Intellectual Property Rights (IPRs) and Genetics

A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector

Professor W. R. Cornish
Dr M. Llewelyn
Dr M. Adcock

July 2003

Research Team

Professor W. R. Cornish
Intellectual Property Unit
University of Cambridge

Dr M. Llewelyn
Sheffield Institute of Biotechnological Law and Ethics
University of Sheffield

Dr M. Adcock
Sheffield Institute of Biotechnological Law and Ethics
University of Sheffield

Project Management

Dr R. Zimmern
Director, Public Health Genetics Unit, Cambridge

For additional copies please contact:
Cambridge Genetics Knowledge Park
Strangeways
2 Worts Causeway
Cambridge CB1 8RN

Tel & Fax: +44 (0)1223 740200
email: cgkp@srl.cam.uk

This report can also be downloaded from the following website: www.phgu.org.uk

This report is published by the Public Health Genetics Unit, a core facility of Cambridge Genetics Knowledge Park. The project was funded by the Department of Health.

CONTENTS

APPENDICES **93**

FOREWORD

Few issues today illustrate the gulf between the pharmaceutical and genomics industries and the healthcare sector as starkly as intellectual property rights (IPRs). IPRs are one of the corner stones of industry. They allow companies to recoup the cost of expensive research and development programmes which in turn ensures that resources are available for future therapeutic and diagnostic products. However, for the healthcare sector there is a danger that IPRs may generate disproportionate claims from right-holders, resulting in undue restrictions and licence charges as well as constraints upon further research. This may lead to unacceptable barriers, restricting access to medicines and diagnosis and thus curtailing the healthcare sector's ability to fulfil its primary role and limiting its generation of healthcare products.

In particular, IPRs are going to be relevant to the provision of genomic healthcare, governing how the Department of Health is able to maximise its use of both protectable genetic material generated "in-house" and protected genetic material "bought in" from third parties.

In commissioning this Report into intellectual property rights and genetics, the Department of Health has realised that IPRs are going to play an increasingly important role in healthcare delivery and have adopted the role of an active rather than passive player in intellectual property issues.

The Report outlines the current IPR legislation, focusing on issues surrounding patents, but also taking into account the impact of other types of IPRs. The Report highlights other relevant areas and issues, such as human rights, that may impact upon access to healthcare. In addition the Report looks at the balance between industry and the healthcare sector, and identifies the main issues of contention. By emphasising the IPR needs of the healthcare sector, the report will be critical in helping to develop a positive, effective and appropriate IPR management strategy and appropriate reward for the perceived benefit to society.

The Report is the collaborative work of Professor Bill Cornish of the University of Cambridge's Intellectual Property Unit and Dr Margaret Llewelyn and Dr Mike Adcock of SIBLE, the University of Sheffield's Institute of Biotechnological Law and Ethics. The project was overseen by Dr Ron Zimmern of the Public Health Genetics Unit in Cambridge who also provided insights into the workings of the NHS and current policy considerations in genetics and healthcare. We also wish to thank all the participants at the workshop held at Hinxton in February 2003 for their invaluable comments, many of which have helped inform the final document.

The views expressed are those of the project team.

EXECUTIVE SUMMARY

This Report was commissioned by the Department of Health because of its serious concern about the impact of intellectual property rights (IPRs) upon research and the use of novel developments in genetics affecting health care. The subject has become increasingly controversial since the completion of the drafts of the Human Genome. The Report is a guide in outline for non-specialists in the field of IPRs. Its main aim is to state the present legal position, so far as it can be ascertained, and to suggest the issues about which it is important to define policy for the future. Expressions of opinion are those of the authors alone and not of the Department of Health.

The type of IPR with widest impact in the field of genetics is the patent for invention. Other rights which are also addressed include copyright and its extension; database right; proposals for a right to remuneration for the copying and other exploitation of genetic information; and the protection of confidential information.

A PATENTS

The patent system has an innate capacity to adapt itself to novel technologies. Unfortunately, unless legislation intervenes, change can be slow being dependent upon practice in patent offices and decisions of courts. It is nonetheless vital to consider, in relation to biotechnology, what developments are necessary in patent law and practice and how they can be achieved.

These are primarily the following:

(i) The definition of what subject-matter is patentable and, in particular, what should be excluded as mere discovery; information without sufficient technical effect; claims to inventiveness which lack sufficient disclosure of how to perform them; and claims which are either not novel or not inventive and so do not satisfy basic criteria of patent validity.

