

Chapter 11

Legal matters : patent issues

Summary

A patent is a monopoly right, granted for a limited period, given to an inventor in return for the publication to the world at large of the details of an invention. The requirements for patentability are as follows: novelty, inventiveness, industrial applicability, sufficiency of description and the absence of any feature that makes for inherent unpatentability. The exclusions to patentability are as follows: mere discoveries, immoral inventions, biological processes and animal or plant varieties.

Both the requirements for, and exclusions to, patentability are examined as they relate to inventions derived from human tissue. Exclusion on the ground of immorality is examined in detail, since it has been important in the arguments about the patentability of biotechnology inventions such as transgenic animals, and, in at least one case covering the hormone relaxin, in arguments about the patenting of inventions derived from human tissue.

We review the options for ensuring that the ethical issues are properly taken account of in the patenting of inventions derived from human tissue. We conclude that a protocol to the European Patent Convention should be devised to set out criteria for applying the immorality exclusion where patents in the area of human and animal tissue are concerned.

Introduction

- 11.1 Recent innovations in the biological sciences have led to many difficulties in modern patent law, as a look at the newspaper headlines and introductory sentences in Fig 11.1 shows. In this chapter, we begin by defining a patent and then go on to discuss the patent issues raised by inventions derived from human tissue.

Fig 11.1

Independent 19 February 1992

Breasts provoked patent conflict

“Patent officials will have to come to a delicate decision in the coming months on how to regard an invention for secreting valuable proteins in the breast milk of women . . .”

The Times 13 January 1993

Cancer mouse protest

“Animal welfare groups have appealed to the European Patent Office against the granting of a patent to a mouse genetically engineered to develop cancer . . .”

Independent 14 January 1993

Royalties demand threatens research into cystic fibrosis

“Research and treatment of cystic fibrosis could be hamstrung because researchers are facing demands for royalty payments following the patenting of the human gene responsible for the disease . . .”

Daily Telegraph 22 September 1994

Patent ends co-operation over breast cancer gene

“Efforts to pinpoint a second defective gene responsible for breast cancer may be delayed by a row between British and American teams over patenting . . .”

Patents and human tissue

- 11.2 A patent may be defined as a monopoly right which is granted for a limited period, extending to the territory of a state. It is given to an inventor in return for that inventor publishing details of his invention to the world at large. The monopoly is the exclusive right to use the invention. This carries with it the right to give consent to (to license) others to use the invention, usually in return for a sum of money (a royalty) and, conversely, the right to prevent others from using the invention, if necessary by means of a legal action for infringement of the patent.

- 11.3 A patent is always granted for a limited term. Currently in Europe this term is 20 years from the date the patent is applied for. However the effective monopoly period is always less than 20 years because of the period between the date of application and the date when the patent is granted. During this period, called the prosecution period, the patent application is examined by patent offices around the world to ensure that it complies with the requirements for patentability.
- 11.4 The requirements for patentability differ in certain important respects in different parts of the world. There has been harmonisation of patent law within Europe but limited progress has been made in harmonising European patent law with that which applies, for example, in the United States and Japan.
- 11.5 The European Patent Convention (EPC)¹, which governs European patent law and practice, is completely silent on the patentability of inventions relating to human tissue. This is not at all surprising since, at the date of the EPC, much of the technology which has led to the making of such inventions simply did not exist. However, it has been the consistent position of the European Patent Office (EPO), which grants patents under the EPC, that the normal requirements of patentability (as set out below) apply to inventions derived from living matter, including human tissue, in just the same way as they do to non-living matter.²
- 11.6 A draft Biotechnology Directive³ which aimed to “clarify” (but not to change) existing European patent law, insofar as it related to biotechnological inventions (the “draft Directive”), was recently rejected by the European Parliament, the first occasion on which the Parliament has voted to reject a Directive.

¹ The EPC was ratified by the United Kingdom in March 1977 and entered into force in October 1977. The provisions of the EPC were enacted by the Patents Act 1977 which came into force in June 1978.

² In the US, it was held in the oft-quoted decision in **Diamond v Chakrabarty** (206 USPQ 193 1980), that patentable subject matter includes “. . . anything under the sun that is made by man”. This **Chakrabarty** approach is therefore similar to that which the European Patent Office has been following for many years.

