

DNA Music: Intellectual Property and the Law of Unintended Consequences

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Patent regulation provides numerous examples of how policy decisions have consequences that run counter to what was intended. One reason that unintended consequences ensue arises from the fact that when powerful and organised business interests consider that a new reform inhibits their economic appropriation opportunities, they seek to make the perceived inadequacies of the law less harmful to their interests. They may achieve this through alternative legal means or by the adoption of new technologies. For certain reasons, regulating DNA patenting is especially vulnerable to unintended consequences. For businesses, one possible alternative to patents is to encode DNA sequences as music and use copyright and trade secrecy rather than patents. Of course, such alternative means of protection can have their own unintended consequences. If we are right in predicting that if molecular biology patenting is suppressed more and more, the legal and technological measures that lock up information will become increasingly attractive to industry, then one should tread very cautiously when reforming the patent system in this field.

Key words: intellectual property, DNA patenting, biotechnology

The law of unintended consequences tells us that “actions of people – and especially governments – always have effects that are unanticipated or ‘unintended’” (Norton, nd). Patent regulation provides numerous examples of how policy decisions have consequences that run counter to what was intended by the makers or supporters of those decisions. One reason that unintended consequences ensue arises from the fact that when powerful and organised business interests consider that a new reform, or

the blockage of one they desire, inhibits their economic appropriation opportunities and they are unable to influence policymakers, they seek to make the perceived inadequacies of the law less harmful to their interests. They may achieve this through alternative legal means or by the adoption of new technologies. As we see below, a good example in the agricultural biotechnology field is the development of genetic use restriction technologies, including the so-called “terminator technology”, which

appear to be at least partially a response to the reluctance among many developing countries to remove subject-matter exceptions to patentability in the field of biotechnology.

Regulating DNA patenting is particularly vulnerable to unintended consequences because both industry and policymakers have to contend with uncertainty about the science, uncertainty about the effects of patent protection in this field, a rapidly advancing knowledge frontier and highly polarised views in society on whether DNA patenting should be allowed at all. And yet, businesses innovating in the field of molecular biology are extremely dependent on intellectual property (IP) protection since they must invest large sums of money in research at very high risk. Patents are the IP right of choice but for the reasons given above, legal uncertainty abounds that recent patent rule-making, especially in Europe, has failed to overcome (and perhaps cannot given the complexity of the science involved). We argue that experience should lead us to expect businesses to seek alternative means to protect their investments in molecular biology as in other fields of science and technology. For opponents of DNA patenting, these alternatives may not be preferable.

We show how one possible alternative to patents is to encode DNA sequences as music and use copyright, database right and trade secrecy rather than patents. One company, Maxygen, is already exploring such a possibility and other companies may follow this trend. The problem is that unlike patents, which require the owner to disclose the invention for his or her 20 year monopoly, these alternative approaches are easier

to acquire and offer longer monopoly protection: trade secrecy, for example, offers protection without public disclosure whereas copyright lasts for the life of the author and seventy years thereafter, and nowadays protects owners from the deployment of devices to circumvent their technological protection measures. If we are right in predicting that if molecular biology patenting is suppressed more and more, the legal and technological measures that lock up information will become increasingly attractive to industry, then one should tread very cautiously when reforming the patent system in this field in order to avoid such an unintended and undesired consequence.

Intellectual Property Policymaking and the Law of Unintended Consequences

The Nature of Patent Regulatory Reform

Patents are a form of economic regulation. As such, they involve four distinct areas of action (Hancher and Moran, 1998). These are the design of general rules, the creation of institutions responsible for their implementation, the clarification of the exact meaning of a general rule in particular circumstances and the enforcement of the rule in those circumstances.

Statutes provide the basic rules and create the implementation agencies, which are the national (or regional) patent offices. In Europe, the European Patent Office acts as an implementation agency in those countries that are member states of the European Patent Convention. These agencies are then made

responsible for interpreting these rules. In individual cases, the patent examiners are charged with determining whether or not the claims submitted in a patent application fulfil the criteria of novelty, industrial application and inventive step. Their work may be assisted by a handbook which clarifies the rules so that they are applied in a standardised manner. But agencies do not always just implement rules made elsewhere. In some jurisdictions, they may take a more activist role. For example, in February 1997, the US Patent and Trademark Office unilaterally announced that discovered gene fragments called expressed sequence tags could be patented and with only minimal disclosure of their function. In June 1999, the Administrative Council of the European Patent Office, a non European Union institution, decided by itself to use the EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions as a supplementary means of interpretation.

Courts also have an important role to play in patent regulation. They may interpret the rules in ways that may bind patent offices. Furthermore, they are normally the final arbiter of disputes over the appropriate scope of specific patent grants. Courts also have the power to legally enforce patent rights, though patent owners also play a major enforcement role both indirectly and directly by monitoring the commercial activities of rivals, and through litigation, threats of legal action, and out of court dispute settlement. In a very real sense companies are not just customers of the regulatory system; to a greater or lesser extent they too are its designers, funders, interpreters and even its enforcers. In North America and Europe, patent of-

fices are increasingly expected to become financially self-sufficient. The danger is that examiners will be pressured to prioritize patent quantity over quality.

National patent systems are rarely static for long, changing over time due to changing domestic and international circumstances. Two important characteristics of patent reforms are uncertainties about their effects, and the likelihood that interest groups will attempt to shape the reforms and will often but not always succeed.

For at least 60 years, economists have attempted to evaluate the economic efficiency of patent rights in the search for an optimal system. Although these studies are worthwhile, one useful inference being that it is impossible to arrive at fixed patent terms and breadths that would be optimal for all industrial sectors, technologies and types of product ("types" here referring to market demand structures or life-cycles) (Primo Braga, 1990: 21), the theoretical complexities and the rather unrealistic assumptions such studies tend to be based on (see Beije, 1998: 160-2) mean that none of them can provide a trustworthy guide to the level of IP protection that would be the most economically efficient or socially optimal for any legal jurisdiction, even less the world as a whole. The conclusion of Machlup (1958: 79-80) in his famous 1958 study of the patent system continues to challenge economists today: "no economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. The best he can do is state assumptions and make guesses about the extent to which

reality corresponds to these assumptions.”

In the face of so much basic uncertainty about patents, interest groups may seek to secure interpretative capture of the patent system by resort to propaganda. Interpretative capture may be taken to refer to a situation where an interest group, or a collection of such groups acting together, has achieved acceptance in government and society as authoritative, definitive and exclusive explicators of a particular issue. Alternative views may not necessarily be absent completely but, to be influential, these unconventional voices will need to find forums in which their way of construing or framing the issue makes their interpretations more persuasive.

The main interest groups are the patent-holding firms and business associations, as well as patent attorneys and lawyers. All of them benefit from patents and have a direct economic stake in any redefinition or reallocation of rights. Of these groups, the large chemical and pharmaceutical firms have usually been among the most powerful and determined, although the biotechnology and computer industries have become influential stakeholders in recent years too (Doern, 1999).