(ii) The scope of the right granted and, in particular, whether protection should extend to all methods of obtaining a product genetically engineered, and whether it should be for all potential uses of the subject-matter or only for the beneficial effect actually demonstrated - the problem, in current jargon, of the "reach through claim".

(iii) The nature and extent of the research exemption for those who make use of patents in order to further clinical knowledge.

(iv) The role of public interest exemptions and constraints on abuse of a monopoly position through competition law, as a means of curbing over-protection.

In relation to (i), the study notes with approval the developments which would exclude from the range of what are patentable claims upon genetic fragments, those which are not shown to have practical advantages (being mere discoveries which lack industrial application). It points out the growing significance of adequate disclosure as a legal requirement, which plays an important role in curbing claims to a gene, polypeptide or protein, whatever the means of production, when the invention is only of one method of production; and it notes the critical approach to patent validity and scope which English courts have taken in reaching decisions on biotechnology patents.

In relation to (ii) it draws attention to the rising concern that patents are being granted over genes as such without any limit to the particular inventive function or use. It contrasts the need for limitation in the genetic field with the forms of claim allowed in respect of novel pharmaceuticals in general.

In relation to (iii) the study notes the current doubts about the scope of the research exemption in European patent law and urges clarification of two issues in particular: when can it be said that the research is upon the subject-matter of the patent? And how far can clinical trials be regarded as experimental use when they seek further information about the patented invention at the same time as providing treatment to patients?

In relation to (iv) it outlines the possible impact on patent rights of (a) the compulsory licence and Crown use provisions in the Patents Act 1977; and (b) Rules of Competition under the EC Treaty, Articles 81 and 82 and the Competition Act 1998 (UK). It suggests that consideration of compulsory licensing could be of use where the demands of one or more patentees are proving importunate and it addresses the use of competition law even against a person holding IPRs where the situation gives rights to an economic monopoly in healthcare provision.

B OTHER IPRS

Of various other forms of IPR which may now or in the future have an impact on the exploitation of genetic knowledge, the Report draws attention to:

Database right: for the right which it confers on the financier of a database over substantial extraction from it – a right with likely impact on SNP libraries and other gene-banks. Database right is distinguished from the protection of personal data, and rights of access to it, given by the Data Protection Act 1998.

Confidential information: for the right which resides in any information imparted or acquired in confidence against any unauthorised disclosure or use of it – a right which in principle has many applications in healthcare provision, but which in practice may prove of less substance than may at first appear.

The Report draws attention to the possibility of future extensions of rights: (i) by way of copyright or unregistered design right in the representation of complex molecules; (ii) by the

introduction of a utility model right; (iii) through the guarantees of life and privacy contained in Human Rights Act; and (iv) by virtue of the Data Protection Act 1998.

C CONCLUSION & RECOMMENDATIONS

It is clear that the Department of Health will be directly affected by the patenting of genetic material. The impact of these patents will be twofold. The Department will stand as a receiver of patented products and processes. It could also stand as provider of patented products and processes developed by NHS trusts.

The Department needs to develop a coherent policy for both the receipt and the provision of patented material. In developing the thinking behind this, the Project has been assisted by three key publications: the Nuffield Council on Bioethics' discussion paper on The Ethics of Patenting DNA; the European Commission's report on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering; and the UK Patent Office's Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office. The Project Team used these three publications to provide a tripartite framework with which to propose recommendations to inform policy within the Department of Health.

The recommendations are as follows:

1 **It should recognise its unique position with regard to healthcare related intellectual property and take an active role in monitoring developments in relevant areas of intellectual property law (most notably patent law).**

2 **It should, as provider and recipient of intellectual property, support the appropriate use of intellectual property law, and in particular patent law, in protecting inventions involving genetic material.**

3 **In light of the ongoing advancements in bioscience and difficulties in establishing and maintaining concrete distinctions between types of genetic innovation, it should focus its attention not on the type of material being patented but on the way in which the UK Patent Office applies the new guidelines to applications involving biological material, and on equivalent decisions in the EPO and should also endorse the position taken by the Nuffield Council regarding the application of the granting criteria.**

