– In the event that a *'genetic underclass'* were to develop, and in the further event that most insurers refused insurance on that basis, it is possible that an insurer would simply take the risk and provide insurance on a different basis. The historical analogy is insurance for gay men in the 1980s.

– It may be anticipated that there will be increased political pressure on Government of the day to fill the gap left by private insurance schemes and provide for those who cannot obtain insurance any other way.

The issue which requires much greater discussion is whether insurers should be allowed to require an applicant to take a genetic test before providing insurance. (The first step down this road may already have been taken with the GAIC decision of 28 September 2000.) It is very important not to overlook the fact that this question, on the face of it a narrow issue, is part of a far wider debate about whether society wants or needs genetic testing and the implications of that testing.

The following further websites may be of interest:
British Society for Human Genetics on *www.bshg.org.uk/*

The UK Forum for Genetics and Insurance on *www.ukfgi.org.uk/:*

The Genetics Forum on *www.geneticsforum.org.uk/*

1 Advisory Committee on Genetic Testing (Code of Practice and Guidance on Human Genetic Services Supplied Direct to the Public) September 1997

2 See, eg: *London Assurance v Mansel* (1879) 11 ChD 363, per Jessel MR

3 *Pan Atlantic Insurance Co Ltd v Pine Top Insurance Co Ltd [1995] 1 AC 501*

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The UK Patents Regulations 2000: A Hostage to Fortune

In July 2000 the UK became one of only three EU Member States[1] to implement EU Directive[2] 98/44/EC and explicitly enshrine in national patent law the principle that biological material should not be treated as *per se* unpatentable. However, whilst the Regulations are applauded by those who believe that they will help foster the bioscience industry, the clear presumption in favour of granting patents, and the open language used in the Regulations[3], raises questions as to whether in fact the protection is appropriate.

Directive 98/44/EC

Directive 98/44 was adopted by the European Parliament in July 1998 and requires all Member States to provide patent protection for biotechnological inventions. The Directive is aimed at eliminating any barriers to trade which would otherwise be detrimental to the development of the biotechnology industry. It is clear that the objective is to promote investment in the biosciences with the patent system as an appropriate mechanism for helping achieve this objective.

The clear presumption in favour of patenting living material can be seen by the fact that the Directive states that where the material claimed is similar to material which occurs naturally, then it can be claimed as a novel invention provided the element has been isolated, or otherwise produced by a technical means, from its natural environment[4].

On this basis genetic material *in situ* is not patentable. However, the isolation of the genetic material from its natural environment will render the material, in patent law terms, novel as it will be regarded as not having been previously available in that isolated form. If the material is put to some use then, providing neither the act of isolation nor the use is obvious to others working in that area, patent offices will regard the isolated material, in that utilised form, as patentable. In respect of human genetic material, the Directive states that the human body at *'the various stages of its formation and development',* and simple discoveries relating to elements of the human body, including simple discoveries of gene sequences[5] are unpatentable. However elements[6] isolated from the human body, or otherwise produced, may be patentable.

Acting as a constraint on this presumption the Directive, building on the existing patent law set down in the European Patent Convention, states that patents are not available over inventions which are contrary to morality[7]. To assist in defining what is an invention contrary to morality the Directive provides a list of those inventions automatically excluded from protection irrespective of the novelty or inventiveness involved.

Article 6(1) sets out the general principle that inventions will be denied patent protection where the commercial exploitation would be contrary to

morality or *ordre public*[8]. (It would appear that an invention which results from an unethical research programme would not be excluded from protection.) Article 6(2) goes on to state that inventions that take the form of processes for cloning humans or for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals which causes suffering without any substantial benefit to man or animal, shall be considered unpatentable. Recital[9] 38 of the Directive makes it clear that this list is *'illustrative'* and intended to provide a non-exhaustive general guide for national granting offices and courts. In addition Recital 26 states that where an invention is based on human biological material, or if it uses human genetic material, then consent to the patent being filed should be obtained from the person from whom the material was taken. This consent being obtained *'in accordance with national law'.*

Protection also shall extend to any material derived from the patented material, or into which the patented material has been placed, provided the patented material carries out the function for which it has been patented. Equally any material which directly results from the use of a patented process, will also be covered by the patent over the process. The only exemptions are the human body and simple discoveries of its elements, although it must be presumed that where another invention involving human genetic material falls within the scope of Article 6 it will also be excluded.

It was against this background that the UK Regulations were drafted and, with limited public consultation, adopted.

The UK Regulations 2000

The Regulations are intended to implement the provisions of the Directive[10] and, therefore, they are based on the presumption that patents should be granted over inventions involving biological material. However, the text of the Regulations differs from the Directive in a number of key respects which may cause concern especially in relation to the protection of inventions involving human genetic material.

Schedule 2 of the Regulations sets out the principle that inventions shall not be considered unpatentable solely on the grounds that they consist of, or contain, biological material.

Paragraph 3 states that the human body, and the simple discovery of one of its elements are not patentable and contains an identical list to that set out in Article 6(2). This seems to be in line with the Directive. However there is a significant difference.