These interest groups, however, do not always get their way. For one thing, groups representing other interests may actively oppose them and be successful. For another, it is difficult for one group, or an alliance of groups, to totally capture all of the agencies dealing with patent regulation. These include patent offices, the government departments in which they are located, the politicians that oversee them, the courts, and in some cases competition regulators.

Consequently, it is extremely difficult for any one interest group to capture the patent “system” outright, at least for any length of time.

So when powerful interests groups are thwarted, what do they do? They may of course simply accept the decision. Alternatively, they may seek solutions in other areas of the law or adopt new technologies. Genetic use restriction technologies and the breeding of hybrid crops are interesting cases of the resort to technological protection measures developed at least partly in response to the lack of effective intellectual property protection. These are worth considering in some detail.

Genetic Use Restriction Technologies (GURTs)

In 1998 a patent was granted jointly to the United States Department of Agriculture and Delta and Pine Land, a major American cotton seed company, describing molecular biological techniques for controlling gene expression in plants, plant parts or seeds so that traits can be switched on and off between generations (Charles, 2001: 218-21; Dutfield, 2003a).¹ Conceivably, farmers could benefit from these techniques, depending upon the traits in question whose expression or non-expression may help determine the success of the harvest. But among the claims is a method for producing seed that is incapable of germination, or to be more specific, a technology that would render harvested seed sterile. On the face of it, it seems extraordinary to invest so much effort and expense in developing a means to produce sterile seed. Despite the involvement of a public sector institution, this is strictly

business. The purpose is to prevent farmers from replanting saved seed and thereby undercut seed company monopolies. In doing so, it provides a means not only of preventing the infringement of intellectual property protection but of ensuring the continuation of the monopoly beyond the life of any patent or plant variety certificate, assuming such activities require the authorisation of the right holder in question.

For many critics, being able to patent such a technology is an indictment of the patent system. One may indeed reasonably question whether or not society should be encouraging such research through the promise of a patent monopoly. Moreover, it is legitimate to be concerned that protecting seeds through both patents and GURTs is overprotective in a similar way that support for encryption through copyright law in the form of banning circumvention devices is overly generous to owners (see below), as provided by Article 8 of the 1996 WIPO Copyright Treaty, Articles 10 and 14 of the 1996 WIPO Performances and Phonograms Treaty, the US Digital Millennium Copyright Act, and the Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society.

We would argue, however, that there is no particular need to respond to terminator-type patents by broadening the application of exceptions.² In fact, if terminator technologies could not be patented on these or other grounds, this might encourage research in this area even more. After all, GURTs would appear to be especially useful in jurisdictions where IP protection is weak.

This is not to say that developing countries should therefore allow modified plants to be patented and assist business in the eradication of patent-seed saving. Neither should we assume that if effective patent protection became available in these countries, business would suddenly lose interest in GURTs. Nonetheless, it is telling that GURTs seem to be targeted at developing countries, where policing the cultivation and trade in private sector-developed seed is likely to be much more difficult than in the developed world. In this sense, GURTs may at least to some extent be considered an unintended consequence of countries' reluctance to provide patent protection for plants and plant-related inventions.

Molecular Biology, Scientific Uncertainty and the Shifting Knowledge Frontier

According to Morange (1998: 1-2), "molecular biology is a result of the encounter between genetics and biochemistry, two branches of biology that developed at the beginning of the twentieth century [...] Strictly speaking, molecular biology is not a new discipline, but rather a new way of looking at organisms as reservoirs and transmitters of information". In similar vein, Gamow (1955: 70, in Kay 2000: 154) conceptualised the cell as "a storehouse of information" and also as "a self-activating transmitter which passes on very precise messages that direct the construction of identical new cells". This suggested to Gamow that "the continuity of all life on our planet depends on this information system contained in the tiny cell nucleus." Molecular biology is a typically immature sci-

ence in the sense that the state of the art is moving forward at a rapid pace. If the recent past is even a halfway decent guide to the near future, there is a good chance that much of what we assume to be true today will seem pathetically misguided in a few years time. Until February 2001, we were told to expect about 100,000 protein-encoding human genes. Yet when the International Human Genome Sequencing Consortium and Celera published their findings that month in *Nature* and *Science*, this estimate had suddenly dropped by about one-third, something rather alarming to those who felt that advanced creatures such as us ought to have many more genes than the average cabbage, in which 57 percent of our genome may also be found (Shakespeare, nd). This was also alarming to investors who had assumed there was a direct relationship between the number of genes and their money-making opportunities (Pollack, 2001). To give another example, non-protein coding DNA sequences within and between genes, previously dismissed as “junk DNA”, are now considered to perform some essential regulatory functions, and also to be central to any explanation for the complexity of higher life forms as compared with bacteria and other prokaryotes (Gibbs, 2003; Mattick, 2004). The sheer complexity, subtlety and context-dependence of DNA leads Kay (2000: xviii-xix) justifiably to cast a sceptical light on the view that genes should be treated as a text in four letters containing instructional information, suggesting that “genetic messages might read less like an instruction manual and more like poetry, in all their exquisite polysemy, ambiguity, and biological nuances”.

Following Watson and Crick’s 1953 discovery of the double helical structure of DNA, scientists in the following decade discovered how DNA instructs cells to assemble amino acids, which form the building blocks of proteins. In brief, each gene contains the instructions for the synthesis of one or more proteins. Just as proteins consist of chains of amino acids, each gene may be sub-divided into units called codons that comprise three nucleotide base pairs and code for (by way of a closely related chemical called ribonucleic acid (RNA)) the preparation of a particular amino acid. These amino acids are then combined in a specified way to form the required protein; that is, the one “expressed” by the gene.

But as scientists know very well now, this is far from the end of the story. It turns out that the famous “central dogma”, which is that DNA makes RNA makes protein, which then regulates gene expression, is not even half the story, at least in the case of multicellular organisms. For one thing, the whole protein-making process is looking ever more complex. In fact, a gene can produce more than one protein, for example by means of a process called “alternative splicing” in which coding sections of the gene are selectively deleted.

For another, genes and RNA in higher life forms perform many roles other than protein production. Indeed, while one-celled organisms lacking nuclei such as bacteria have very little DNA that does not code for proteins, as much as 98.5 percent of human DNA is non protein-encoding. Yet much of it is still transcribed into RNA for reasons that we hardly understand (but probably will in the next few years). The conundrum as

expressed by Mattick (2004: 32-3) is that “either the human genome (and that of other complex organisms) is replete with useless transcription, or these nonprotein-coding RNAs fulfil some unexpected function”. He suspects that “these RNAs may be transmitting a level of information that is crucial, particularly to development, and that plays a pivotal role in evolution”. To make matters even more complicated, different genes may occupy the same strand of DNA to the extent that it may be extremely difficult to determine where one begins and another ends (Sulston and Ferry, 2002: 40).