4 **It should have in place a mechanism for assessing:**

- **(i)** **Whether to send information to the EPO or UKPO during the examination of a patent application which would restrict the scope of any patent on the disclosed genetic invention**
- **(ii)** **Whether to challenge the validity of a genetic patent once granted, either in the UK before the Comptroller of Patents or in court; or (for a European patent) by opposition proceedings in the EPO (commenced within 9 months of grant)**
- **(iii)** **Whether to challenge any abuse of monopoly in the manner in which a patentee exploits his rights by referring the matter to the UK Office of Fair Trading or the EC Competition Directorate.**

5	**It should seek clarification of the research use exception to patent infringement at the UK, EU, EPO and International levels, particularly with regard to use in clinical trials; and offer advice on good practice concerning the use of patented material and procedures in the course of research conducted by or in relation to its services.**
6	**It should establish a framework for partnership between the Department of Health and commercial providers of intellectual property (e.g. pharmaceutical companies and universities).**
7	**It should instigate a robust central policy for "licensing in" designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use.**
8	**It should adopt a balanced approach for "licensing out", particularly over the question of exclusivity, and where appropriate the Department should provide model agreements for use by hubs and Trusts.**
9	**It should seek greater interaction with the Department of Trade and Industry, with which it should consider the establishment of a single UK policy on IPRs and healthcare provision (encompassing both internally generated and externally sourced innovation).**
10	**It should make full use of existing monitoring and horizon scanning work being undertaken by groups such as the Human Genetics Commission, the Nuffield Council on Bioethics, and the Intellectual Property Advisory Committee and make representations to these groups where necessary.**

SECTION ONE:
INTRODUCTION OF INTELLECTUAL PROPERTY RIGHTS RELATING TO HEALTHCARE

A INTRODUCTION

Since the first steps towards commercial exploitation of biotechnological inventions, tension has been growing over intellectual property protection of the information contained in genetic material. The publication of the first drafts of the human genome has heightened that tension. Foremost is the question of who may have patent rights, and over what subject-matter, in the fields of human, animal and plant genomics. The Department of Health's evident interest in such issues means that patent rights will be at the forefront of this Report. The licensing of patents both into and out of the NHS will be discussed. The law also provides protection of information that is confidential against breaches of that confidence – a protection which may now be enhanced by the direct impact of the Human Rights Act 1998; and through copyright[1] and its extension, the database right;[2] the expression of this information may be protected from publication and copying. Note must also be taken of the UK Data Protection Act 1998, though its legal shields are not of the IPR typology.

In recent years there have been projects to create a new form of right in genomic information which typically aims to procure a return from users to discoverers without stopping actual use of the information. These have not so far made significant political headway. A variety of pressures have instead steered these attempts to establish novel types of property rights towards adaptations of existing forms of IPR, and that is the likely course for genetic information. The prime policy goal of IPRs is to ensure that such protection is reasonably adequate for the encouragement of further research and development of useful products and tests in the field. Nonetheless the protection should be proportionate to the contribution to knowledge made by the initial holder of the rights. This is unquestionably a difficult balance to maintain.

The Report is confined to questions concerning IPRs and closely related legal topics. IPRs confer exclusive rights (monopolies in a legal sense) over the use in commerce of specific kinds of information. Generally they stop the competitors of the IPR owner from making and putting out a product embodying the information or from providing processes and services based upon it. In a few instances, when there is no real alternative to the product or service which makes use of the information, the right gives real power to dictate qualities and prices in a market (thus giving an economic monopoly). The prime policy goal of IPRs is to ensure that such protection is reasonably adequate for the encouragement of further research and development of useful products and tests in the relevant field; but nonetheless that the right is not out of proportion to the contribution to knowledge made by the initial holder of the rights.

---

[1] Copyright, Designs and Patents Act 1988, Part I

[2] Directive 95/46/EC of the European Parliament and of the Council of 24 Ministers October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

IPRs are not concerned with restraints in the public interest on exploitation of the information by anyone, including the IPR owner. That is the sphere of health and safety laws or of controls upon experimentation involving living material (for instance, authorisation of the marketing of medicines or for stem cell research). Nor are IPRs concerned with the ownership and transfer of physical material (including human and other DNA). So the Report does not deal in any detail with the rights of a person who provides DNA from which a product is developed by a researcher, such as consent to taking and use, or a share in commercial returns from the product. It does not address rights either of depositors or of users over access to material in gene banks and private collections; or indeed claims on behalf of indigenous peoples to a share in profits from developing pharmaceuticals from traditional bioinformation.

