

Robin Nott

a solicitor, now an independent consultant, and formerly a partner in Cameron McKenna, has acted in a wide range of IP matters. His clients have included companies in the pharmaceutical and biotechnology industries. He also acted for the successful plaintiffs in the seminal English copyright case *British Northrop v Texteam Blackburn* and in the copyright case *Centri-Spray v Cera*.

Danny Huntington

is a partner in the Alexandria, Virginia offices of Burns, Doane, Swecker & Mathis, LLP. Mr Huntington is involved in all phases of intellectual property law, including US and foreign patent prosecution, litigation in the Federal and State Courts, licensing, US International Trade Commission proceedings and general client counselling.

Erin Dunston

is an associate in the Alexandria offices of Burns, Doane. Her practice focuses on district court patent litigation, interferences before the US Patent and Trademark Office, patent prosecution and opinion work.

Keywords: *biotechnology, copyright, database, sequence protection, design right, contract, secrecy*

Robin M. C. Nott
3 St Peter's Square,
London W6 9AB, UK
Tel: +44 (0)20 8748 6399
Fax: +44 (0)20 8748 6696
E-mail: robin@nott.fsbusiness.co.uk

Danny Huntington/Erin M. Dunston
Burns, Doane, Swecker & Mathis, LLP, 1737 King St, Alexandria Virginia 22314, USA
Tel: +1 (703) 836 6620
Fax: +1 (703) 836 2021
E-mail: dannyh@burnsdoane.com
erind@burnsdoane.com

Database protection in the UK and the USA: What, if any, protection might those who work so hard receive?

Robin M. C. Nott, R. Danny Huntington and Erin M. Dunston

Date received (in revised form): 17th February, 2003

Abstract

This paper discusses the nature and extent of protection afforded under UK and US laws for sequence listings, with an emphasis on databases containing sequence listings.

INTRODUCTION

In recent years, the scientific community has made exponential advances in biotechnology. In particular, great insight has been made into the human genome and the genomes of other organisms of interest. Information gained by these advances holds the promise of ameliorating or even curing diseases that currently afflict millions. However, such information comes with a hefty price tag. Companies funding biotechnology research wish to reap the economic benefit of their hard work, yet may have difficulty doing so. As discussed below, laws (other than patent law, where an invention is involved) afford little, if any, protection to the databases compiled as a result of the companies' research. This lack of legal protection makes the companies' abilities to structure licences and similar deals of greater importance, whereby effort in creating the databases is rewarded.

The state of international copyright law was described as 'unsettled' by Richard Lambert, a senior intellectual property lawyer with the US National Institutes of Health, in an article by Biopeople;¹ and another expert, who preferred to remain anonymous, described it as 'a mess'. This paper addresses some of the problems of protecting sequence listings in biotechnology databases in the UK and in the USA. It may not make very happy reading for some.

This paper does not consider patent protection. That would be an article in itself. In practice, some of the problems detailed below may be dealt with by the existence of patent protection. The availability of patents for biotechnological inventions in the EU should have been settled by the Biotechnology Directive,² which was due to have been introduced into national laws by 30th July, 2000. As everyone knows, most of Europe is still arguing about (a) whether they will implement it at all, despite the fact that under European law they were obliged to do so nearly three years ago; and (b) if they do implement it, on what terms? The authors happily report that the UK is one of the countries that has fully implemented the Directive. In the USA, patents are available to biotechnological inventions, but such inventions must meet the stringent requirements of US patent law. The written description, enablement and utility components of US patent law currently pose particular difficulty to biotechnology inventions.

This paper addresses only the protection available to someone who has elucidated a sequence listing for a biotechnological product: a single nucleotide product (SNP), an expressed sequence tag (EST), a protein, a genome. The UK portion focuses on the position in England, although the position is likely to be the same elsewhere in the UK.³

Under English law copyright would subsist in a sequence listing of sufficient length, but there is a threshold

Much of the law is uncertain in relation to biotechnology simply because the subject matter is so new

This paper does not address questions of fair dealing or experimental use. While they may be relevant in development situations, they are not relevant when a product is being produced commercially. This paper also does not deal with the ownership of rights. That is a matter for national law. The most common situation in both the UK and the USA will be that the work is done by an employee working for his employer. In general, the law provides that any resulting rights shall belong to the employer, although there are variations on that rule.