³ The draft European Directive on the legal protection of biotechnological inventions was first proposed by the Commission to the Council of Ministers in November 1988 (European Commission, Office for Official Publications (1988) **Proposal for a Council Directive on the legal protection of biotechnological inventions** COM(88) 496 final - SYN 159). There then followed a lengthy period of consultation, and in October 1992 the European Parliament approved the draft in its first reading, with 45 proposed amendments. The Commission then put these amendments to the Council and in February 1994 a Common Position was adopted. This received its second reading by the European Parliament in May 1994, which voted in a number of controversial amendments (although doubts existed as to whether a quorum was present). The amendments were rejected by the Council of Ministers and a Conciliation Committee began to meet on 28 November 1994 to see whether a compromise could be achieved. On 23 January 1995 a compromise was apparently achieved between the Council and the Parliament but on 1 March 1995 the Parliament rejected the draft Directive by a vote of 240 to 188 with 23 abstentions.

- 11.7 Despite the deficiencies of the draft Directive (see below) it had been hoped that some of the uncertainties in this area of law would have been resolved by its implementation by member States. It now seems unrealistic to expect further legislation in this area from the European Union within the foreseeable future. This emphasises the need for clarification of, and possible amendment of, the EPC.⁴

The current position

- 11.8 Over the last decade the European Patent Office (EPO) has granted many patents relating to inventions derived from human tissue. Thus it has granted patents covering the use of, or processes for the production of, human cell lines (for example, a human lymphoblastoid cell line and a human hepatocyte culture process), human cell-derived protein products (for example, interferons) and DNA fragments (genes) for coding for useful proteins (for example, the hormone relaxin). A recent search of human tissue-related patents in the period 1982-1994 revealed 235 published patent applications covering mainly cultured human-derived cell lines, as well as techniques or substances relating thereto. Since the search only covered published applications and granted patents, the number of unpublished applications for patents pending in this field will be far greater than the above figure.
- 11.9 The patentability requirements which must be satisfied by an invention under European law are as follows:
- ▶ Novelty
 - ▶ Inventiveness
 - ▶ Industrial applicability
 - ▶ Sufficiency
 - ▶ Not inherently unpatentable (for example, discoveries, immoral inventions, essentially biological processes and animal or plant varieties are all expressly excluded from patentability).⁵

Each of these requirements is briefly considered below insofar as it applies to human tissue-related and/or biotechnological inventions.

⁴ Paragraphs 11.37 - 11.43 and 11.47

⁵ Patents Act 1977, Section 1.

Novelty

11.10 An invention must be new, in the sense of not having been made available to the public anywhere in the world before the filing date of the application for a patent (the “priority date”). A substance which already occurs in nature, for example in humans, will nevertheless satisfy this requirement, if what is claimed in the patent specification is something which is **not** naturally available – for example if it is highly purified. To take a specific example, tissue plasminogen activator (t-PA) is an enzyme active in humans in the dissolution of blood clots. In a patent covering the production of human t-PA by means of recombinant DNA technology, one of the claims read: “*Human tissue plasminogen activator unaccompanied by associated native glycosylation*”.⁶ This would be regarded as satisfying the novelty requirement for a patent. Even if the identical substance is available in nature (for example, a DNA sequence in humans) the substance will be regarded as novel when identified and isolated for the first time.⁷

Inventiveness

11.11 An invention must be inventive, in the sense that it would not have been obvious to a person of ordinary skill in the relevant art at the priority date. Again, for inventions derived from human tissue, this rule applies as it does to any other type of invention. Thus, for example, if the invention is a process for obtaining a given human gene, and that process was not obvious to the person skilled in the art at the priority date, then it will be inventive. Even if the process is entirely conventional, there may still be invention if the process provides a useful substance which was previously unknown.⁷

Industrial applicability

11.12 An invention must be capable of industrial application. In practice, pharmaceutical or biotechnological inventions for use in treating human beings will normally satisfy this requirement.⁸

⁶ **Genentech Inc’s Patent** [1989] RPC 147

⁷ Decision of the EPO in the Opposition to Patent No 112 149 in the name of the Howard Florey Institute of Experimental Physiology and Medicine dated 18 January 1995 (“the Relaxin Opposition”)