Work for the Report involved the acquisition and analysis of materials relating to the various intellectual property issues affecting healthcare provision, including terminology, research use and exemption, licensing in and out, compulsory licensing, "reach through" claims and Crown use. The analysis is of the types of material which form the subject-matter of an IPR (including the categories of excluded material). The Report identifies the different IPR issues which will, or might, arise, such as genetic testing, genetic technologies, bioinformatics, proteomics, and pharmacogenetics. Furthermore, the scope of the research exemption within patent law is appraised and the significance of this exemption for genomic research is assessed. In addition to a search of existing literature on the subject, consultations have taken place with those already involved with IPR matters and healthcare provision. These have included meetings with some of those responsible for setting up the proposed NHS hubs and those responsible for IP matters within the university sector. The project team has held meetings with bodies including The Wellcome Trust, The Medical Research Council, The Association of Medical Research Charities, and The Nuffield Council of Bioethics.

It is clear that this project is timely and parallels other ongoing activity. Those also involved in the UK in looking at the issues of gene patenting include the British Medical Association, Department of Trade and Industry, Human Genetics Commission, and Nuffield Council of Bioethics. The project team has been in discussions with each of these. In addition the issue is also the subject of attention at the international level and government organisations such as the Canadian Biotechnology Advisory Committee Steering Group have produced reports on the matter. The issue is also being discussed by the UK Commission on Intellectual Property Rights[3] and by the TRIPs Council of the WTO. In respect of these two latter groups the focus has been primarily on the impact of IPRs on access to healthcare within developing countries.

The Department of Health has to tackle a range of issues concerning patents and other IPRs in the sphere of genetics at a time when much is unclear, much hotly contentious. In this Report we concentrate on how the present system can be expected to operate, both in relation to contracting in patented products and procedures for the benefit of patients of the NHS, and in relation to contracting out of patents and other IPR which may result from internal research and experience. It will be for the Department of Health to consider the

[3] The final report can be found at http://www.iprcommission.org/graphic/documents/final_report.htm

impact of the Report on its future strategy. Nothing said here must be taken to reflect any view of the Department of Health about its policy in respect of any of the matters discussed.

The Report was drafted in two stages. The First Report (now Section One) was drafted in early 2002. The Second Report (now Section Two) was drafted at the end of 2002. During the interim between the Two Reports three important papers appeared which, in our view, suggested strongly that the tide of opinion which has been very concerned about IPR developments in the field of genetics is sweeping forward[4]. Policy trends favouring modifications to the extent and impact of these rights are now making headway.

The three papers are:

- Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (July 2002)[5]

- European Commission, *Report on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (October, 2002)[6]

- UK Patent Office, *Guidelines for Examination of Applications Relating to Biotechnological Inventions* (September, 2002)

These Reports are discussed in more detail in Section Two and summaries appear in Appendix Six. Reference is made to these Reports at various points in what follows.

[4] In addition in April 2003, the Royal Society published its long awaited report, *Keeping science open: the effects of intellectual property policy on the conduct of science* - it stated that there were concerns over the 'gold rush' mentality towards obtaining patents and that if more care were not taken over the granting of patents that research and development will have a detrimental impact on researchers and on science and society in general.

[5] The Report can be found at http://www.nuffieldbioethics.org/publications/pp_0000000014.asp

[6] COM (2002) 545(01) at http://europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0545en01.pdf

B INTRODUCTION TO PATENT LAW

1 Introduction

In recent years there have been a number of legislative developments, at the international, European and national levels relating to the protection of genetic material. These include an extension of patent protection, and the introduction of data protection measures. A number of contentious issues remain including the scope of the research exemption, the role of compulsory licensing, the scope of the methods of treatment exclusion and the role of other intellectual property (and related) rights.

Sections 1 to 3 outline the development of UK and European patent practice in light of the demand for increased protection for technological innovation. In particular Section 2 explains the developments within the EC and at the international level which have led to developments within the UK. Sections 4 to 8 set out the mechanisms which exist to curb excessive patenting and possible abuse of a monopoly position - these include the public interest exemptions in patent law (including the research exemption and methods of treatment), the role of competition law and compulsory licensing and explores the limitations and exclusions to patentability. It can be seen that, in the absence of any definitive case law, the role of each of these remains, at present, indeterminate.

To present the current situation it will be necessary to explain, at least in outline, how patents and other relevant IPRs operate. There can be no doubt that the various rights are having to undergo major adaptation to fit hugely important and novel scientific advances. The extent of this "re-fit" can be appreciated only if the existing mechanism is understood.