While many of the laws that may apply are well established in relation to conventional matters, much of the law is uncertain in relation to biotechnology. This uncertainty exists simply because of the relative novelty of the subject matter and the fact that there has not yet been an opportunity for the Courts to consider the matter. In some areas, however, such as the EU Database and Design Right laws, the law is so new that its application generally is unclear. As a result, this paper represents the views of the authors. Although those views are in accordance with what is generally understood to be the position, and so to that extent 'conventional', final answers to some of the points raised will have to wait the outcome of proceedings before the House of Lords/Privy Council in the UK, the European Court of Justice and the US Courts.

Given that the laws of the UK and the USA are quite different, this paper deals first with the UK and then with the USA.

PROTECTION IN THE UK

In English law there would appear to be five possible forms of non-patent protection available: copyright, protection under the EU Database Directive, designs, contract and secrecy. They are considered in turn.

Copyright

The right to copyright

Under copyright law⁴ an author is protected from having the whole or a

substantial part of his or her original literary works copied. (That position appears to apply substantially worldwide under the various International Copyright Conventions⁵ that are in force.) English law has always required a very low threshold of originality for copyright protection and there is no doubt that under English law copyright would subsist in an original sequence listing of sufficient length.

Although the originality threshold is low, there is a threshold. For example, in the *Exxon*⁶ case the English Court held that the word 'Exxon', which had no doubt been developed by advertising agents and marketing consultants after enormous effort, deliberation and expense, was not sufficiently original to benefit from copyright protection. By analogy, a short sequence listing, an EST, an SNP or a codon, might not be entitled to copyright, and so would not receive protection. However there can be no doubt that a substantial sequence, taking the extreme the sequence for the human genome, would enjoy copyright protection.

The protection given by copyright

Copyright is a right to prevent copying of the copyrighted work; and this right extends to preventing making translations of the work – putting the work into another format. In computer terms, converting a high-level language into a lower, operating language. In relation to the copyright in a database making 'an arrangement or altered version of a database or a translation of it.'⁷

Infringement of copyright

So how is the copyright in a sequence listing to be infringed? Obviously it must be copied. But how may this occur? Certainly if a copyist photocopies or copies out the sequence listing there will be infringement. Arguably there would be infringement by making the physical (ie biological) sequence by assembling the constituents of the sequence one by one – but that may be an unlikely scenario.

If design right applies, there will be no copyright protection

There would certainly not be infringement if another investigator identified the sequence for himself and recorded it. There would be no copying; in exactly the same way as the copyright in a painting of a flower would not be infringed by independently making another painting of the same flower.

Where might the boundary between infringing copyright, and not, by making the physical (ie biological) sequence, lie? There appears to be no relevant authority. Certainly, there would have to be a reproduction of the whole or a substantial part of the sequence as recorded in the copyright work. What might be required for infringement might well depend, not only on the amount of material taken, but on the nature of the sequence (or partial sequence) being considered, and the reason for the taking. If the alleged copyist was seen to have behaved improperly, a court might be more inclined to find that he had infringed.

If the copyist is seen to have behaved improperly, a court might be more inclined to find that he had infringed

For example, if the copyright sequence is an artificial sequence, that is one not found in nature, which has beneficial properties, as an improved antibiotic perhaps, and the alleged copyist has used the copyright record of the sequence as the basis from which he or she constructed his or her own sequence, perhaps using a method described in the document recording the sequence as well, a court might very well find copyright infringement. Conversely, if the alleged copyist has merely used the information that the modified sequence provides an improved antibiotic and generated other modified sequences, based on the same natural or artificial sequence, perhaps even obtained from the same source but otherwise owing nothing to the copyright sequence, the author does not believe that a Court would find copyright infringement. It would be hard to say that there had been any copying of the sequence recorded by the copyright owner; merely that there had been use of the information that he or she had developed, a suitable subject for patent, rather than copyright, protection.

There is a further possible difficulty in relying on copyright, design right. The arguments as to why design right may apply to a molecule are set out in a later section. If those arguments are correct, and design right does apply to a molecule, design right law may prevent any reliance on copyright. Under design right law, 'It is not an infringement of any copyright in a design document . . . recording or embodying a design 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'; '“design” means the design of any aspect of the shape or configuration . . . of the whole or any part of the article' (the identical definition as that for a design under that section of the Act dealing with design right, below); and '“design document” means any record of a design whether in the form of a written description, . . . , data stored on a computer or otherwise.'⁸ This provision, if it applies, would exclude from copyright protection anything which was a design which, if the arguments below succeed, includes a molecule. (For a full explanation see the section entitled 'Designs and design right: UK design right' below.)

