilst DNA molecules themselves cannot be 'literary works', their written representation is, in most cases, likely to be considered a literary work – note, however, that the authors are not aware of any cases before the UK courts that have considered this specifically. In much the same way as copyright was found to subsist in telegraph code cases in the 1800s and 1900s [11], it is arguable that a string of letters written down to represent a sequence of nucleotides (e.g. ATGC… etc.), which take their meaning from a highly specialized context, should be considered a 'literary work'. The sequence would probably need to be over a certain minimum length to enjoy protection; for example, the single word 'Exxon' was found not to be a literary work [12]. The Court of Appeal considered that a literary work was something that was intended to afford either information or instruction, or pleasure in the form of literary enjoyment, and that the word 'Exxon' was not intended to, and did not, do these things.

Other cases where the subject matter can perhaps be viewed as analogous to the position of written down DNA sequences include the following:

- Bookmaker's Afternoon Greyhound Services Ltd [1994] FSR 723: where a formula using symbols and numbers was found to be a literary work;
- Microsense Systems Ltd v Control Systems Technology Ltd noted at [1992] I.P.D. 15006; where the three-letter mnemonics comprising the language code for communication with a pelican-crossing controller was arguably a literary work.

Although a DNA sequence when written as shorthand as a series of letters to represent the nucleotides adenine, guanine, thymine and cytosine is copied from the sequence found in nature, this does not necessarily mean that the representation as a series of letters cannot be considered 'original'. The situation is perhaps analogous to that of the shorthand-writer's copyright cases where the courts considered that the fact that the nature of the subject matter is such that the author has no option but to arrive at a given result, or that no independent act of the human imagination is required for its creation, are not valid objections [13].

Accordingly, as long as the DNA sequence code is considered to be over a certain bare minimum structurally to qualify as a literary work, it is the authors' view that copyright subsists in such sequences.

Synthetic DNA

We have considered above that copyright should generally subsist in the code for DNA sequences that are wholly elucidated from what is found in nature (albeit this will be a question of fact for each situation). Turning now to synthetic DNA; the thought and care that is usually required to design a sequence (even if this is a completely automated process, such as in codon optimization), should be able to overcome the relatively low hurdle of originality. Where the synthetic DNA is based or inspired on a sequence or sequences

DOI: 10.18609/cgti.2017.062

already found in nature, so long as the DNA sequence is different to some extent from what is found in nature then that should normally pass the low originality threshold. Assuming the synthetic DNA sequence code is long enough to be considered a literary work, copyright should also subsist in such sequences.

DESIGN RIGHT IN DNA: SUBSISTENCE

For design right to subsist there must be a design within the meaning of the CDPA, which defines it as "the design of any aspect of shape or configuration (whether internal or external) of the whole or any part of an article" [14]. The design must also be original both in the copyright sense of the word, and in the sense that it is not 'commonplace' [15] in the relevant design field. Finally, the design must have been recorded in a design document or an article must have been made to the design.

The first question to consider is whether a DNA molecule is an 'article' within the meaning of the CDPA. A molecule is clearly a three-dimensional thing and 'article' should arguably be given a wide meaning in line with the policy of moving three-dimensional things into this part of the CDPA and away from copyright protection. In the authors' view, the fact that a DNA molecule cannot be seen by the naked eye should not be an impediment to it being considered an 'article' under the CDPA such that design right is capable of subsisting with regards to the DNA molecule itself, so long as other requirements are also met.

The second question is whether the written down representation of a DNA sequence is a record of any aspect of shape or configuration of the article (i.e., the DNA molecule). A sequence of nucleotides written as a series of letters on paper clearly dictates to a great extent the resulting shape of a DNA molecule and includes information about the 'internal' configuration of that molecule, although the exact 3D shape will be determined by its environment. By contrast, the link between a written representation of an amino acid sequence which codes for a protein, and the shape and configuration of that protein is more tenuous. This is because the shapes of proteins cannot be reliably or entirely predicted by an amino acid sequence. The fact that the CDPA just needs a record of "any aspect of shape or configuration of the article" may mean that the link between the written code (whether a DNA or amino acid sequence) does not need to predict the whole shape or configuration of the molecule that it encodes. Until some test cases go through the courts, it is difficult to predict whether the courts will adopt a strict or broad interpretation to this.