The United Kingdom has had an adequately functioning patent system for around 150 years, most other countries for somewhat less. In all countries patenting continues to be seen as an instrument of national economic policy. For the most part, therefore, patents are obtained by application to a patent office, country by country. The rights which patents give - essentially to stop competitors from acting within the scope of the patent *claims* as they are set forth in the patent *specification* - extends to their activities in the geographical area of the country concerned. So far as the Department of Health is concerned, only the UK situation is relevant to the licences which it must take. Of course when it comes to its own research results it must consider how far and wide across the globe it needs to procure patent coverage.

2 Overview of patent legislation

To a considerable degree there has been a drawing together of patenting for the countries of Europe (and in particular those of the EU). The result is complex. The old national patent offices still grant patents for the country concerned, but alternatively an applicant may go to the European Patent Office (EPO) with headquarters in Munich. That is the efficient route for a great many applicants, since they may seek a standard bundle of national patents from that one Office. Thereafter (subject to a further EPO opposition procedure) each patent in the

bundle is a patent for the designated country and it is governed by national law. Much of the law is, however, harmonised between the different European countries. The relevant UK law is the Patents Act 1977 which covers both the British and the European systems for granting patents. It takes its major substantive provisions from the European Patent Convention (EPC) of 1973 and the Community Patent Convention (CPC), initially signed in 1975 and somewhat revised since, but not itself in operation.

The EPC covers all EU member states and also non-EU countries – notably Switzerland - and soon will include numerous Eastern European countries. The European Patent Convention and its administrative body, the European Patent Office, was introduced by the Council of Europe and as such it falls outside the legislative boundaries of the European Union. It is an autonomous organisation subject only to its own internal review and appeal mechanisms. It is an institution in its own right which is outside the EC and is governed by an administrative council made up of government representatives from each contracting state. It has long been the intention that the EU states should use the EPO granting system to produce a single patent for the whole EU territory in the form of a Community Patent, hence the signing of the CPC in 1975. But arguments, latterly in the main over the languages to be used, have prevented this long-anticipated addition from being introduced. Under the Brussels and Lugano Conventions on the Recognition and Enforcement of Civil and Commercial Judgments[7] it is possible to get a court order in one member state of the European Economic Area (EEA) relating to infringements in several EEA countries, but this is not possible over challenges to the validity of the patent which seek to secure its revocation[8]. The great advantage of the Community Patent would be to give competence to a specified European court to deal with all matters relating to the patent across the Single Market territory as a whole. In 2000 the European Commission adopted a Regulation for a EU Patent - this will not affect substantive patent law, but will primarily concern administrative structures[9].

The EPC and CPC settled the main provisions of current patent law before the impact of biotechnological inventions had come to prominence.

In respect of the protection of biological material, after over ten years of argument, the EU enacted its *Directive on the Legal Protection of Biotechnological Inventions* 1998 (98/44/EC) and this became UK law via the Patents Regulations 2000 (SI 2000, No: 2037). The EU Directive requires that biotechnological inventions, provided they meet the granting criteria, be patentable with minimal exclusions from protectability. These exclusions are of the human body and simple discoveries of its elements[10], plant and animal varieties[11], and inventions the

[7] Brussels and Lugano Conventions (1968).

[8] A plan for a Hague Convention which would extend this approach to legal disputes *vis-à-vis* non-EEA countries, notably the US has come to nothing.

[9] COM (2000) 412

[10] The exclusion is taken, within patent circles, to refer to the human body and to the unutilised elements thereof. Once an element, e.g. a gene or protein, has been isolated and put to a novel and inventive use then it is possible to obtain a patent over it. This is supported by EPO decisions such as *Howard Florey/Relaxin* [1995] European Patent Office Reports 541 where a human protein, H2-relaxin, was held to be patentable. Article 5(2) of the EU Directive on the Legal Protection of Biotechnological Inventions states that: "[an] 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".

commercial exploitation of which would be contrary to morality[12], a non-exhaustive list is provided of types of inventions which would fall to be treated as contrary to morality[13]. Human genetic material which can be shown to be the subject of an invention is patentable. The provisions of the Biotechnology Directive are additions to patent law in general and are therefore built upon a number of relevant principles in that law – notably that methods of medical treatment (in a specially restricted sense discussed below) are excluded from what is patentable, as are a number of other cases of technical advances relating to living material (also discussed below).