⁸ This requirement would not present a problem in many cases. For example, the Genentech claim to “*Human tissue plasminogen activator as produced by recombinant DNA technology*” (paragraph 11.10) would satisfy it. However, it might have constituted a bar to two rather controversial patent applications filed in Summer 1991 and February 1992 by the US National Institutes of Health (NIH) relating to over 2,400 DNA fragments,

Sufficiency

- 11.13 The invention must be clearly and completely described in the patent specification, sufficient to allow someone else skilled in the art to perform it.⁹

Exclusions to patentability

- 11.14 Finally, certain specific exclusions to patentability exist. Thus if the invention falls within one or more of these, it is **not** patentable. The more relevant of these exceptions are noted below.

known as Expressed Sequence Tags, or ESTs. These ESTs correspond to partial sequences of genes expressed (that is, translated into proteins) in human brain tissue. The genes in question are estimated to represent about 5% of all human genes. Any alleged industrial applicability of this invention is probably speculative, because for most of the claimed ESTs, the genes to which they correspond and the proteins for which they code remain largely unidentified.

The NIH argued the usefulness of the claimed ESTs as markers (among other things). However this was not enough to satisfy the US Patent & Trademark Office, which in August 1993 rejected one application on the ground *inter alia*, of inutility (effectively the US equivalent to the European requirement of industrial applicability). The NIH did not appeal the decision and has since withdrawn its other application and all foreign equivalents of the applications. In September 1992, Congress asked the US Office of Technology Assessment (OTA) to review the implications of NIH-like filings. That report is awaited. Meanwhile the inventor of the NIH patents is now working independently of the NIH and the US company for which he now works has filed new patents on gene sequences.

In the UK, the Medical Research Council and the Government have stated that they are in favour of an international agreement not to patent such sequences, in the interests of promoting the Human Genome Project – the 15-year international effort to sequence all human genes. However, it had felt obliged to file two patent applications similar to those of the NIH, as a “protective measure”, but these were also withdrawn in early 1994.

As regards the European Patent Office, it is not yet clear whether NIH-like patent applications will be granted. In the Relaxin Opposition (footnote 7) when distinguishing between invention and mere discovery, the European Patent Office relied upon the fact that the patentee had found a use for the protein coded by the relevant human gene.

⁹ Rule 28 of the EPC states that for those inventions which relate to a micro-organism which is not publicly available and cannot be described, this requirement will be met by the micro-organism’s **deposit** in a recognised culture collection. Thus for many human tissue-derived inventions, a need may arise for the deposit of a sample of the human cell line in question.

By their nature, biotechnological inventions often cover many variants (eg. sequences, vector constructions, epitopes, etc). When it comes to obtaining patent protection, naturally the claims are drafted as broadly as possible, so as to cover as many variants as possible. However, only **some** of these may actually be disclosed in the specification – or indeed, may be workable. It was held in decision **T292/85/Genentech I/Polypeptide Expression** that the sufficiency requirement is met if at least **one way** is clearly indicated which enables the skilled person to carry out the invention. However, in 1994 this was modified in the European Patent Office and the English Court of Appeal : what is required is that the skilled person is enabled to carry out the invention across the whole range of what the patent claims (in decision **T409/91/Exxon/Fuel Oils**; *Biogen v Medeva*, CA unreported).

Exclusions : discoveries

11.15 A discovery, scientific theory, or mathematical method, is not patentable. At first glance, it would seem that identifying a substance which occurs in nature (for example in humans) could be said to amount to a discovery, and hence to be unpatentable. However in general, if an invention is the **practical application** of a discovery, it will be patentable. Thus a natural substance may be patentable if it has first to be isolated from its surroundings in pure form, and/or if the process for doing so is patentable. To give an example, in the EPO a claimed invention to a specific human DNA sequence for use in expressing a useful polypeptide encoded therein would not be considered a discovery, and so would fall outside this exclusion.^{7,8}

Exclusions : immorality

11.16 Any invention which would be expected to encourage offensive, **immoral** or antisocial behaviour, is not patentable.¹⁰ In June 1978, when the Patents Act 1977 came into force, biotechnology was in its infancy. Thus the “*immoral*” inventions which the legislation contemplated at that time included such things as instruments of torture and letterbombs – which were so clearly immoral as to require little detailed consideration of the meaning of the exclusion. It was only with the emergence of biotechnology and the creation of such entities as transgenic animals and attempts to patent human genes (see below) that the meaning of the immorality exclusion has begun to be tested in any depth in the EPO. It is to be expected that this exclusion will be invoked increasingly in future in cases of inventions derived from human tissue – as indeed has already been the case unsuccessfully with at least one application, covering the DNA sequence for the protein hormone relaxin (see below), derived from the human ovary.