The EU Database Directive

The EU Database Directive⁹ gives copyright protection to a selection or arrangement of the contents of a database which constitutes the author's own intellectual creation;¹⁰ and also protects the substantial investment in obtaining, verifying or presenting the information in the database.¹¹

The copyright protection, as might be expected, is the right to prevent reproduction (copying) in any form of the whole or part of the copyright work; and also to prevent translation, adaptation, arrangement or any other alteration, distribution to the public, and any communication, display or performance to the public of the database.¹² In the UK that protection is given by the Copyright, Designs and Patents Act 1988. (Note that the words 'whole or part' in the Directive

govern only the act of reproduction; while under UK law¹³ a person infringes copyright if he or she copies, etc., all or a substantial part of the database.¹⁴ It remains to be seen whether translation, etc., of the whole will be required for infringement, but as the Directive is apparently not intended to cut down existing national protection, probably not.)

The protection of the investment in the information in the database is a *sui generis* right allowing the owner of the right in the database to prevent 'extraction' or 're-utilization', the transfer to another medium or the making available to the public of all or a substantial part of the contents of the database.¹⁵ The right runs for 15 years 'from the 1st January of the year following the date of completion.'¹⁶ 'Any substantial change . . . including any change resulting from the accumulation of successive additions, deletions or alterations, which would result in the database being considered to be a substantial new investment . . . shall qualify the database resulting . . . for its own term of protection.'¹⁷ So updates of the database qualify for a new period of protection.

However, in considering what is a 'database' it must be remembered that the Directive was designed to protect assemblies of individual items of information, for example a 'Good Food Guide' to London restaurants. So the definition of 'database' is somewhat limited in scope to: 'a collection of *independent* works, data or other materials arranged in a systematic or methodical way and individually accessible'¹⁸ (emphasis added).

Again there appears to be no authority as to what constitutes an 'independent' work. However, the elucidation of a substantial piece of genetic information may not be entitled to protection as a database. The whole human genome is, arguably, a single independent work, just as a book would be a single independent work, and so not of itself entitled to protection as a database (although a compilation of a number of genomes or a

number of books might). Indeed the human genome has been described as 'The Book of Life'. This conclusion would seem to apply regardless of whether the genome has been decoded by a single team or, as in practice, by a large number of teams. They have simply produced a single work. It can hardly be said that each team's work is a product that is independent of all the other teams. The combination of their work to produce the whole is what is important. Note also that the Database Directive provides that it is the creator of the [Data]base who owns the right, not the originator of the information.¹⁹ So the copyrights in a sequence and any Database Right may be owned by different people.

(In passing it should be noted that 'the compilation of several recordings of musical performances on CD does not come within the scope of [the Database] Directive, both because, as a compilation, it does not meet the conditions for copyright protection and *because it does not represent a substantial enough investment to be eligible under the sui generis right*'²⁰ (emphasis added). In the author's view that supports his opinion about the lack of protection available under the Database Directive.)

A series of sequences from, say, the same genome which had been combined on a single record (and suitably accessible) might be argued to constitute a series of independent works. However, if the whole genome cannot get database protection, the author cannot see a part of it being allowed such protection; and in any event the compilation of such information on a single record (analogous to a CD) is unlikely to represent a sufficiently substantial investment to be eligible under the *sui generis* right. Even the assembly of a number of genomes on to a single record might, arguably, not satisfy the investment criteria.²¹

If a series of sequence listings qualifies for protection under the Directive, then there will be infringement if the contents of the database are extracted or reutilised.²² However, as with copyright, there will

The Database Directive was designed to protect a 'Good Food Guide'

There seems to be no reason why a molecule should not be an article for UK design right law

The protection of the Database Directive is not available to those who are not EU nationals, residents, companies or firms

have to be extraction or reutilisation of the information of the database itself and independent work to develop the sequence will not be infringement.

Another difficulty in respect of the Database Directive is that only individuals that are nationals of or habitual residents of, or companies or firms formed under the laws of and having a genuine business presence in, a member state are entitled to protection under the Directive, unless specific agreements are made with other countries.²³ So far as the writer is aware there are no such agreements in place or proposed with any other countries, so limiting the protection of the Directive to EU nationals, residents, companies and firms.

So it appears that the Database Directive will not be available to prevent copying of sequences either, and is certainly not available to those who are not EU nationals, residents, companies or firms.