In consequence of these discoveries, the “regulatory architecture” (Mattick, 2004: 37) of living things has never looked so sophisticated or complicated than it does today. Indeed, even the “gene” is beginning to look like a rather fuzzy concept. A scientist at the Karolinska Institute in Sweden was quoted as admitting that “we tend not to talk about ‘genes’ anymore; we just refer to any segment that is transcribed [to RNA] as a ‘transcriptional unit’” (quoted in Gibbs, 2003: 29).

This complexity, the conceptual fuzziness and the rapid learning curve that scientists are experiencing are all very relevant to any discussion on the applicability of intellectual property rights in the field of molecular biology, as we will see below.

Gene Technologies and the Biotechnology Industry

Commercial biotechnology began with the 1973 development of the recombinant DNA technique (often shortened to “rDNA”) by Stanley Cohen at Stanford University and Herbert Boyer at Univer-

sity of California at San Francisco. The technique, which enabled foreign genes to be inserted into micro-organisms and passed on to others through cell division, was patented by Stanford and licensed widely, earning over \$200 million in royalties between 1975 and 1997, when the patent expired (McKelvey, 1996: xix).³ In 1982, the first rDNA pharmaceutical product, Genentech’s human insulin, was approved for sale (Dutfield, 2003b: 150-1).

After rDNA, the next major scientific breakthrough with commercial implications was the 1975 development of hybridoma technology by Köhler and Milstein (1975), working at the Medical Research Council’s Laboratory of Molecular Biology. Hybridoma cells result from the fusion of a type of cancer cell known as a myeloma with another antibody-producing cell. Hybridomas produce multiple antibodies of a highly specific type, which are called monoclonal antibodies. The MRC chose not to patent the technology. The first monoclonal antibody (MAb) drug to reach the market, Centocor’s ReoPro (abciximab), which was approved in 1995, has been a great commercial success. In 2000, it was reported that “about a quarter of all biotech drugs in development are MAb, and around 30 products are in use or being investigated” (Breedveld, 2000: 735).

Unlike rDNA and hybridomas, the polymerase chain reaction (PCR) technology came out of a corporate laboratory. Kary Mullis, a scientist working for Cetus Corporation, was credited with the invention, which is usually dated to 1985 (see Rabinow, 1998). PCR technology provides a means rapidly to replicate potentially vast quantities of a selected

DNA section in a test tube. The technology works by using taq polymerase, an enzyme from a thermophilic (heat resistant) bacterium that was discovered in a hot spring in Yellowstone National Park. PCR is an extremely valuable research tool with many applications including genome sequencing and diagnostics.

During the 1980s and 1990s, genetic engineering became increasingly sophisticated with genes being transferred not just to micro-organisms but also to plants and animals. Another new technique developed during this period was animal cloning based on nuclear transfer; that is to say the insertion of a cell nucleus into an egg cell that has had its nucleus removed. In 1996, the world famous, but short-lived sheep called Dolly was cloned by Ian Wilmut and Keith Campbell at Roslin Institute in Scotland from a cell taken from a mature sheep's udder. It was not the first cloned animal but the first to be cloned from an adult mammal (Wilmut *et al.*, 2000). Sadly, Dolly suffered from arthritis and was put down in February 2003 after contracting a lung disease.

The "biotechnology industry" is not a discrete industrial sector. Rather, there are dedicated biotechnology firms (DBFs) that do nothing but biotechnology, and other companies, universities and public research institutes that conduct biotechnological work but do not specialize in it. The new biotechnology and genomics revolutions have created completely new commercial opportunities, and spawned four types of business. These are (i) the technology providers who manufacture the DNA sequencing machines and other equipment; (ii) the information providers that collect and

organize sequencing information; (iii) the research firms, consisting mainly of the DBFs that generally do the upstream research but lack the resources or the ambition to do the downstream product development and marketing; and (iv) the health, agricultural and industrial biotechnology firms. These include the larger vertically integrated DBFs, and much longer established businesses, which are mostly pharmaceutical, chemical and life science corporations. These business types are not necessarily discrete. For example, while Incyte and Celera are essentially information providers, Millennium Pharmaceuticals and Human Genome Sciences are also involved in drug discovery and development.

As with other science-based sectors, the road leading from basic research to product development is long, winding, and has many branches, some of which may be short cuts but are mostly dead ends. It is also very expensive to use, especially as journey's end approaches. The companies best equipped to carry a product to the end of the road are not necessarily the most competent to start the journey, just as the front runners are often ill-equipped to complete the course.

This situation provides both obstacles and opportunities for business. For new start-up firms it is hugely difficult to transform themselves into biopharmaceutical corporations. The opportunities lie in the fact that as the big firms concentrate on their core competences they outsource more and more tasks that may be essential elements of the research and development (R&D) process. Therefore niches are created that new small and medium-sized science-based firms can

occupy profitably.

The Patenting of DNA Sequences – Current Controversies and Uncertainties

Arguably, biotechnology patents encourage such a diversification of business activity by stimulating the foundation of small but highly-innovative firms and then by helping them to survive and remain independent. It has always been crucial to have access to large amounts of investment capital just to stay in business. Patent portfolios are the main magnet for outside investors – which also include larger science-based firms – and the larger the portfolio, the greater the interest from investors. In common with other industries, patents also become a form of currency in inter-firm transactions: “few products can be developed, tested, approved by regulatory agencies, and on the markets in time to generate enough cash to save most biotechnology companies. For many companies, the patent becomes the product – the product that can be dangled before the investment community for more funds, or the product that can literally be sold to other companies” (Fowler, 1994:173). Research decisions in many companies can depend as much, if not more, on the advice of patent lawyers as the opinions of the scientists. For example, “the biotech firm Genetics Institute decides which version of a drug to develop partly based on which iteration shows the best results in clinical trials but also according to which version can command the strongest patent protection. Genetics Institute’s patent counsel says the strength of the potential patent position is ‘a leading factor’ in deciding which

research to pursue” (Rivette and Kline, 2000: 58). Naturally, companies have a strong interest in securing patents that encompass the broadest possible scope and whose claims are drawn in ways that seek to anticipate future scientific developments.

Policy Implications

As is well known, the extent of biotechnology patenting has increased tremendously in the last two decades, including those claiming DNA. DNA sequences “first began appearing in patents in 1980, just 16 sequences all year. By 1990 that figure had risen to over 6,000 sequences. Throughout the 1990s the growth in the patenting of sequences expanded exponentially, and this looks set to continue. In 2000 over 355,000 sequences were published in patents, a 5000 per cent increase over 1990” (Stokes, 2001).

It is of course also well known that DNA patenting is highly controversial. Some critics argue that as a natural substance DNA can only be a discovery and not an invention and should therefore not be patented at all. Others take the view that it is immoral or even sacrilegious to patent “life”. However, we do not discuss these fundamental issues in this article; rather, we focus on the debate surrounding the policy implications of DNA patenting.