11.17 The Guidelines for Substantive Examination in the European Patents Handbook provide that an invention is “*immoral*” if the general public would consider it so abhorrent that patenting would be inconceivable. There are no express guidelines which go beyond this general statement, and the EPO has stated that it considers it the responsibility of individual patent examiners to determine on the facts of each case whether a given invention is “*immoral*”, or not.¹¹ As mentioned above, until very recently, the morality requirement was a relatively obscure provision which was rarely invoked. It has now come to prominence in the context of patents relating to human parts and transgenic animals.

¹⁰ Patents Act 1977, Section 1(3)(a) and EPC, Article 53a

¹¹ However, the draft Directive did expand on this position as regards the patentability of human tissue (paragraphs 11.21 - 11.24)

- 11.18 In the case of **T 19/90 Harvard Mouse/OncoMouse** in the EPO, the invention concerned a mouse with a genetically inserted predisposition to cancer, for use in cancer research. In deciding that the invention was **not** immoral, and was therefore patentable, the EPO's approach was to weigh the suffering to the patented animal against the invention's usefulness to mankind. In doing so it considered such factors as the invention's benefit to mankind, the threat it posed to the environment (which, in the case in question, was regarded as controllable), and the reduction in the overall level of animal suffering which would be expected to result by decreasing the numbers of animals used in conventional testing. The **OncoMouse** patent is now being opposed in the EPO.¹²
- 11.19 By contrast, in the case of a patent application filed by the Upjohn company, the EPO is understood to have decided that it is immoral to patent transgenic animals for the purposes of screening agents for wool growth and hair promotion in humans. The animals in question carried a promoter from a gene coding for a hair-specific protein, linked to a reporter gene, which latter gene had an observable phenotypic effect. A specific embodiment of the gene was an oncogene - such that the animals developed cancer when used in the hair-growth tests. It was this to which the EPO

¹² The **OncoMouse** patent was first granted in the US in 1988 and in the European Patent Office in 1992. In the US Patent Office, after a hiatus of four years, patents are now being granted covering transgenic animals. An estimated 180 applications for transgenic animals are pending. It is widely expected that such "animal models" will become a growth industry. However, in February 1993, the European Parliament passed a resolution (B3-0199, 0220, 0249/93) requesting the European Patent Office to revoke the **OncoMouse** patent, on the grounds of immorality, and to institute a moratorium on future patent applications covering transgenic animals. The European Parliament's resolution has of course no direct legislative effect on the European Patent Office. However, the Parliament has now exerted its influence by voting down the draft Directive.

In January 1993, a coalition of system animal welfare groups and one individual, headed by the British Union for the Abolition of Vivisection (BUAV) and Compassion in World Farming, filed an opposition to the **OncoMouse** patent. The BUAV attack, based solely on the immorality exclusion, has two limbs. It is argued that:

- (1) The European Patent Office did not weigh the merits and demerits of the **OncoMouse** patent with sufficient care, because "oncomammals":
 - (a) suffer considerably, and higher oncomammals (such as oncochimpanzees) suffer most of all;
 - (b) are not very useful - because of the doubts which exist as to the inherent unreliability of extrapolating from animal models to human beings, and because oncomammals exhibit a high "background" incidence of spontaneous tumours; and
 - (c) constitute a risk to the environment, because they may escape, breed with domestic/farm animals, and so spread the oncogene.
- (2) It is inherently immoral genetically to predispose animals to painful diseases. In other words, the end - of benefiting mankind - does not justify the means. Thus the EPO's balancing act - even if properly carried out - is wholly misconceived.