The Directive has, as of February 2002, only been implemented in six EU member states, Denmark, Finland, Ireland, the UK, Greece and Spain[14]. One of the reasons for the lack of implementation in some countries is the concern that the Directive runs counter to the principles set down in the Council of Europe's *Convention on Human Rights and Biomedicine*. This states that "the human body and its parts shall not, as such, give rise to financial gain". Those who support the patenting of genetic information do not think there is any incompatibility between this provision and rights arising out the development of inventions using genetic information derived from the human body and its parts[15]. Following the decision of the European Court of Justice (ECJ) in October 2001, in which the ECJ rejected the Dutch and Italian challenges to the validity of the Directive, there is likely to be greater pressure placed on member states to implement the Directive. Certain provisions of the Directive have also been adopted by the European Patent Office for the purposes of supplementary interpretation of the EPC, a step which serves to bring a greater coalescence in the area of intellectual property[16].

---

[11] These are given very restrictive interpretations (as can be seen in the EPO decision in *Novartis/Transgenic Plant* [1999] European Patent Office Reports 123). A plant variety is taken to mean any material regarded as protectable under the International Convention on the Protection of New Plant Varieties (UPOV) (this provides protection for plant groupings which are distinct, uniform and stable following reproduction). It is clear both from the wording of the Directive and the practice of the EPO that any plant material not comprising a plant variety, e.g. genes or species, is patentable. An animal variety has not been similarly defined, but it is clear from EPO cases such as the *Harvard/Oncomouse* [1990] O.J. EPO 476; [1992] O.J. EPO 589, that genetically altered animals are patentable.

[12] As with the other categories of excluded material this exclusion has been given a limited application. It would appear that the practice of patent offices is that an invention would fall within this exception if its sole purpose would be regarded as so abhorrent as to be contrary to European cultural morality. The example used by the EPO is a letter bomb. Where an invention has both a beneficial and detrimental aspect then granting offices will assess whether the benefit to society outweighs the detriment. It is important to note that the granting of a patent does not mean that the patent holder has an automatic right to commercialise the invention. The ability to commercialise could be subject to other legal constraints regulating experimentation, health, safety or environmental impact. It is not clear whether an invention which results from unethical research practices would be denied a patent.

[13] These include processes for cloning human beings, processes 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 are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes.

[14] According to the Commission both Portugal and Sweden are close to implementing. In November 2002 the Commission sent a letter to those member states which have not implemented the directive stating that if they do not implement by the end of January 2003 then it "may decide to refer the member states to the Court of Justice."

[15] This view is given support in Article 3(2) of the EU Directive on the Legal Protection of Biotechnological Inventions. This states that "biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

[16] Decision of the Administrative Council 16 June 1999 to Amend the Implementing Rules of the European Patent Convention. 1999 OJ EPO 437, 1999 OJ EPO 573.

It is important to stress these legislative structures at the outset, because they severely limit the ability of any organisation – even one as large and involved as the Department of Health – to procure legislative change. Since the 1977 Act took effect, patent policy in Europe has largely been set in the Administrative Council of the EPO, with some growing intervention by the European Commission (together with the European Parliament and Council of Ministers). The EPO is a major player in forming patent policies on an international scale and is regularly in tri-partite discussions with the US and Japanese Patent Offices. Beside these, the UN's World Intellectual Property Organisation (WIPO) in Geneva administers the major international conventions in the patent field[17] and is active in promoting further international agreements. By its side the World Trade Organisation has a considerable position in the whole IP field, thanks to the TRIPs Agreement. This Agreement falls within the gamut of WTO obligations binding its 144 member states[18] to certain minimum standards of intellectual property protection and enforcement[19].

3 Basic purpose of patent law

The majority of economists and other public policy makers accept that a patent system is on balance a desirable piece of machinery in any country or region committed to technological development. It is one technique for attacking the inevitable tendency to under-invest in R&D which arises because the initial costs of invention and innovation are usually considerable when compared with those of imitation - in many cases today, startlingly so. The system has to be contrasted with other incentives, such as tax concessions, research grants from the state or foundations and e*x post facto* prizes, rewards and career enhancements. It is widely considered that market exclusivity, which is the patent's particular mechanism, must find a place alongside such alternative forms of encouragement.

The growing appeal of patenting in a world which is moving towards "intellectual capitalism" is marked both in rapidly rising patent statistics and in the writings of theorists of industrial management. The part which patents and other IPRs now play in sustaining the position both of global corporations and of innovators of radically new technologies is far more prominent than it was a decade ago.