The final question is whether DNA sequences found in nature or synthetic DNA sequences are 'designed' (in terms of meeting the requirement for originality and not being common place). When the sequence is a straight elucidation from nature, it seems unlikely that it will be classed as a 'design' and there will be no corresponding protection under the CDPA. By contrast, synthetic DNA sequences are 'designed' in that they do not come from nature and

are a creative contribution to the shape or configuration of the molecule. But in what circumstances is DNA synthetically generated and how different does it need to be from DNA found in nature to be deemed to be synthetic and not commonplace?

For the purposes of determining whether a design is commonplace or not, regard has to be taken to the relevant technical field, which in this case would be biotechnology. It is for this reason that the authors believe that synthetic DNA molecules, whilst having a similar overall structure common to all DNA (the DNA double helix), are unlikely to be considered common place under the CDPA so long as the sequence of nucleotides, what they encode and the sequence length are sufficiently unique to make them not common place to a biotech specialist.

The authors expect most disagreement as to whether a 'design' exists in circumstances where it is difficult to clearly establish that the DNA is 'synthetic'. If mutations are induced in an organism by mutagenesis (e.g., by chemical means or exposure to x-rays), and the DNA sequences of altered genes are subsequently elucidated, are those sequences 'natural' or 'synthetic'? If hybrid plants or animals are purposefully created by man, are new DNA sequences that are created by the mixing of two different genomes 'natural' or 'synthetic'?

In summary, copyright is likely to subsist in the written down code of DNA sequences found in nature, as well as those that are synthetically derived. By contrast, design right is likely only to subsist in synthetic DNA molecules and not in naturally derived DNA molecules.

INFRINGEMENT OF COPYRIGHT

A copyright owner has the exclusive right to copy the work in the UK; copying means reproducing the work in any material form, but it must be of a substantial part [16].

DNA code

A strong argument can be made that there will be copyright infringement (subject to any statutory exceptions – see below) when the DNA sequence of letters is copied by someone on paper, or stored digitally. This is likely to be the case whether the literary work is of DNA sequences found in nature or of synthetic DNA. Such copying is increasingly likely to be of commercial value especially given the rise of engineering/synthetic biology in recent years, including businesses focussing in providing software related services in which all that is ever used and copied is the DNA code. (It will of course be necessary to demonstrate that copying has taken place; copyright does not protect against independent creation.)

DNA molecules found in nature

Although the DNA molecule made by use of the record of a DNA sequence (the literary work) may be an indirect copy of that record of a DNA sequence in the sense understood by copyright law, for infringement to occur a reproduction of a substantial part of that which is original in the copyright work is required (as noted above). What is original in the record of a DNA sequence taken from nature? If a molecule is made from a published DNA sequence, it may be difficult to argue that the original aspect of the literary work is taken because the resulting product

DOI: 10.18609/cgti.2017.062

is exactly the same as the sequence written down, albeit communicated via different medium.

In the authors' view, the position is comparable to a translator's copyright. The skill and labor goes into making the antecedent material or work available to those who may not understand or appreciate the antecedent material, and copying that involves the reproduction of the product of that skill and labor (e.g., by copying the elucidated sequence in written form) may be an infringement. But when robbed of the added skill and labor that went into elucidating the sequence, it cannot be said to be a reproduction of a substantial part of that which is original in the literary work.

The Court of Appeal's decision in London General Holdings Ltd v USP Plc [17] can be seen as supporting this analysis. In that case, the copyright work was a draft template used in relation to retailers' warranties. On the facts, the claimant had suffered no damage arising from the unauthorized deployment of the actual text of the template, as opposed to the idea it contained. Consequently, the loss did not flow from the protectable subject matter of the copyright. Applying this to a DNA sequence found in nature: there will arguably be no infringement if all that is reproduced is that sequence, even where use has been made of a representation of that sequence that itself required much skill and labor (or at least labor) to produce.

Synthetic DNA molecules

If the DNA molecule, or part of it, is considered to be a synthetic DNA sequence, we believe that there would be a strong argument that the synthetic DNA molecule (or the part that is synthetically derived) would be considered to be a design (as explained above). The consequence of this is that the making of the synthetic DNA molecule by using the record of the synthetic DNA sequence whether in digital or written down form (the literary work), would not amount to infringement of the copyright in that literary work. This is because under the CDPA it is not an infringement of copyright to make an article to the design or to copy an article made to the design (as noted above). Consequently, only design right infringement would be relevant in this situation.