Designs and design right

UK design right

In English law, and so far as the author is aware, in English law only, protection against copying is given, without registration, to any 'original design'.²⁴ 'Design' means the design of any aspect of the shape or configuration (whether internal or external) of the whole or part of an article²⁵ but 'does not subsist in . . . features of shape or configuration of an article which . . . enable the article to be connected to, or placed in, around or against, another article so that either article may perform its function'.²⁶ 'A design is also not "original" . . . if it is commonplace in the design field in question at the time of its creation'.²⁷

The questions arise:

- Is a molecule an article? There seems to be no reason why not.
- Is the design original (in the sense of being new in the copyright sense; and not being commonplace)? It is suggested that a molecule existing in

nature is not original, it has been there for many years (perhaps many millennia); however there would seem to be no reason why a newly designed molecule might not be original, provided it was sufficiently different from the natural molecule and every pre-existing synthetic molecule.

- Are any of the exclusions of design right relevant? While it would be possible to design molecules that were not to be connected to, or placed in, around or against, another (molecule), in practice molecules in biotechnology will almost always be created so that they will interact with another molecule in some way: for example as a probe, or at a binding site to inhibit some biological action (in a drug, for example). So the binding site in any such newly designed molecule will be excluded from design right protection by virtue of the exclusions from design protection in S 213 (3). The rest of the molecule could benefit from design right protection, subject to it being 'original'. It is not clear how valuable that protection would be. If the rest of the molecule is suitably original to have design right protection it will probably be entitled to patent protection, which, as it prevents any making of the molecule, not merely copying, is far more valuable. In practice the rest of the molecule will frequently be the functional section of a known marker or drug, will not therefore be 'original', and so will not be entitled to protection. If it is a variant of a known molecule interesting questions will arise as to whether some part (or all) of the variant is 'original' for design right purposes, but any protection given may be easy to design round by re-engineering the original molecule.

For practical purposes there seems to be no, or at best very limited, practical protection available for sequence listings of commercial utility under design right.

National and community-wide design protection is available to designs that 'are new and have individual character'

EU design protection

European law also gives monopoly protection (that is the right to prevent third parties using the design whether they copy the design or develop it independently) for designs under the Design Directive²⁸ and the Design Regulation.²⁹ Under the Directive national laws on Registered Design are to be harmonised to give a monopoly protection to a qualifying design for up to 25 years from the date of filing of the Design.³⁰ The Regulation creates Community-wide rights, both an unregistered design right (which protects qualifying designs against copying only for three years from the date when the design was first made available to the public within the Community³¹) and a Registered Design Right (which gives monopoly protection to a qualifying design for up to 25 years from the date of filing of the Design³²). [It is not within the scope of this paper to discuss the details of the dates from which protection runs and the provisions for priority and grace periods available for designs, nor the problems of complex products and the protection which may or may not be available to features of the design relating to joining the design to other articles. The sections that follow must be read in that light; and the legislation consulted for the details.]

All three rights protect designs, defined as 'the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.' Product means 'any industrial . . . item'.

A design shall be protected 'to the extent that it is new and has individual character'. 'A design shall be considered new if no identical design has been made available to the public'. 'Designs shall be deemed to be identical if their features differ only in immaterial details', and 'to have individual character . . . if the overall impression [the design] produces on the informed user differs from the overall impression produced on such a user by

any design which has been made available to the public'. 'In assessing individual character, the degree of freedom of the designer in developing the design shall be taken into consideration.'

'A design right shall not subsist in features of appearance of a product which are solely dictated by its technical function.'

Can the European Design Rights protect sequence listings? The situation is not clear. The rights are relatively new. Indeed applications for Registered Community Designs were only possible as of 1st January, 2003, so at the date of writing no such Designs have issued. It does not seem that the rights have been used in an attempt to protect a sequence listing. What follows is necessarily speculative.

Is a sequence listing 'an article?' Clearly the listing itself is not; but the molecule or part of the molecule that is to be used commercially will be the product of a commercial process and be an industrial item. So that the whole or part of that product should be entitled to protection; and in particular for a molecule, its contours and shape – the disposition of the elements in the molecule.

Note that under the European law there is no requirement for any artistic element such as UK lawyers have become accustomed to in UK Registered Designs, although there are references to parts being visible. This paper assumes that such visibility does not have to be visibility to the unaided eye, which accords with the definition of 'article' and the comment in the Design Directive that 'protection is conferred . . . for those design features . . . which are shown visibly in an application [ie, on a piece of paper], and made available to the public by way of . . . the relevant file.'³³ The same requirement appears to apply to the Design Regulation which requires '[t]he substantive provisions of [the] Regulation . . . [to] be aligned with the respective provisions in [the Directive]'.³⁴

Is the molecule 'new' and does it have 'individual character'? To be 'new' the

There is no requirement for any artistic element

molecule must not have been made available to the public. So many molecules will not qualify because they will have been so made available. But a new synthetic molecule will not have been made available and so would qualify as new, at least. The further question arises as to whether a molecule that has existed in nature, but has not previously been identified, can be 'new'. In patents a natural molecule, previously unknown, can be patented if an industrial use can be found for it. By analogy a newly discovered molecule will not have previously been made available to the public and should be entitled to design protection if it has a new design.