In July 1994 Harvard filed a lengthy reply brief. The opposition proceedings continue and are expected to be heard in November 1995.

objected, saying that the potential suffering to the animals was not outweighed by the invention's benefit to mankind.¹³

- 11.20 On 18 January 1995 the EPO published its decision in the opposition to European Patent No 112 149 in the name of the Howard Florey Institute of Experimental Physiology and Medicine, of Melbourne, Australia ("the Relaxin Opposition"). The patent covers the DNA sequence (ie the gene obtained from a human ovary) which codes for hormone relaxin, which relaxes the uterus during childbirth. An opposition to the patent was filed in January 1992 by members of the Green Party in the European Parliament on a number of grounds, including the immorality exclusion. The opponents objected specifically that, since the DNA relaxin gene could only be isolated from the tissue of a pregnant woman, the use of pregnancy for profit was an offence against human dignity. They also objected more generally on the basis that to patent human genes was patenting "life" and therefore intrinsically immoral, and also that patenting of human genes amounts to slavery contrary to the fundamental human right to self-determination.
- 11.21 The EPO, in its decision, acknowledges that it is not the right institution to decide fundamental ethical questions. It confirmed that its general approach to the immorality exclusion in Article 53(a) of the European Patent Convention (EPC) would remain that as set out in the EPO Guidelines (see paragraph 11.17 earlier) and that the exclusion would be narrowly construed and applied in only the clearest cases.
- 11.22 Applying these general principles, the EPO rejected the opposition. It noted that the original ovarian tissue had been donated during the course of necessary gynaecological operations. This use of donated tissue, according to the decision, was no more immoral than using donated blood as the source of life-saving substances, such as blood clotting factors. So far as slavery was concerned, the EPO stated that the opponents had fundamentally misunderstood the nature of a granted patent. A patent does not give the proprietor any right over a human being but merely the right to prevent another from practising the same invention **outside** the human body. Finally, the EPO rejected the argument that a patent on a DNA fragment or gene was equivalent to patenting "life". In the view of the EPO, DNA is not life but rather a chemical substance which carries genetic information to produce medically useful proteins.
- 11.23 In this rather strongly worded decision, the EPO refused to draw any distinction in principle between the patenting of genes and the patenting of other human substances that might be useful in treating humans. It also denied that such a distinction is drawn by members of the public generally. In support of this view the EPO pointed to the existence of the draft Directive which allowed for the patenting of genes. Now of course the draft Directive has been rejected by the European Parliament.

¹³ It is understood that Upjohn have since re-submitted revised claims, having deleted those covering oncogenes.

- 11.24 It is to be anticipated that the decision in the Relaxin Opposition will be the subject of an appeal to the relevant Technical Board of Appeal at the EPO. If the normal procedure is followed, the appeal will not be considered for approximately two years.
- 11.25 The draft Directive was until 1992 completely silent on the morality of patenting. Ultimately the draft Directive was voted down by the European Parliament precisely because agreement could not be reached between the Council and the Commission on the one hand and the Parliament on the other hand as to the extent to which the patenting of human parts should be permitted. On 23 January 1995 a Conciliation Committee comprising members of the Council and Parliament appeared to have agreed on a compromise text for the critical draft Recital 10 dealing specifically with body parts. The compromise appeared to allow the patenting of human parts provided that the ordinary technical requirements for patentability were satisfied and provided that the parts: “*are no longer directly ascribed to a specific individual.*” It was not at all clear how this wording distinguished the patentable from the non-patentable. The Council proposed to adopt a declaration to clarify its understanding of Recital 10. Regrettably the Parliament proposed to adopt a second declaration which was substantially inconsistent. In particular, the Parliamentary declaration seemed to require the part in question to be “*modified*” to some extent from the natural part as it exists in humans even though no such requirement existed in the compromise Recital 10. Perhaps with all the confusion it is not surprising that the draft Directive was voted down. Both industry and representatives of the Green Group have expressed themselves satisfied at the outcome.
- 11.26 Although the decision of the EPO in the Relaxin Opposition has clarified to some extent the patentability of human genes, a number of important questions remain. It is not clear to what extent the morality exclusion will apply to patents concerning germ-line gene therapy as distinct from somatic gene therapy. (Somatic gene therapy is one which brings about non-hereditary changes in an existing human being; germ-line gene therapy brings about hereditary changes). The draft Directive appeared to allow for patenting of germ-line gene therapy. Now that the Directive has been lost, the patentability of such therapy will be tested for the first time in the EPO during the prosecution of WO93/11228, a patent application in the name of the Trustees of the University of Pennsylvania. This application covers *inter alia* a method of germ-line gene therapy involving replacing the sperm-producing cells of a male mammal with sperm-producing cells not native to that mammal. Thus, this technique allows for the genetic manipulation of a male animal’s sperm so as to produce alterations in that animal’s progeny. Claim 27 of the application covers this method of gene therapy for use in human beings.