INFRINGEMENT OF DESIGN RIGHT

Here we are just dealing with synthetic DNA as explained above. Similar principles to those set out above in relation to copyright apply in relation to infringement of design right. To infringe an article must be made to the design, which includes substantially to the design [18]. As the sequence is part of the originality of the design, reproducing it as a molecule would arguably infringe design right.

COPYRIGHT & DESIGN RIGHT: SUMMARY OF SUBSISTENCE & INFRINGEMENT

Table 1 summarizes the position discussed above regarding the subsistence and infringement of copyright and design right in DNA molecules and the codified sequences.

Whether copyright and design right will subsist in specific scenarios and whether such rights will be

TABLE 1

Subsistence and infringement of copyright and design right in DNA code and DNA molecules

	Natural		Synthetic	
	DNA code	DNA molecule	DNA code	DNA molecule
Copyright				
Subsistence	✓	x	✓	x
Infringement	✓	NA	✓	x due to s.51
Design right				
Subsistence	x	x	x	✓
Infringement	NA	NA	NA	✓

infringed will depend on the specific facts of each case.

EXCEPTIONS TO COPYRIGHT INFRINGEMENT

If there is found to be copyright infringement of the DNA code (whether natural or synthetic), some infringing activities would be allowed under the fair dealing exceptions to infringement. The most applicable ones are fair dealing with the copyright work for the purposes of non-commercial research and private study [19].

The scope of what constitutes research for 'non-commercial purposes' has yet to be fully explored in the courts, but it is likely that they will take a relatively narrow view of non-commercial purposes. If, for example, a post-doctoral researcher is conducting research at a university and is solely funded by the university or by a research council, then such research is, in the authors' view, likely to be considered non-commercial. That said, as universities become more commercial and attempt to protect and exploit the fruits of their researchers' labor through patents or by other means, then this position may well shift. If, on the other hand, the same researcher was to conduct research at the same university, but this time he is funded by a commercial entity, say a pharmaceutical company, then such research is likely to be deemed for commercial purposes, particularly if the commercial entity has any rights over the IP generated by such research.

Besides the fair dealing exception, the CDPA does not contain any other exceptions to copyright infringement that may prove to be a viable defence for a third party accused of infringing the copyright in DNA code.

EXCLUSIONS TO DESIGN RIGHT PROTECTION

There is no equivalent to the fair dealing exception in copyright law for design right infringement. There are, however, two specific exclusions that might be relevant. The first is the exclusion that design right is excluded in a method or principle of construction [20]. The purpose of this exclusion is to prevent design right from protecting the method of achieving a certain design. Whilst a particular synthetic DNA sequence for which design right subsists may encode a protein such that it

DOI: 10.18609/cgti.2017.062

includes information required to construct another biological molecule, the authors would argue that the sequence itself is not a method or principle of construction of the relevant design (i.e., the DNA molecule).

The second is the exclusion that precludes design right in relation to features of shape or configuration of an article that enable the article to be connected to, or placed in, around or against, another article so that either article may perform its function (the 'must-fit' exclusion) [21]. This exclusion may be more relevant in the context of proteins that interact with other proteins. So where you have signaling molecules (e.g., cytokines) that bind specific receptors to regulate specific biological activities (such as cell growth), then the parts of the signaling molecules that are bound to the receptor and serve a functional purpose are likely to be deemed to be excluded from design right protection. In the context of synthetic DNA molecules, other molecules may well bind to them (such as, for example, transcription factors) but so long as such binding is not deemed to be a specific connection or fit, the authors submit that the exclusion is less likely to apply. In any event, the exclusion would only apply to those parts that 'must-fit' and not the whole of the design. As there is no judicial guidance on this point, or indeed much of what is discussed in this article, we will only have a better grasp of how the law is likely to develop in this arena once we start seeing some cases go through the courts.

CONCLUSION

As we have discussed, when considering DNA sequences found in nature, protection is likely to be limited to copyright in the DNA code and design right is unlikely to subsist in the DNA molecules themselves. By contrast, copyright is likely to subsist in synthetic DNA codes and, moreover, design right is likely to subsist in the synthetic DNA molecules. What this means for owners of such rights is that they could stop third parties from copying DNA code that they own and synthetic DNA molecules that they have designed by seeking a court injunction and also by seeking other remedies such as damages.

The authors expect resistance in some circles against the idea that copyright might protect the DNA code (as opposed to the underlying DNA molecule). The accepted mantra is that anything related to DNA should be protected by the patent system so long as it satisfies patentability criteria and is more than just claiming the sequence per se (i.e., it is somehow isolated from the human body or otherwise produced by means of a technical process).