Will that new molecule have individual character, that is will 'the overall impression it produces on the informed user [differ] from the overall impression produced on such a user by any [molecule] which has been made available to the public'. That is a question of fact, but in some cases the molecule will have the necessary individuality. What is not clear is what degree of individuality is needed. For example, will a new synthetic penicillin molecule be sufficiently individual, given that many penicillins are known? In many cases the similarities between molecules in the same 'family', and even with molecules in different 'families', will be sufficient that a new molecule will not have the necessary individuality. However, in some cases certainly the new molecule will have the necessary individual character. Where the line will be drawn will only be clearer after a number of actions have been decided.

'A design right shall not subsist in features of appearance of a product which are solely dictated by its technical function.' However it must be rare that all the features of a molecule will be dictated by its technical function. For example, the penicillins must have the penicillanic acid grouping; but there may be considerable freedom in the design of the rest of the molecule. So not all the design features will be *dictated* by technical function. There will be some design freedom.

So in some cases new molecules, not

previously made available to the public, will be entitled to design protection under the EU legislation. As Registered Design Rights give monopoly protection for 25 years they may be an attractive addition to patents, notwithstanding that they are likely to be limited to specific molecular shapes and molecules 'which [do] not produce on the informed user a different overall impression'.³⁵ The unregistered Design Right is unlikely to be of any great value since it lasts for only three years and can prevent only copying.

Contract and secrecy

Clearly it is possible to protect the information in a sequence listing by contract with those to whom the listing is disclosed, or by keeping it secret and not disclosing it at all. As to the former, the obligations of confidence will, in practical terms, normally only bind the person with whom the contract is made.³⁶ It is not usually practical to expect a series of contracts to be developed with successive people who acquire the knowledge; and even in so far as the contractual framework is in place there will inevitably be problems of enforcing the contract down the chain (notwithstanding any help which may be given by the provisions of the Contracts (Rights of Third Parties) Act 1999).

Even if work on a sequence is to be done by a single organisation for a limited purpose, the ultimate goal is likely to be a commercial result which makes the information public.

As to secrecy, while it may benefit a pharmaceutical company while it works on particular information in-house, it will not benefit a small research company or an university that wants exploit the work it has done in elucidating a sequence. Contract may be the only solution. In any event, it is not desirable that laboriously and expensively acquired data should be kept secret. Better that it be made available for use, but subject to there being a reasonable reward for the producer.

Neither contract nor secrecy prevents a third party identifying and using the

It is not usually practical to develop a series of contracts with people who acquire the knowledge down the chain

Once a product is marketed secrecy goes out of the window

Facts are not copyrightable in the USA

US copyright law no longer rewards hard work

Patent protection for biotechnology database content is difficult, potentially impossible, to obtain

Copyright protection for biotechnology databases is also inadequate

US copyright extends only to the particular selection or arrangement of a database

sequence itself, which is probably just as it should be. Once a product is marketed any secrecy goes out of the window, of course, and the world is free to use the information.

PROTECTION IN THE USA

In the USA, one may call upon the copyright laws (laws generally less complex than the UK laws described above) to protect original works.³⁷ Unlike the patent laws, which require novelty, utility and non-obviousness, the copyright laws require only that the work be original and fixed in a tangible medium of expression from which it can be communicated.³⁸ A copyright owner, subject to certain exceptions,³⁹ has the exclusive right to reproduce the work, prepare derivative works, to distribute copies of the work, and to perform the work publicly.⁴⁰ The duration of copyright in the USA is the life of the author, plus 70 years.⁴¹

In many settings, one may seek copyright protection in lieu of patent protection because, for example, the subject matter may be original and fixed in a tangible medium, yet not sufficiently novel, useful or non-obvious on its own to warrant patent protection. One such setting is that of a biotechnology company which has expended great time, money and effort to discover genetic information and to compile the information into an automated database. Because such genetic information may not, by itself, be novel or useful, companies may attempt to turn to the copyright laws in an effort to protect their hard-earned information.

Unfortunately, such companies may be dismayed by the protection afforded under US copyright law. This is because US copyright law no longer rewards hard work alone. Instead, the aspect now rewarded by US copyright law is originality. Therefore, to determine whether biotechnology databases⁴² enjoy copyright protection is to determine whether the databases are original.