Exclusions : biological process

- 11.27 Any essentially biological process for the production of animals or plants is not patentable – although a microbiological process or the product of such a process **is** patentable.¹⁴ This is a difficult distinction for most to understand. There is some guidance on the meaning of “*essentially biological process*” from the EPO, namely that it is “*the routine manipulation of a known and naturally occurring biological event*” such as, for example, traditional methods of selective breeding. Thus for an invention to fall outside this exception (and hence to be patentable) there needs to be “*significant technical intervention*”, going beyond routine manipulation.¹⁵
- 11.28 “*Microbiological processes*”, which **are** patentable have in practice been construed so widely as to include, among other things, human cell lines.

Exclusions : animal or plant variety

- 11.29 Any variety of animal or plant is prohibited from patent protection.¹⁶ The meaning of “*animal variety*” remains unclear. In the **OncoMouse** decision the EPO held that although they did not understand the meaning of this term, “*rodents*” or “*mammals*” (the words used in the **OncoMouse** patent) “*constitute a taxonomic classification unit much higher than species (“Tierart”)*”.¹⁷ An “*animal variety*” or “*race animale*” is a sub-unit of a species and therefore even lower ranking than a “*species*.” Therefore the claims fell outside the exception and were patentable.

¹⁴ Patents Act 1977, Section 1(3)(b)

¹⁵ Decision T 320/87 Lubrizol Genetics Ltd

¹⁶ The animal and plant variety exception came about as follows. In the 1950’s when the idea of plant variety rights was taking hold, a convention was signed which specifically prohibited double protection – that is, by both patents and plant variety rights – of the same plant variety (the UPOV Convention). This notion was adopted by the EPC in 1973, in respect not only of plant but also animal varieties. However, the difficulty is that the term “*animal variety*” does not have an unambiguous scientific meaning (which was acknowledged by the European Patent Office in the **OncoMouse** decision referred to above). Moreover, the text of the EPC exists in three languages, which are recognised by the EPC as being equally authentic. A problem arises in that the English term “*animal variety*” and the French “*race animale*” are both vague and ambiguous, compared with the more specific German term “*tierarten*” – which is apparently more akin to the English term “*species*”. This problem has so far not been resolved by the European Patent Office, and the draft Directive did nothing to assist.

¹⁷ Two representative claims in the **OncoMouse** patent read as follows:

- “1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage.
2. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the 8-cell stage, said oncogene optionally being further defined according to any one of claims 3 to 10.”

Conclusions on patentability

- 11.30 From the above it will be clear that human genes, human cells, and the products and processes derived from them, are already patentable (and patented) under European patent law and that, in the first instance, the patentability of such inventions (including the question of morality) is determined by individual examiners at the EPO on a case by case basis. The European Patent Office has for over a decade been applying the established patentability criteria to such inventions. There is a body of opinion that the immorality exclusion, at least, needs clarification. Now that the draft Directive has been rejected, the preferred course may be amendment to or clarification of the EPC itself.
- 11.31 It is also important to note that the decision of an examiner at the EPO is not necessarily the final decision on the patentability of a given invention. It is possible to oppose a patent in the EPO within nine months of its grant – and such opposition proceedings involve a review of the original examiner's decision. This review can be the subject of a further appeal within the EPO. Moreover, even after the opposition period has expired, or after an unsuccessful opposition, it is open to an interested party to apply to have the patent revoked in a relevant national court on one or more of the grounds set out earlier.