In discussing the policy issues concerning DNA patenting, we first remind readers of the problems mentioned earlier, namely, of increasing complexity, conceptual fuzziness and the rapid learning curve, while adding another one, which is that patent granting offices, the courts and legislators must try their best to keep up with the shifting

knowledge frontier but cannot possibly succeed entirely.

At least two situations have arisen that should be of major concern to policy-makers. First, a disproportionately large quantity of patents is being granted in relation to the number of commercial products based upon them. This is because of the enormous quantity of patents on genes and gene fragments that are basically research tools. Of course, companies file such patents because the rules allow them to do so. But their patenting decisions are related to the fragmented nature of the genomics innovation chain. For new DBFs that provide genetic information to the drug development firms, what they sell are to them final products but to their customers further down the chain are mere research tools. In order to protect these “products” – and to secure funding to produce further ones – the DBFs have a strong incentive to privatize their information through IP rights. But since the development of future commercial products such as therapeutic proteins or genetic diagnostic tests often requires the use of multiple research tools, such as gene fragments, an increasing number of which are being patented, companies intending to develop such products will need to acquire licences from other patent holders. In doing so, they will incur large (and possibly prohibitive) transaction costs. To return to the road metaphor, the danger is that more and more tollgates will be installed making the journey ever more expensive and excluding more and more potential travellers. So not only is the product development race becoming a relay race with more and more runners, but each runner is being forced to pay for the privi-

lege of receiving the baton from the previous runner. The question is, will this slow down innovation and lead to fewer products on the market than would otherwise be available?⁴

At the very least one should be cautious about granting patents that claim genes on the basis of a single disclosed function or discovery, such as that it codes for a particular protein, or that it is associated with a disease. After all, the assumption that genes operate independently and perform single functions has been conclusively shown to be highly problematic. Indeed, genomes can more accurately be seen as consisting largely of multiple intersecting mini-ecosystems forming one larger one (i.e. the genome itself) rather than as a single collection of separately functioning “Lego bricks” (i.e. the individual genes) that can be combined and recombined precisely, predictably and with no possibility of unintended consequences (see Krimsky, 2000). Treating genes as patentable inventions because a single function has been discovered may even stifle innovation. This is because it potentially hinders opportunities for follow-on researchers to carry out further investigations on genes and find out much more interesting things about them, including how they interact with other parts of the genome and with what effects.

Second, the scope of a patent can sometimes be drawn so broadly as to allow monopoly protection to cover a range of potential products including many unforeseen by the applicant. This problem has been with modern biotechnology from the start, being especially common in new and fast moving technical fields. This problem is also the most

potentially damaging in its effects on innovation. Moreover, this can be a life or death issue (see Anand, 2001; Montgomery, 2001). Patents on genes linked to particular diseases tend to claim a range of applications including diagnostic tests and owners can be quite determined in enforcing their rights even though the validity of such patents is often considered to be extremely questionable. Even non-commercial entities like public sector hospitals may be the target of companies demanding royalties. It was recently reported, for example, that “after the gene for the iron overload condition haemochromatosis was patented, 30 per cent of labs surveyed stopped testing for the disease-causing gene variant, or developing such tests” (Kleiner, 2002). David Porteous, Head of Medical Genetics at Edinburgh University, has complained of patent-related legal problems affecting the freedom of scientists in Scotland to conduct gene-based diagnostic tests for breast cancer. This is despite the fact that geneticists do not even need to read Myriad’s patent specifications since all the knowledge required to conduct the test is already in the public domain.⁵

Perhaps these problematic situations can be solved through more careful examinations, but here lies another concern. Nowadays, patent offices are required to become more service oriented and financially self-sufficient. They are expected to demonstrate their efficiency by examining patents speedily and avoiding backlogs. The danger is that the proportion both of excessively broad scope patents and of issued patents lacking genuine novelty and inventive step will increase. In fact, this is known to be a serious problem in the USA, where

patent examiners are not given sufficient time to do their work properly.

The Patentability of Genes in Europe and the United States – the Present Situation

To what extent are genes patentable in Europe? There is no easy answer to this question. In July 2003, the European Commission decided to refer Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden to the European Court of Justice for failing to implement Directive 98/44/EC on the legal protection of biotechnological inventions, which states that “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”⁶ as long as the patent discloses an industrial application.⁷ While public disquiet about the morality of gene patenting is probably the main reason for the lack of legislative action by these countries, disagreement about how far the patent incentive operates in this field is also a factor.

These non-implementing countries have not been completely inactive, though. In December 2004, France finally passed its implementing legislation.⁸ That same month, Germany’s Bundestag passed legislation allowing genes to be patented, but limiting patent claims on human gene sequences to “disclosed functions”. This means that patents cannot cover the gene in relation to other functions discovered subsequently. This seems quite sensible in the light of our earlier discussion. However, it is possible that the European Commis-

sion will consider that this measure does not fully comply with the Directive. Why? Because Article 5 and Recital 24 of the Directive require that protein-expressing genes be patentable if the proteins in question or their functions have been specified, yet it is far from clear that member states can allow the scope of patents on genes to be limited to their role in coding for the disclosed protein or protein function (Stafford, 2004).

Even in the United States, where “anything under the sun that is made by man” is considered patentable,⁹ the situation is in a state of flux. In a 1998 article in *Science*, John Doll, director of biotechnology examination at the US Patent and Trademark Office (PTO), had clarified that DNA sequences can be patented if the applicant discloses specific utilities, such as that the sequence is useful for chromosome mapping or identification, gene mapping, tagging genes with known function, such as including increasing predisposition to a disease, and forensic identification (Doll, 1998). But in the face of criticisms that too many dubious patents were being granted, the PTO adopted a new rule for DNA-related patent examinations that applications disclosing DNA sequences must provide convincing evidence that their utility is specific, substantial, and credible (USPTO, 2001).

But whatever the rules actually state, the discovery of new genes is becoming easier. Consequently, it is getting more difficult for applications claiming them to pass the inventive step or non-obviousness tests. Indeed, many discoveries that would have been patentable a few years ago are not any more. The point to be made here is that irrespective of whether the criticisms of DNA patenting

are justified, legal uncertainty abounds in both Europe and the United States, but the trend is likely to be for patents claiming genes to be harder to acquire. In response, businesses are bound to seek alternative means to appropriate their discoveries. The next part of the paper considers the possible alternatives.

Alternative Routes to Protection

Trade Secrecy, Confidentiality and Non-disclosure Contracts

In February 2001, the International Human Genome Sequencing Consortium that was implementing the public Human Genome Project, and the company Celera, which was in a bitter race with the Consortium to be first to complete the sequencing, both announced they had almost completed their tasks. The Consortium reported on its work in *Nature* (IHGSC, 2001), while Celera did so in *Science* (Venter *et al.*, 2001). It is noteworthy that the Celera (i.e. Venter *et al.*) article embedded the following notice on data availability in the final endnote:

The genome sequence and additional supporting information are available to academic scientists at the Web site (www.celera.com). Instructions for obtaining a DVD of the genome sequence can be obtained through the Web site. For commercial scientists wishing to verify the results presented here, the genome data are available upon signing a Material Transfer Agreement, which can also be found on the Web-site.