Paragraph 3 clearly states *'the following are not patentable'.* This implies that what follows is an *exhaustive* list of non-patentable material. Recital 38, however, states that the list is intended to be illustrative and non-exhaustive. No mention is made in paragraph 3 that the list is illustrative. It is possible that both the Patent Office and the courts may look behind the list and treat it as non-exhaustive, but the fact remains that they could treat only those inventions listed as *automatically* unpatentable. This does not mean that other inventions involving human genetic material not on the list will be patentable. Their exclusion, however, will depend on the interpretation and application of s1(3) of the *Patents Act* 1977 which allegedly implements Article 6(1).

Section 1(3) states that *'[a] patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality'.* The term *ordre public* is omitted. No explanation has been given for the change in language, but it is important for the term *'public policy'* has a specific meaning in English public law which does not correspond to *ordre public.* This could give rise to a challenge to the Regulations on the grounds of improper implementation and that the Regulations create a barrier to trade through differences in application between the UK and other EU Member States.

Another key omission is the absence of a requirement that the person from whom the genetic material originates must consent to a patent being obtained. The reason for the omission is that the existing law of the UK does not require such consent in respect of patent applications. However, in light of the coming into force of the *Human Rights Act 1998,* it might have been thought apposite to include such a requirement.

A number of more general patent questions remain. What must a patent applicant demonstrate in order to obtain a patent? There appears to be consensus outside the patent community that the threshold for protection, eg novelty and the distinction between discovery and invention, has been lowered to the point where little needs to be shown before a right is granted. Within patent circles the view is that if the invention meets the patent law definitions it is an invention for patent law purposes and therefore it is appropriate to grant the right. The justification for this appears to be the commercial importance of the bioscience sector. Despite this, many who work in UK bioscience research question if this approach will ensure that the patent system serves its primary function, providing a framework of protection within which scientists can carry out research and development for the benefit of the public, or if it will act as a curb on research thereby depriving the public of vital advances.

Conclusion

It is clear that the cost of developing new products based on human genetic material will be considerable. It is equally clear that there are many who feel that the development of such products will be for the public benefit and that the public, through state sanctioned monopolies, should reward those who undertake the financial risk involved. However, the public approval for such monopolies depends on their being properly granted. The presumption in favour of granting patents over inventions involving biological material brings into question whether the public good will ultimately be served by such a policy. One thing is certain, the apparent erosion of the bright lines of distinction between patentable and unpatentable means that the role of the courts will become more important and the issue could depend on the ability (not least financial) of those seeking a more restrictive approach to undertake litigation. In this way at least the Regulations could be regarded as a hostage to fortune.

1 The others were Denmark, Finland and Ireland. Germany has also recently adopted the Directive.

2 As the European Patent Convention (EPC) governs existing European patent law, in practice the Directive can do little more than offer guidance on how this law should be interpreted.

3 The Regulations amend and supplement the *UK Patents Act 1977.*

4 Articles 3(2) and 5(2).

5 Article 5(2).

6 No distinction is drawn between elements of a human origin and parts of the human body. It is not clear at which stage an element becomes a part of the human body and thereby excluded.

7 Article 53(a) of the EPC; section 1(3)(a) *UK Patents Act 1977* as amended by the Regulations.

8 According to the case law of the EPO, morality is determined according to whether common European culture would regard the invention as *'abhorrent'* (Guidelines for Examination in the EPO CIV 3.5), and *ordre public* relates to inventions which would breach public peace or social order.

9 For a discussion of the legal status of Recitals see Beyleveld *Why Recital 26 of the EU Directive on the Legal Protection of Biotechnological Inventions Should be Implemented into National Law* [2000] Intellectual Property Quarterly No 1, page 1

10 The Regulations only serve to implement part of the Directive, some relating to plant material remain outstanding.

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Regulation of Gene Technology in Australia

In Australia, as in Europe and USA, the debate over gene technology, genetically modified organisms *('GMOs')* and products derived or produced from a GMO *('GM Products')* is alive. While the benefits of gene technology are widely recognised, there are a number of community groups expressing strong concerns surrounding the implementation of gene technology. These concerns are based on ethical and religious grounds regarding the manipulation of DNA, concerns over the safety of genetically manipulated foods and, to a lesser extent, pharmaceuticals and fears that rogue genes could escape from commercial crops or animals and lead to widespread uncontrollable contamination and damage to the natural environment.

Current regulatory regime

Gene technology is currently regulated in Australia by a number of independent organisations, depending on the end use of the relevant GMO or GM product with the assistance of guidelines drafted by the Genetic Manipulation Advisory Committee *('GMAC').* For example, therapeutic goods, foods, agricultural, industrial and veterinary chemicals and the importing and exporting of GM products or GMOs are regulated under a number of different Federal, State and Territory Acts and regulations.

Genetic Manipulation Advisory Committee

GMAC was formed in 1987 and comprises approximately 20 part-time members from a variety of scientific disciplines with interests in biotechnology and those with legal or ethical backgrounds. Its mandate was to develop guidelines for GMO research and provide advice on the bio-safety and environmental implications of GMOs to the regulatory organisations

GMAC is a non-statutory body with no direct legal power to enforce its decisions. Its role effectively extends to overseeing laboratory based research and the release of GMOs into the environment, for example, in field trials and commercial GMO crops.

The main criticisms of the current regulatory system arise because of an apparent lack of transparency in GMAC's decision-making process, its apparent incapacity to ensure that conditions placed on field trials are strictly complied with, its insufficient capacity for legally enforceable auditing and monitoring and inability to impose penalties for breach. The number of regulatory organisations is not seen as a concern.