The current position : ownership of patents derived from human tissue

11.32 Under European law, the following persons are entitled to apply for a patent:

- ▶ the inventor (or co-inventors); or
- ▶ the inventor's successors in title – that is, his assignees, licensees or heirs; or
- ▶ where the inventor is an employee, his employer may be entitled to the patent, depending on the circumstances.¹⁸

The right of ownership in a patent derives from the act of invention. In the case of inventions derived from human tissue, the act of invention is carried out by the person who extracted and purified or manipulated the human tissue by some inventive means – and it is this intervention which confers the right to apply for a patent. It follows that the owner of the monopoly is not the donor of the tissue in question; he has played no part in the intervening inventive act. Hence the donor

¹⁸ Patents Act 1977, Section 39

has no right to interfere with the lawful owner's exercise of his monopoly - irrespective of whether the tissue was obtained and/or experimented on with or without his consent.¹⁹

The current position : possible restrictions on the exercise of the patent monopoly

- 11.33 As with all other patents, the effect of the grant of a patent for an invention derived from human tissue is to give its proprietor a monopoly. As stated earlier, this may be characterised as the exclusive right to practise the invention, the exclusive right to prevent others from making unauthorised use of the invention and the exclusive right to authorise others to practise the invention (usually in return for payment) by means of the grant of a licence.
- 11.34 Particular problems as regards the scope or exercise of the monopoly do not appear to have arisen in the case of inventions derived from human tissue. However it may be considered more important in the case of these inventions that the monopoly should not be exercised by the patent owner in such a way as to prevent or restrict academic research.
- 11.35 As the law stands an act done for "*experimental purposes relating to the subject-matter of the invention*" is not an infringement, ie a breach of the monopoly. However, the limits of this exception are unclear. In particular there is no statutory definition of "*experimental purposes*" (although it has been conceded that this can include testing with a commercial end in view, provided that commerce is not the **sole** end). Similarly, the meaning of "*relating to the subject-matter of the invention*" is unclear. For example, if a patented growth factor-producing cell line were used to research the production of other factors, such as a proliferation inhibitor, could it be said that such research "*relates to the subject-matter*" of the patented cell line, and hence is not an infringement by virtue of the exception? The better view is probably that such an act should be an infringement, because the exception should be narrowly construed. Proposals to clarify, and possibly to widen, this exception have received widespread support in the pharmaceutical industry, which regards the present lack of clarity as an unnecessary and undesirable fetter on research. In particular, in 1992 the International Association for the Protection of Industrial Property (AIPPI) passed a resolution on how the exception should be clarified.²⁰

¹⁹ Patents Act 1977, Section 60(5)

²⁰ The resolution is as follows:

"1. *Experimental use comprises any use of the patented invention which is effected for purely academic purposes*

The current position : compulsory licensing

11.36 European law allows a compulsory licence to be granted under patents in certain circumstances.²¹ This means that if certain statutory criteria are satisfied a company or organisation can obtain the right to practise a patented invention even against the wishes of the patent owner. The question arises whether the statutory criteria need special amendment in the case of patented inventions derived from human tissue. Our view is that there is no evidence to suggest that there is a public interest in further legislation in this area.

The way forward : possible options

11.37 We support the view that as a general rule (and subject to the major qualification in paragraph 11.38 below) the criteria for patentability laid down by the EPC should be applied to inventions relating to human tissue, just as they are applied to all other inventions.

11.38 It is however recognised that the field of human tissue-related inventions raises ethical and moral questions that have not been encountered to the same degree (or at all) with other technologies. This poses a challenge for patent law. On the one hand, there is a need to satisfy legitimate public concern about the ethics of these inventions – while on the other hand, there is a political and economic need to do so in a way that does not inhibit innovation and discourage economic investment.

and without commercial character.

2. *Experimental use comprises any use of the patent invention in a manner which is suited to experimentation (and not commercial use), the aim of which is to improve the invention, to advance it or to find an alternative thereto, but not commercial exploitation of that improvement or advance.*
3. *Experimental use comprises tests which are carried out to evaluate the teaching of the patent and the validity of the patent.*
4. *Experimental use is to respect the principle that such use is to involve work on the subject of the patent and not use of the patented invention as means for other uses or subjects, even experimental.”*

This resolution is now being considered by the World Intellectual Property Organisation with a view to an eventual amendment to the Paris Convention. However, to date nothing has been implemented.