Academic scientists expecting unconditional access to Celera's human genome sequence data would have been disap-

pointed. They are required to sign and submit a document known as the “Celera Free Public Access Click-On Agreement”, which provides a royalty-free, non-exclusive and non-transferable licence to access the genomic data for non-commercial research use.¹⁰ Such licences are only granted to an “Academic User” i.e. an employee, student or scientist legitimately affiliated with an academic, non-profit or government institution and who uses the information for such interests and not on behalf of a commercial entity. Distribution to other academic scientists is forbidden. The Agreement, which applies to the company’s human and drosophila (fruit fly) genome sequence databases, states that “the Celera Data, both the primary sequence assembly and the representation thereof, is a copyrighted work of PE Corporation (NY).” For access to the company’s mouse chromosome 16 sequence database, there is a similar Agreement.¹¹

What is interesting is their use of contract to assert their position in the marketplace and to control the publication and usage of their information. Celera is not the only firm to indulge in this practice – US firms such as Human Genome Sciences (HGS) and Incyte are also resorting to subscription agreements and the like to restrict access and use of the contents of their databases of genetic information. These latter firms employ yet another legal weapon – trade secrecy or confidentiality laws.

Trade secrecy and confidentiality laws are not “property” rights, and nor do they arise generally from statute laws. These laws generally arise under a contractual obligation or under common law. Trade secrecy or confidentiality laws arise primarily by law made by judges

though some parts of these laws have been codified and turned into statute law. Their objective is not to protect the information *per se*, but the secrecy within which the information is encased. Nevertheless, a trade secret usually concerns information with commercial value which the firm wishes to conceal from its competitors and to prevent duplication. Due to the fact that trade secrecy law is not a property right, the position of any user vis-à-vis the confidential information depends on whether he is a licensee or not. If the user is a licensee, secrecy is imposed via the contract, and any attempt to disclose the information constitutes a breach of contract. Should the user be a non-licensee and have no contractual relationship with the firm, then the question turns on whether the law regards the information as having the necessary characteristic of secrecy or confidentiality. Note the above stated Celera examples – their agreements actually act as types of confidentiality agreement in that they forbid licensed scientists to offer others access to the genetic information, and also impose confidentiality by stating that the Academic User agrees to “[t]ake sole responsibility for maintaining the confidentiality of [his] password, and for any and all use and access to the service which occurs under [his] account”, thus implying that the information within the service is confidential. Although the user in both types of agreements is permitted and encouraged to publish his results and discoveries in scientific journals, Celera insists that the user not only cite the relevant publications of Celera (which is normal academic practice, in any event), but also to provide a reference or link to the web site, celera.com,

if the publication includes reference to Celera data.

Licensees are bound by their contractual position, whilst non-licensed users do not even have a right to access secret information. This is unlike the position under patent law where the patent owner may be able to prohibit duplication of the invention, but cannot stop anyone from buying, borrowing or accessing the invention or work. Thus, a patent licensee bound by patent laws alone can allow a third party to access the invention and any information revealed from reverse engineering or experimental usage – if these are statutory defences under the jurisdiction concerned. Trade secrecy or confidentiality laws, on the other hand, do give the owner of the information a right to stop access to that information.

Why would firms resort to trade secrecy laws since it is not a secured means of protecting DNA sequences? Landes and Posner (2003: 356-7) point out two reasons why technology firms would opt for trade secrecy protection: (i) patent law requires disclosure which may render the invention worthless where the invention comprises mainly pure new information; and (ii) trade secrecy protects non-patentable or sub-patentable inventions. We can add a third reason: by cloaking the information as “trade secrets”, non-disclosure or secrecy agreements can usurp the public’s right to know, and bypass the safeguards offered under patent laws. The only real defence offered under the law of trade secrecy or confidentiality is the general defence of public interest,¹² whereas a researcher may be able to avail himself of defences such as repair, reverse engineering or experimental use of informa-

tion under patent law. It has long been accepted that the purchaser of a patented article may use or deal with the patented article in any manner, including repair and reverse engineering, as long as it is for private and non-commercial purposes.¹³ The position is different under United States patent law. Although patent jurisprudence there has developed a line of authority which indicates that defendants who make or use a patented product or process for non-profit research or experimentation do not infringe the patent, this judicially created research exemption is under threat as a result of the judgment in *Madey v Duke University* (307 F.3d 1351, [U.S. Federal Circuit, 2002]). The judgment gave rise to concerns that US courts may have gone too far in interpreting the research exemption into a state of virtual non-existence, and that in doing so it may well hinder universities from conducting the basic research upon which future commercially-oriented research ultimately depends and which the private sector cannot be relied upon to carry out all by itself. Again, by examining the Celera Agreements, one finds that Celera specifically stipulates that the Academic User agrees not to “[r]ent or loan access to the Service... or reverse engineer, decompile, disassemble or otherwise attempt to access any source code for any software program included in the Service.”

Bypassing or supplementing patent law is detrimental to society as the length of protection under trade secrecy or confidentiality laws can be perpetual – as long as the underlying information remains secret, it is non-accessible to the world. Indeed, a big plus for gene patents is that they do ensure publication

and distribution of knowledge to the public. Given the way these strategies can lock up information so completely and for so long, one ought to be concerned that companies are resorting to such legal protection. Needless to say, claiming legal ownership over raw genetic information via contract and trade secrecy laws hardly encourages the open exchanges of raw data and research results that scientific progress depends on. Indeed, as the discussions below show, firms are determined to explore all manners of constructing proprietary databases of genetic information.

DNA and the Utilitarian Aspects of Copyright

The Celera example above also indicates another weapon wielded by the biotechnology industry – the non-disclosure agreement purports that copyright subsists in the “primary sequence assembly and the representation thereof”. But can we really claim copyright protection for DNA sequences?