An automated database may be viewed as having two parts: the data contained in

the database, and the overall database itself. Viewing the inquiry this way, one recognises quickly that often the first part of a database – underlying data – is fact. Facts, under US copyright law, are not copyrightable.⁴³ This is because facts do not owe their origin to an act of authorship.⁴⁴ The distinction is one between creation and discovery: The first person to find and report a particular fact has not created the fact; he or she has merely discovered its existence.⁴⁴

For nearly a century there was an exception to this rule – US copyright law rewarded the efforts of those who compiled facts under the ‘Sweat of the Brow’ doctrine.⁴⁵ Copyright protection was granted for the underlying facts and ideas used by an author if there was sufficient effort and expense used in generating the information.⁴⁶ However, the highest US Court, the Supreme Court, disposed of this doctrine in 1991. In a case involving two competing telephone directory publishers, the Court held that the names, towns and telephone numbers in the directories were uncopyrightable facts, and that ‘factual compilations [are] eligible for copyright if it features an original selection or arrangement of facts, but the copyright is limited to the particular selection or arrangement.’⁴⁷

While it may seem unfair that much of the fruit of the compiler’s labour may be used by others without compensation, the Court explained that the primary objective of copyright is not to reward the labour of authors, but to promote the Progress of Science and useful Arts. This, according to the Court, is the essence of US copyright.⁴⁸

The demise of the Sweat of the Brow doctrine poses a formidable problem for biotechnology companies trying to protect their databases. Copyright protection will extend only to portions of the second aspect of a database, ie the particular selection or arrangement of the database.

Addressing the second component first, computerised databases do not initially

The protection for sequence listings and biotechnology databases appears to be depressingly ineffective

organise information into any definite 'arrangement' because of the nature of computer data storage.⁴⁹ Moreover, even the 'arranged' output from a database is not eligible for copyright protection.⁵⁰ Courts in the USA have held that the mode of arranging information by the computer is a procedure, process, system or method of operation – all of which are excluded from protection under US copyright law.⁵¹ In practice, a definite, physical arrangement of information in a database would severely decrease the utility of the database.⁵²

Faced with only the 'selection' element of potential copyright protection, a biotechnology company may consider selecting certain types of information to include in its database. For example, a company could select only sequences that share a certain region or are found in certain tissues. However, this runs contrary to the primary goal of providing a thorough database. 'It is ironic, then, that only the less useful database receives copyright protection because it is the only database with enough 'selection' to warrant coverage.'⁵³

Limiting content to obtain copyright protection reduces the utility of a database

In sum, for a biotechnology company to receive protection of its automated database, it must select the contents of its database carefully. Even then, copyright protection will extend only so far as the original selection and arrangement of the database.

Alternatives to copyright are similarly inadequate

Owing to the thin copyright protection afforded databases, some have tried to protect their creations in other ways. The most common copyright alternatives are state misappropriation, contract⁵⁴ and trade secret laws.⁵⁵ Unfortunately, misappropriation claims are likely to be pre-empted by federal copyright law.⁵⁶ Contract claims are more likely to succeed,⁵⁷ but may be thwarted by the Commerce Clause of the US Constitution and are difficult to enforce.⁵⁸ Trade secret law is also an unacceptable substitute for copyright law because databases are normally intended to disseminate information to many users. Such dissemination, of course, ruins the

'secret' nature of potential trade secret protection.⁵⁹

CONCLUSION

Outside the protection given by patents the protection available for sequence listings and biotechnology databases in both the UK and the USA appears to be depressingly ineffective. This, by itself, is troubling in light of the effort and expense associated with creating such listings and databases.

It is the authors' view that consideration should be given to making a right available to protect the listings from copying (it should not be a monopoly) for a limited period of time to allow the person who elucidated the structure a reasonable opportunity to earn a reward for his or her efforts, perhaps to recover the costs of the sequencing. If the authors are correct that no single legal avenue provides adequate protection, development of a new right should be explored. Such a right might be limited to a right to be paid for the use of the sequence information, to allow the discoverer a reward without allowing him or her to sterilise the fruits of their work, on the basis that they have done no more than produce, albeit at great expense, information that can, in theory at least, be discovered by anyone. Nevertheless, due consideration must be given to how such a right would mesh with existing protection for sequences, eg patents, to ensure that conflicts would be minimised and the proliferation of new intellectual property rights minimised.