²¹ Patents Act 1977, Section 48 *et seq.*

- 11.39 It was once hoped that the draft Directive would eventually provide some guidance on the application of the immorality exclusion, but the draft Directive has now been lost. Thus other options need to be considered.
- 11.40 One option would be to remove the immorality exclusion altogether from the patent application process – in other words, to obviate the need for patent examiners to decide complex ethical issues for which their training has left them unprepared. It would then be for national courts to resolve ethical questions. There are two principal disadvantages to this approach. First, removing the immorality exclusion would require amendments to the EPC and the harmonising national legislation such as the UK Patents Act 1977. Secondly, national courts might differ in their determination of ethical issues – just as they have already been observed to do in their approach to other patentability issues. Significant national differences in the extent to which inventions derived from human tissue are patentable within the European Union would cause ethical, political and commercial confusion.²²
- 11.41 A second option would be to retain the immorality exclusion and to ensure that it continues to be invoked only in extreme cases of obviously abhorrent inventions – leaving a more considered determination of the scope of the exclusion to national courts, as occurs with other patentability issues.²³ This so-called “*light approach*” would have the advantage of not requiring a change in the law, but by relegating the problem to national courts it may still result in national differences in the application of the exclusion, with the concomitant disadvantages mentioned above.
- 11.42 A third option would be to retain the immorality exclusion, but to ensure that its scope and application was determined not by patent examiners, but by a specially constituted Europe-wide ethics committee concerned exclusively with the resolution of ethical issues. Such an ethics committee might either form part of the patent application process (that is, part of the EPO), or alternatively, some commentators have suggested that it should exercise some kind of post-grant “*vetting*” process,

²² The Community Patent Convention provides for the eventual grant by the European Patent Office of a single patent which would be valid for the whole of the European Community. Such a patent would in the first instance be assessed by national courts but thereafter there would be a right of appeal directly to a new Community institution, namely the Community Appeal Court – otherwise known as “COPAC”. Thus COPAC would effectively supersede national appeal courts as regards the determination of patent issues. However, it is expected to be some years before COPAC will be in place to express Community wide views on patentability issues.

²³ The two former Comptrollers of the UK Patent Office support this approach, based upon the history and practice of the European patent system. See their monograph; Armitage and Davis, “Patents and Morality in Perspective” (Common Law Institute of Intellectual Property 1994) which is a response to a more interventionist analysis of the morality provision by Beyleveld and Brownsword, “Mice, Morality and Patents” (Common Law Institute of Intellectual Property 1993)

examining the ethics of each attempt by industry to put a given invention into effect.²⁴ We do not regard the latter, post-grant, approach as being desirable – since this would create significant uncertainty as to the scope and effect of **granted** patents as well as delaying the exploitation of inventions – both of which would be prejudicial to industry.

- 11.43 A fourth option would be for the signatory states to the EPC to adopt a protocol to the EPC which would set out in some detail the criteria to be used by national courts when applying the immorality exclusion to patents in the area of human and animal tissue. This approach would have the advantages of: avoiding the delay inherent in bringing about changes to the EPC itself and harmonising national legislation; avoiding the uncertainty and additional bureaucracy of a separately constituted ethics committee; minimising the risk of national differences in applying the exclusion; and providing much-needed guidance to the courts. Although of necessity this approach would be time-consuming, we would regard it as the most practicable and balanced of the available options. We would in the meantime prefer the maintenance of the light approach by the EPO itself. We do not regard patent examiners as the right people to decide complex ethical issues.

Conclusions and recommendations

- 11.44 We recognise that inventions derived from human tissue are open to patenting. Over two hundred patent applications have been published where the criteria for patentability have been met (paragraph 11.8). We accept this position as a matter of fact.
- 11.45 There is at present a major controversy about patenting in the area of human genes. The law, as it stands, discriminates between discoveries and inventions (paragraph 11.15). Fundamental to the application of the notion of invention in this area is that some technical intervention should have taken place that justifies the granting of an intellectual property right. We note that questions of fact arise in each case on whether patent applications meet the existing legal criteria.
- 11.46 The immorality exclusion, which has a long-standing existence, has now a greater influence than was originally intended (paragraphs 11.16 – 11.26). We recognise that there is a need to take account of ethical factors and sensitivities in the patenting of inventions derived from human tissue (paragraphs 11.37 – 11.43).

²⁴ Price, R. and Cohen, S. (1994) *Nature* 369:589

11.47 We attach great importance to the fuller consideration and review of the process by which ethical issues are taken account of in relation to the question of patenting inventions derived from human tissue. We recommend that the Government joins with other member states of the European Patent Convention (EPC) in adopting a protocol to the EPC which would set out in some detail the criteria to be used by national courts when applying the immorality exclusion to patents in the area of human and animal tissue (paragraph 11.43).