Some may scoff at the capability of copyright law to extend its scope to utilitarian works. There is no clear international standard or law which sets out the criterion of copyright protection, but it is a generally accepted tenet in almost all major developed countries that copyright law will protect “an original work”, although the criterion of originality is interpreted differently in different jurisdictions (Macdonald and Suthersanen, 2005). The civil law copyright systems (such as France and Germany) only protect works that constitute a “personal intellectual creation” or display the personality or individuality of the author;¹⁴ whereas the common law countries

(such as UK, Australia and India) protect works which evince “skill, labour or judgement” (Suthersanen, 2000: 197-199). Similarly, the US copyright law protects a “work of authorship” if it has a “modicum of creativity”.¹⁵ Some authors argue that DNA sequences may not be protectable in many countries as they do not contain the requisite level of authorial creativity or individuality. Another argument that has been levelled against copyright protection of DNA sequences and gene fragments (especially those that constitute mere research tools) is that the underlying policy of copyright law is to deny protection to raw scientific data, ideas, procedures, processes, concepts, principles of discoveries (McBride, 2002: 1348; Westkamp, 2004: 115). Copyright protection may also be refused protection if genes are viewed as existing largely as interoperable organisms. Interoperability has always been a difficult point under both EU and US copyright laws as the debate on computer programs has shown (see Samuelson and Scotchmer, 2002). Finally, it is argued that even if copyright protection is granted to a DNA sequence, an accused infringer can claim that the sequence was being used for the purposes of non-profit or academic study, research or teaching, and such activities are excepted under the US “fair use” defence or under the British/Australian “fair dealing” defence. (McBride, 2002: 1347).

Nevertheless, these objections can be rationalised away and much depends, as always in legal debate, on semantics. Take for example the bar against patent protection of discoveries under the European patent law – we still find patent protection being granted to DNA sequences under the reasoning that these

do not constitute discoveries “as such”.¹⁶

There is a popular and long-standing perception that the role of copyright law is to reward the sole and struggling creator who embellishes our social environment with books and music. This romantic vision is, and has always been, very much open to challenge. Copyright law is, as other intellectual property rights, a marketing tool enabling the maker to exploit his product of the mind. This product, moreover, need not be a work of literature or art. The law now has the capability of protecting not only the works of Shostakovich and Eminem, but also functional and technological works such as computer software, informational databases and functional subject matter. Indeed, one can go so far as to analogise DNA sequences to computer programs on the basis that both manifest themselves as a series of instructions to a “machine” to operate. Just as the algorithm within the computer program instructs the hardware to operate, the DNA sequences contain instructions for the performance of various essential functions including the manufacture of proteins. Those accepting such an analogy would presumably have no philosophical qualms about extending copyright protection to highly technical subjects such as DNA sequences. The US Copyright Act of 1976, for example, grants copyright protection to all “original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device” (17 USC §102(a)). The EU Member States’ copyright laws do not limit the type of subject matter that can be protected and

most laws merely state that copyright protection will extend to all “original” works of literary, artistic and scientific nature; instead it is often left to the court’s discretion to determine whether a particular type of work comes under the aegis of copyright protection. (Suthersanen, 2000: 200).

For those seeking legal protection, it is true that the scope of copyright protection is much less than that under patent law. Copyright should be distinguished from the exclusive rights granted under patent law where the proprietor is granted a monopoly: copyright law does not prohibit third parties from producing works which are identical to the protected work provided they were made independently. The law merely provides an anti-copying right. Nevertheless, there are several advantages to copyright law compared with patent law. First, the term of protection under patent law is only twenty years from the date of registration of the patent application, whereas copyright offers protection for a period of the life of the author plus seventy years thereafter in the EU, US and Australia. Secondly, it can be both expensive and lengthy to obtain patent protection, but copyright protection arises automatically upon creating a work, without any registration or examination process.¹⁷ Note that the existence of copyright protection is an addition to patent protection, not an alternative to it.

Therefore, it is entirely possible that both “artificial” and “original” sequences of DNA will increasingly find themselves protected through copyright. There is even a dedicated DNA copyright firm in the United States called the DNA Copyright Institute which, for a fee, collects a

sample of DNA from any firm or individual, determines the “DNA profile” of any organism and reports this profile back to the client in order to establish copyright protection.¹⁸

It is also arguable that copyright law has long since accepted the fact that many works are of low authorship value, being built upon pre-existing data and facts, or if new, comprise largely unprotectable data and facts. Innovative character may be found in either compiling such information or “discovering” such information. It is not difficult to envisage the expansion of copyright law to encapsulate such innovation. The threshold of originality has, historically, been less demanding than that required under patent law. It is clear that the laws of some jurisdictions (such as the UK and US) have strived to bring such utilitarian works, especially software, databases and other compilations, within the copyright penumbra due to the market demand for such works and their ensuing commercial value (Dutfield and Suthersanen, 2004: 391-4).

DNA as Notation, Design and Compilation

DNA strands can be understood, in Morange’s words, as reservoirs and transmitters of genetic information. Traditionally, copyright law has protected reservoirs and transmitters of information as literary, artistic or musical works. US copyright, for instance, recognises that the notion of literary work can be wide enough to include any work which is expressed in “words, numbers, or other verbal or numerical symbols or indicia”, regardless of the nature of the material objects in which they are em-

bodied.¹⁹ One can compare DNA sequences to circuit boards, for example. The British courts have protected circuit diagrams both as graphical representations, as well as literary works, the judicial view being that circuit diagrams constitute engineers’ notation.²⁰ An unravelled DNA sequence may, perhaps, be viewed as a geneticists’ notation. Yet another possibility is if we view genomes as largely comprising a multiple intersecting modular system rather than a single collection of separately functioning “Lego bricks”. From this perspective, one can perhaps claim protection for the shape and configuration of the DNA gene sequence under design law. This is especially true under the British unregistered design right which extends to microscopic design features invisible to the naked eye.²¹

Another perception of DNA sequences is as databases of genetic information. Copyright protection of databases varies from jurisdiction to jurisdiction. In the EU, for example, recent legal development has curtailed copyright protection to databases, which, by reason of the selection and arrangement of their contents, evince some sort of creativity. A scientist would have difficulty claiming copyright protection for DNA sequences as such. Combinations of DNA sequences, however, may be accepted as being worthy of protection. It is true that copyright law is constrained into protecting the selection, arrangement or structure of the whole compilation as opposed to the individual genes or proteins within the database. Copyright protection would extend only to the original selection or arrangement – a competitor who creates his own database using individual elements of the

scientist's copyrighted database would not infringe the scientist's copyright so long as the competitor does not use the same selection or arrangement as the scientist's copyrighted database. Therefore, copyright protection for databases within the EU is limited. A second alternative route is available under some European jurisdictions such as Sweden and the Netherlands. In addition to this normal copyright route, the Dutch and Swedish laws provided a limited term of protection to producers of non-original compilations under the "catalogue" rule or the *geschriftenbescherming* rule²² (Dutfield and Suthersanen, 2004: 392).