© R. M. C. Nott 2003

© R. D. Huntington 2003

© E. M. Dunston 2003

References

1. McCoy, H. D. III (2000), 'Copyright confusion: The riddle of biotechnology database copyright', *Biopeople*, Autumn, pp. 36–41.
2. Directive 98/44/EC.
3. The article refers sometimes to English law and sometimes to UK law. This has depended on

- the basis of the law to which we refer. English judge-made law will strictly apply only in England. Unless there is a relevant House of Lords/Privy Counsel decision, Scottish and Northern Ireland judges can, and do, differ from their English brethren. Even if the House of Lords or the Privy Counsel has given a relevant decision, it is not strictly binding on courts that do not appeal to that judicial body. In practice, of course, since the House of Lords and the Privy Counsel are the same individuals in different roles, a decision of one body is usually binding on the other, and so on courts which are subordinate to that other. Where UK law is referred to, the basis of the law is statute, binding throughout the UK; although even here it sometimes happens that judges in different jurisdictions differ.
4. Copyright, Designs and Patents Act 1988.
 5. The two most important international Copyright Conventions are the Berne Convention, which is now the dominant Convention since the USA became a party, and the Universal Copyright Convention.
 6. *Exxon Corp v Exxon Insurance Consultants International Ltd.* [1982] Ch 119 CA.
 7. Copyright Designs and Patents Act 1988 S. 21 (3) (ac) introduced by the Copyright and Rights in Databases Regulations 1997 (SI 1997/3032).
 8. Copyright, Designs and Patents Act 1988 S 51.
 9. Directive 96/9/EC of 11th March, 1996. Member states had until 1st January, 1998, to implement it into national law.
 10. Database Directive Article 3.
 11. Database Directive Article 7.1.
 12. Database Directive Article 5.
 13. The Database Directive has been enacted in English law by the Copyright and Rights in Databases Regulations 1997 (SI 1997/3032) which amended the Copyright, Designs and Patents Act 1988 and came into force on 1st January, 1998, but with certain retroactive provisions.
 14. Copyright, Designs and Patents Act 1988 S 16, particularly Ss 16 (1) and (3).
 15. Database Directive Article 7.2.
 16. Database Directive Article 10.1.
 17. Database Directive Article 10.3.
 18. Database Directive Article 1.2.
 19. Database Directive Article 4.
 20. Database Directive Recital (19).
 21. For a contrary view on the protection given to databases by the Database Directive: see [2001] EIPR 361 Jasper A. Bovenberg 'Should Genomic Companies set up Databases in Europe? The E. U. Database Directive Revisited'.
 22. Database Directive Article 5.
 23. Database Directive Article 11.
 24. Copyright, Designs and Patents Act 1998 S 213 (1).
 25. Copyright, Designs and Patents Act 1998 S 213 (2).
 26. Copyright, Designs and Patents Act 1998 S 213 (3).
 27. Copyright, Designs and Patents Act 1998 S 213 (4).
 28. Directive 98/71/EC dated 13th October, 1998, which was incorporated into UK Registered Design law on 9th December, 2001.
 29. Regulation (EC) No. 6/2002, dated 12th December, 2001. The unregistered design protection came into force on 6th March, 2002; and the registered design right protection was available on 1st January, 2003, through the Office for Harmonisation in the Internal Market, Trade Marks and Designs (OHIM) in Alicante.
 30. Incorporated into UK law by amendments to the Registered Designs Act 1949.
 31. Article 11.1 Design Directive.
 32. Article 12 Design Directive.
 32. Recital (11) Design Directive.
 34. Recital (9) Design Regulation.
 35. For an article reaching a similar conclusion in relation to the protection of aptamers see Sampson, T. (2002), 'Aptamers and SELIX Part 2: Protecting IP rights', *CIPA J.*, Vol. 31 p. 377 at p. 382.
 36. This statement is not absolutely true. People acquiring information in circumstances of confidence may also be bound by that confidence; but it can be a difficult case to prove. It is an even less satisfactory and unreliable way of achieving protection than a series of contracts. The authors cannot envisage a prudent businessperson being willing to commit money to a substantial investment in developing a sequence listing relying solely on the protection available from implied obligations of confidence.
 37. Today, Copyright in the USA exists from the moment that the original work of authorship is fixed in a tangible medium. Prior to 1989, however, it was necessary to affix a copyright notice on any published copy of the work. See Copyright Act of 1976. Copyright notice consists of the symbol ©, the word 'copyright', or the abbreviation 'Copr.' 17 USC. §401(b). While copyright notice is no longer essential, no action for copyright infringement may be instituted until the copyright is registered. 17 USC §411(a).
 38. 17 USC §102.