In 1990, the ambitious international Human Genome Project funded by, amongst others, public bodies such as the Wellcome Trust and the National Institutes of Health (NIH) set about sequencing the human genome and making the data freely available online. The aim was to provide tools for researchers to improve and accelerate our understanding of human disease and to develop new strategies for their diagnosis, treatment and prevention. Then, in 1998, Craig Venter entered the arena through his company Celera Genomics promising to sequence the genome much faster and only make the information available

to paying customers. He also expressed his intention to file many patents based on what had been sequenced.

There was a strong public view that the information derived from sequencing the human genome should be in the public domain for effective open source use and there was an outcry about Craig Venter's plans. Within days of the launch of Craig Venter's company, the Wellcome Trust announced a significant increase in funding to accelerate the progress of the project.

Similar concerns to those raised during the Human Genome Project may well be expressed now with the genome editing revolution if other IP rights are used to prevent third parties' access to DNA codes, particularly where such code relates to naturally derived DNA molecules. On the other hand, why should the skill, effort and labor that goes into decodifying DNA sequences (even of natural molecules) not be rewarded? A third party can always independently sequence and determine the DNA code for a particular DNA molecule and thereby not infringe a copyright owner's right in the DNA code – copying being an essential element in establishing copyright infringement.

When considering the term of protection and whether that is proportionate, the standard period of protection for copyright for literary works of the author's life plus 70 years could be deemed to be too long from a policy perspective, especially in relation to DNA sequences found in nature. By contrast, we believe that it will be more palatable to accept the full term of copyright protection for synthetic DNA sequences and some have suggested that the period of protection afforded to design right would be more acceptable in all situations concerning DNA, with licences of right in the last 5 years [22].

What about other sequences found in nature? This article has focused on the application of copyright and design right to DNA sequences. The same logic could, of course, be applied in respect of any other sequences found in nature or synthetically derived such as protein and RNA, as well as analogues of DNA, RNA and amino acid sequences.

This is an exciting period for engineering biology. As with other technologies, it is important that IP rights are there to provide adequate protection to reward and not stifle innovation. Whether the right balance is achieved in the application of copyright and design right law to DNA code and DNA molecules will depend on how the law is applied by the UK courts.

FINANCIAL & COMPETING INTERESTS DISCLOSURE

The authors have no relevant financial involvement with an organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock options or ownership, expert testimony, grants or patents received or pending, or royalties. No writing assistance was utilized in the production of this manuscript.

DOI: 10.18609/cgti.2017.062

REFERENCES

1. Directive 98/44/EC.
2. Article 5, Biotech Directive.
3. Association for Molecular Pathology v Myriad Genetics, Inc. No. 12-398 (569 U.S. ___ June 13, 2013).
4. Alice Corp. v. CLS Bank International, 573 U.S. __, 134 S. Ct. 2347 (2014).
5. Subject Matter Availability: www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility
6. Ascot Jockey Club Ltd v Simons [1968] 64 WWR 4110.
7. Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society.
8. JIPLP Conference on present and future of UK and EU copyright, January 2017.
9. Section 51(1), CDPA.
10. Section 3(1), CDPA.
11. Anderson & Co Ltd v Lieber Code Co [1917] 2KB 469; Ager v Peninsular and Oriental Steam Navigation Co (1884) 26 Ch D 637; Ager v Collingridge (1886) 2 TLR 291.
12. Exxon Corp v Exxon Insurance Consultants International Ltd [1982] RPC 69 CA.
13. Walter v Lane [1900] AC 539 HL; Sawkins v Hyperion Records Ltd [2005] EWCA Civ 565.
14. Section 213(2), CDPA.
15. Section 213 (4), CDPA.
16. Sections 16(3) and 17, CDPA.
17. [2005] EWCA Civ 931.
18. Section 226, CDPA.
19. Section 29(1) and section 29(1C), CDPA.
20. Section 213(3)(a), CDPA.
21. Section 213(3)(b), CDPA.
22. Modern Law of Copyrights and Designs, Laddie, Prescott and Vitoria, Chapter 21, 2nd edition.

AFFILIATIONS

Dr Beatriz San Martin[1] & Heidi Hurdle[2]

[1]Partner at Fieldfisher, London, UK.
[2]Senior Associate (PSL), Fieldfisher, London, UK.