A third alternative route has also been recently opened up in the European Union i.e. protection under the new *sui generis* database right which covers any "collection of independent works, data or other materials" which are arranged in a systematic or methodical way.²³ A database right is granted to a "maker" of a database who can show that there has been "a substantial investment in either the obtaining, verification or presentation" of the database. A liberal interpretation of the law allows the maker to claim protection without having obtained an "original" DNA sequence – the maker need merely show that he has "verified" the contents of the database,²⁴ with some "deployment of financial resources and/or the expending of time, effort and energy".²⁵

There are arguments to the contrary. Thus, one commentator has opined that DNA sequences do not come within the legal definition of "database" which calls for independence (Westkamp, 2004: 113). Apparently, this means that the database right will only apply to such data which is individual and has the ca-

capacity to stand on its own and not be an integrated part of a work. Thus, a film cannot be considered to be a database because the individual frames, while ostensibly representing data that can be individually accessed, are inter-related and dependent on one another (see Rees and Chalton, 1998: 27-8). However, irrespective of what the law theoretically states today, laws tend to eventually reflect social and mercantile customs. Databases of genetic information are regarded as proprietary objects which can be protected and traded. Note for instance the Icelandic saga where Iceland's Parliament passed a law in 1999 to give DeCODE, a biotechnology company, the right to market a database comprising the genetic, medical and genealogical information of the Icelandic people for 12 years. DeCODE subsequently signed a five-year contract with Hoffman-La Roche to access the database for \$200 million (Check, 1999).

Moreover, recent case law suggests that courts are not that adverse to such a creative interpretation of the law. The idea of extending copyright and database right protection to chemical products has recently been discussed in *Lancôme Parfums et Beauté et cie S.N.C. v. Kecofa B.V.*²⁶ by the Dutch Court of Appeal. In a landmark decision, both jurisprudentially and internationally, the Dutch Court ruled that Lancôme's perfume Trésor was protected under copyright law – which has, as we stated above, higher thresholds of protection than the database right protection. The court held the Trésor perfume as having an original character bearing the "personal imprint of its creator", and on that basis ruled that copyright protection may extend to the scent-generating substance

in the perfume. The court went further to stress that the scope of protection covered the chemical combination, but not the smell of the perfume, which was deemed too transient and too variable to be copyrighted. Physicochemical analysis and the laws of probability played an important role in determining whether infringement had occurred. The analysis indicated that the two perfumes had 24 olfactory components in common, while only two components of Trésor had not been used by the defendant. Moreover, the only component that was unique to the defendant's perfume was gamma dodecalacton, a cheap substitute for musk keton, used in Trésor. The probability of a perfumer other than Lancôme independently and coincidentally creating a perfume containing 24 of the 26 olfactory components of Trésor was shown to be about the same as that of winning the lottery every day for a hundred-year period!

Of course, the most intriguing aspect of this unusual case is that copyright protection was deemed to be available for a selection and blend of chemical ingredients. But if we can accept this ruling, there is surely no reason to find it strange for somebody to encode DNA sequences as music and be able to claim copyright.

...and Music

Can one take the “information reservoir and transmitter” perception of DNA further and postulate that DNA sequences can be expressed as a musical work? This is already being accomplished. For instance, artist John Dunn and biologist Mary Anne Clark (n.d.) have collaborated on the “sonification” of protein

data to produce an audio CD entitled “Life Music.” Despite the qualms discussed above as to the view of some regarding copyright protection of DNA sequences, Clark has no problems as to seeing the aesthetic aspects of genetic material, and the parallels between musical structure and the structure of proteins and the genes that encode them. Moreover, the musical transformation of DNA sequences is not merely an aesthetic exercise. It can be biologically informative to both the specialist and the lay person. For instance, in musicology a musical theme is defined by the intervals from note to note, not by the absolute pitches of the notes; similarly, proteins are defined by their overall patterns rather than by their absolute sequences. Thus, two amino acid sequences may be different: the phrase (in amino acid letter names) FSDGL in human beta globin is visually different to the phrase FGEAV in tuatara (an exotic 3-eyed lizard). However, the amino acids at the last four positions of each cluster have similar charge and solubility characteristics; these differences are, in musical and biological terms, said to be conservative, and act a little like a musical key change, because they maintain the shape of the line even though the absolute sequence is changed.²⁷ Moreover, the notion of viewing proteins as expressions of music makes one think of genes not as “pieces of information”, but rather as biological composers which produce new protein variations by recombining their constituent parts in different ways.

A geneticist might well consider converting a DNA sequence into a musical sequence for purely research, exploratory or aesthetic reasons. But why would a large genomic research company or

DBF consider embarking on this rather bizarre avenue? Maxygen, for example, has started encoding its DNA sequences as MP3 files. Is there legal or commercial relevance to this phenomenon? The requirement that a work be original shifts according to the genre of work – thus, a lower level of originality and creativity is required in relation to musical works than to literary works (Strowel, 1993, para. 334). Moreover, irrespective of the fact that protection is obtained in one medium or expression (e.g. musical works), intellectual property rights grant the rights holder the power to control a work in different corporeal states and derivative forms. Thus, copyright in a novel will extend to cover derivative manifestations of the novel in the form of a translation, a screenplay, a cartoon strip, or a film. Similarly, the copyright holder of DNA music may prevent reproduction of the work in “any material form”, which includes storing the work in any medium by electronic means.²⁸

But will copyright protection be forthcoming, especially on the grounds as discussed above that a musical transcription of a naturally occurring DNA sequence is not original? Case law from yesteryear has already determined this question: the transcription or arrangement of music from one type of instrumentation to another type is an independent musical composition.²⁹ Although the DNA is the “first” composer and author of the first work i.e. the protein sequence, the subsequent human author (or more likely software user) is the second composer of the second original work i.e. the DNA music. Moreover, it is not as simple as pressing the computer button and letting the software translate the DNA sequences – the

software user has to decide the length of each note, which instruments to use and the overall tempo of the tune (Shachtman, 2002).

At the practical level, a very good reason why copyright may be an attractive alternative to patents is that DNA music could be a safe way to transfer DNA sequences between scientists. Thus, one scientist would purchase encoded DNA music from a biotech company and download it rather than as one purchases an iTunes from Apple. By encoding one’s work, one can claim not only copyright protection, but also protection under the anti-circumvention measures.³⁰

The problem with these measures is that they may be employed to over-protect works. Indeed, technological measures do not merely prevent copying or downloading, but, similar to terminator technology, they also prevent access to a work. Such measures have the ability not only to prevent access for potential infringers, but also for those who have a legitimate right to access that technologically protected work. Below we provide examples of technological measures employed by the copyright owners, and show how they may obstruct the exercise of such legitimate rights.

Access locks: Such technological locks can prevent access to works which are not subject to copyright protection at all for example where the work comprises wholly or substantially of pure data or ideas or comprises of materials which are not subject to copyright protection under certain jurisdictions (such as laws, government reports and court judgements³¹), or the work comprises public domain materials which have fallen out of copyright protection. Another scenario which librarians have often complained of is when the work is subject to copyright protection, but

the user merely wishes to inspect the work prior to purchasing, but is unable to do so without circumventing the technological lock.

Copy locks: Such technological measures allow access to the work, but prevent copying altogether even where the user wishes to either copy insubstantial parts of the work (which is a non-infringing act under copyright law) or where the user has a valid defence for copying parts of the work (for example, archival usage or fair use).