39. 17 USC §§107–121.
40. 17 USC §106.
41. 17 USC §302(a) (this is the duration for works created by a single author on or after 1st January, 1978).
42. The US Copyright Office defines automated databases as 'a body of facts, data, or other information assembled into an organized format suitable for use in a computer and comprising one or more files.' While databases are not mentioned specifically in the copyright statute, 'the legislative history indicates that Congress considered computer databases and compilations of data as "literary works" subject to copyright protection.' US Copyright Office, Library of Congress, Circular 65, Copyright Registration for Automated Databases (June 1999), which may be found at URL: <http://www.copyright.gov/circls/circ65.html#definition/>.
43. See *Feist Pubs., Inc. v. Rural Tel. Serv. Co., Inc.*, 111 S. Ct. 1282, 1288 (1991).
44. See *Feist*, 111 S. Ct. at 1288.
45. See *Jeweler's Circular Publ'g Co. v. Keystone Publ'g Co.*, 281 F. 83 (2nd Cir.), cert. denied 259 US 581 (1922) ('A man's name, his occupation, his place of business, and his residence are none of them subjects of copyright. . . . [But the] man who goes through the streets of a town and puts down [such information] . . . produces by his labor a meritorious composition, in which he may obtain a copyright, and thus obtain the exclusive right of multiplying copies of his work').
46. See *Jeweler's*, 281 F. 83 at 94–95.
47. See *Feist*, 111 S. Ct. at 1290, 1293 (explaining that the copyright statute requires three elements for a work to qualify as a copyrightable compilation: '(1) the collection and assembly of pre-existing material, facts, or data; (2) the selection, coordination, or arrangement of those materials; and (3) the creation, by virtue of the particular selection, coordination, or arrangement, of an "original" work of authorship').
48. See *Feist*, 111 S. Ct. at 1289–1290 (explaining application of the idea/expression or fact/expression dichotomy to factual compilations).
49. See Jeffrey C. Wolken, Note: *Just the Facts, Ma'am. A Case for Uniform Federal Regulation of Information Databases in the New Information Age*, 48 SYRACUSE L. REV. 1263, 1276 (1998) (explaining that a 'computer physically stores data at random on a computer diskette, CD-ROM, or optical diskette using the computer's operating software. Consequently, the information in a computer database is not physically 'arranged' in any discernible manner') [hereinafter *Wolken*].
50. *Wolken*, at 1277 (stating that a database's operating software arranges information in a systematic way only after a user selects certain parameters. The computer's search engine then sifts through information in the database for entries that match those parameters. Only at this point does the computer arrange the information in a meaningful format, such as alphabetically, chronologically, etc. Because the output is not related to the arrangement of the database itself, the author cannot attribute the 'arrangement' to the underlying database).
51. King, S. H. (2001), 'Are we ready to answer the question?: *Baker v. Selden*, the post-Feist era, and database protections', 65 *J.L. & Tech.*, 68.
52. *Wolken*, at 1277 (explaining that when data are stored in this fashion, the entire database must be searched completely to find discrete information).
53. *Wolken*, at 1279 (stating that a database that contained only the phone numbers and addresses of Asian-American businesses in a specific geographic location had enough selection to receive copyright protection).
54. Several US companies have licensed their biotechnology databases to others by way of contract. Generally, these companies receive a flat fee for the license, and/or payments based on clinical trial milestones that result from the use of their databases, and/or royalties on sales of products that result from use of their databases. Such companies include Incyte (URL: www.incyte.com), Celera (URL: www.celera.com) and Human Genome Sciences (URL: www.hgsi.com).
55. *Wolken*, at 1283; see Alexander K. Haas (2001), 'The Wellcome Trust's disclosures of gene sequence data into the public domain & the potential for proprietary rights in the human genome', 145 *Berkeley Tech. L.J.*, 16.
56. *Wolken*, at 1283–1285 (explaining that Section 301 of the Copyright Act pre-empts state laws which grant legal or equitable rights that are equivalent to any of the exclusive rights within the general scope of copyright and explaining how state misappropriation claims mirror rights given by the Copyright Act).
57. See, eg, *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1454 (7 Cir. 1996); *Taquin v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1501 (5 Cir. 1993).
58. *Wolken*, at 1285–1287 (indicating that a database producer could gain protection by contracting with the end-user of the information for use of his database for a pre-set fee. The contract could specify that the user could not make any unauthorised copy of the database or use the information in the database in any manner that would hinder the producer's market for the database).
59. See *Wolken*, at 1289–1290.