Access and/or copy limit locks: This is where the technological measure allows a lawful purchaser of the copyright work to access (and maybe to copy) the product but limits the number of times this may be done. For example, the user may only play a CD-ROM for a certain number of times before access is denied completely and the purchaser may have to buy or licence a new version of the data.

Playback locks: This is a variation on the above themes, but merely limits the ability of the lawful purchaser to play the work on one type of media rather than another. Thus, recent CDs have been released which allow playback on regular CD audio players but not in CD-ROM drives of personal computers – the argument being that this prevents unauthorized downloading and uploading of music on the Internet.

The question being posed by those concerned about the diminishing public domain is: how effective are the traditional copyright exceptions and defences against the “anti-circumvention measures” clauses? Indeed, part of the problem is that the anti-circumvention or copy-control measures do not work uniformly and instead of merely preventing unauthorized reproduction, tend also to prevent playback of music

completely. Thus, at least one organisation has protested to the US Copyright Office that the practical effect of these malfunctioning copy control measures has been to prevent consumers from accessing protected music.³²

Clearly, applying copyright to DNA sequences is possible, but would not be a positive development when we consider how far copyright law has been pushed out of balance in order to protect the interests of the music industry, publishers and Internet content owners. Consequently, we should hesitate to introduce any measure that would, intentionally or otherwise, encourage the application of copyright protection to bioinformatics and genomics.

A Note of Caution; or, Beware of Getting What You Ask for

We should not give big business or patent professionals what they ask for just because they want it. It cannot be assumed that adopting their preferred patent policy is good for society or even the economy. But just because their demands are thwarted, they are unlikely to go away and let sleeping dogs lie if their economic interests are being affected. If they cannot get the legal support they demand, they will seek protection in other areas of the law or outside of the law entirely. Consequently, while we have sympathy for opponents of gene patenting, we would caution against pushing for an outright ban. Instead, we urge patent granting offices to improve or maintain high examination standards. A ban could well have the effect of encouraging companies to appropriate their discoveries in a less publicly accountable manner, of which DNA copy-

right may be among the most deleterious possibilities. Industry is already exploring this option and may well embrace it completely if such a ban were introduced.

Acknowledgements

The authors would like to thank the participants of the Sociology of Science and Technology Network workshop on the Biotech Age at Lisbon University in January 2005 for their insightful questions and comments on a draft of this paper.

Notes

- 1 US Patent No. 5,723,765 (issued March 3, 1998) (Control of plant gene expression).
- 2 This is not to deny the possible existence of other grounds for doing this.
- 3 The initial patent application was filed in 1974, but was overridden by subsequent applications. The definitive patent (number 4 237 224) was filed in 1979 and awarded in 1980. The title of the patent was "Process for producing biologically functional molecular chimeras".
- 4 For a discussion on "the innovation dilemma", which is that to protect cumulative innovation, we require a low threshold but by accommodating this low threshold, which benefits the innovators of today, we may hinder the innovation of tomorrow, see Dutfield and Suthersanen, 2004.
- 5 He made this point at an April 2001 conference hosted by Edinburgh University that one of the authors attended.
- 6 Article 5(2), Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, July 30, 1998.
- 7 Article 5(3).
- 8 Loi no 2004-1338 du 8 décembre 2004 relative à la protection des inventions

biotechnologiques.

- 9 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
- 10 Available at <http://publication.celera.com/humanpub/terms.html>
- 11 Available at <http://publication.celera.com/mousec16/terms.html>
- 12 Public interest in the British context is not construed widely but is confined to cases where the court finds that there is, irrespective of the secrecy of the information, "just cause or excuse" to allow a revelation of the information. The more ancient sentiment of the law is that works which reveal *turpis causa* cannot claim legal protection, *Bile Bean Manufacturing Co. v Davidson* (1906) 23 Report of Patent Cases 725; *Hubbard v. Vosper* [1972] 2 Queen's Bench 84 (Court of Appeal), and Cripps, 1994.
- 13 This is an especially old principle under UK intellectual property law - see *Jones v Pearce*, 1 WPC 120 (1826), and s. 60(5)(a) of United Kingdom Patents Act 1977.
- 14 See for example Art.1(3) of EC Council Directive 91/250 on the legal protection of computer programs [1991] O.J. L122/42, and Art. 3 of European Parliament and Council Directive on Legal Protection of Databases 96/9 [1996] O.J. L77/20.
- 15 *Feist Publications v Rural Telephone Services* 499 US 340 (1991).
- 16 See *Howard Florey/Relaxin* [1995] *European Patent Office Reports* 541.
- 17 The exception is the US copyright law where registration of a work with the US Copyright Office is required before enforcement of the copyright is allowed.
- 18 <http://www.dnacopyright.com/>
- 19 US Copyright Act, 17 USC §101. In comparison, s. 178 of the British Copyright Act 1988 defines "writing" to include "any form of notation or code, whether by hand or otherwise and regardless of the method by which, or medium in or which, it is recorded."

- 20 *Mackie Designs Inc. v. Behringer Specialised Studio Equipment (UK) Ltd & Ors* [1999] R.P.C. 717.
- 21 See *Ocular Sciences v AVCL* (1997) RPC 289, at 345.
- 22 *Business Communications Ltd v Planit Media AB* [2000] E.C.D.R. 93; *Nederlandse Omroep Stichting v NV Holding-maatschappij de Telegraaf* [2000] E.C.D.R. 129.
- 23 Art. 1(2), European Parliament and Council Directive on Legal Protection of Databases, 96/9/EC, 11 March 1996, OJ L 77/20.
- 24 Art. 7, *ibid.*
- 25 Recital 40, E.C. Directive *ibid.* Also see Art. 2(iv), WIPO Database Proposal, Diplomatic Conference on Certain Copyright and Neighbouring Rights Questions, Geneva, December 20, 1996, Doc. CRNR/DC/6.
- 26 Court of Appeals at Den Bosch (C0200726/MA), June 8 2004, available in Dutch at <http://www.rechtspraak.nl> (LJN number: AP2368); English translation at (2004) 45 *IDEA* 63 (2004).
- 27 To hear beta-globin music, go to <http://whozoo.org/mac/Music/BetaGlobin2.mp3>. For more DNA music, see <http://algoart.com/music.htm>.
- 28 See, for example, Sections 17(2) and 17(3) of British Copyright, Designs and Patents Act 1988.
- 29 *Wood v Boosey* (1867) LR 3 QB 223 (in relation to copyright in a musical composition called *Die Lustigen Weiber von Windsor*).
- 30 Art. 5(2)(b), Directive 2001/29/EC of the European Parliament and of the Council on the harmonisation of certain aspects of copyright and related rights in the information society, adopted on 9 April, 2001; s.512, U.S. Copyright Act.
- 31 For example, Art. 5, German Law; Art. 5, Italian Law of 1942; s. 105 US Copyright Act.
- 32 See <http://www.copyright.gov/1201/2003/hearings/schedule.html>

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