---

[17] Paris Convention for the Protection of Industrial Property (last revised 1971) and the Patent Co-operation Treaty (1970)

[18] The TRIPs Agreement serves to reduce distortions and impediments in international trade via the harmonisation of the minimum standards of intellectual property provision. With regard to patents, Article 27 of the TRIPs Agreement states that member states shall provide patent protection for all types of inventions irrespective of the field of technology or place of invention. The only proviso is that such inventions must be new, involve and inventive step and be capable of industrial application (this latter being synonymous with utility). Member states, if they wish, can exclude inventions the grounds that there commercial exploitation is contrary to morality (included within the list of types of activity which could be protected using this provision is the protection of human life), diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animal (but there is a requirement to provide protection for micro-organisms and plant varieties). The Agreement also provides for certain exceptions to the rights granted. Article 30 is generally accepted to permit a research exemption and Article 31 provides a right to grant compulsory licences in certain, limited, circumstances. Following the Doha meeting of the WTO in November 2001, the ability of countries to use Article 31 in order to respond to a public health situation has been recognised. The exact ambit of this right, however, still remains unclear. It is not certain the extent to which the Agreement affects Crown (i.e. government) use, but in the UK, at least, the provision is subject to Article 31.

[19] Articles 41-60 of the Agreement require member states to provide effective mechanisms of enforcement which should not be unduly costly, complicated or time-consuming (Art 41(2)).

Almost in proportion to this, attacks on patent systems have grown more intense. Why is this? A patent gives an exclusive right over technical advances to the first applicant to demonstrate an inventive step over whatever the industry already knows (the so-called "prior art"). Inventions are out there waiting to be made by whoever reaches them first, whether it is by brilliance, luck or dogged persistence. On many occasions there is a race to solve a particular problem or make a particular sort of improvement because the knowledge garnered within an industry and by academic or government research has reached that point. At times when the course of scientific and technological research intensifies the competition for particular new developments, there is likely to be increased feeling that the patent prize is awarded rather arbitrarily and that it goes to lucky winners who may seek to use it in ways which hamper further research by others, leaving them only with the wasted expenditure of their initial entry into the race[20]. Such conditions have arisen in relation to biotechnological patenting at present and there is serious concern that the stresses may soon be even more acute.

4 Legal controls within the existing patent systems

Hard experience long ago showed the dangers of granting patents without preliminary investigation for then, some patentees may all too easily steal a march without having done anything more than simple tinkering in the laboratory or machine shed. Indeed there will always be those who, intentionally or with the good faith of the ignorant, seek to monopolise things which are themselves already known. Two basic consequences have followed in patent law and practice. First, patents are not valid if their content is already known at their "priority date" and equally if the difference from what is known is an obvious one to the uninventive worker with skills in the technology concerned. Such objections remain open during application for a patent and throughout the patent's life (which today, with annual renewals, can be up to twenty years from filing the application). Secondly, in practice, it has been deemed necessary, expensive though it is, to examine applications in the patent office to see if they satisfy these and other criteria. Patents are expensive to challenge and if they are issued merely upon deposit an aggressive right-holder can frighten many competitors into submission despite the patent being of highly questionable validity.

In addition to this, a patent system will only function equitably if the scope of the right given to a successful applicant is proportionate to the significance of the invention which has been made public in the patent specification. It is one basic purpose of the system that, in return for the exclusive patent right, the industry concerned should learn how to perform the invention from the patentee's description. The examination of a patent application by the patent office has, first, to ensure that there is an adequate disclosure of the invention, and, second, that the patent is based only on that disclosure. The crucial legal requirement is found in the *claims* with which the patent specification ends. In modern systems, such as that of the EPC, these claims define the protected invention in general terms and very largely

[20] The majority of countries, including all in Europe, operate a "first-to-file" patent system, which means that the patent will be awarded to the person who is first to apply to a patent office (provided that the granting criteria are met). The most notable exception to this is the patent system of the United States of America which operates on the basis of the first to invent being entitled to the patent. The argument for the former practice is that it is often easier to prove who was the "first-to-file" as opposed to who was actually the first to invent, particularly in a highly competitive area.

determine the scope of that protection. It is in the patentee's interest to draft the claims in as broad language as possible; equally it is for the patent office to see that the language of the claims is confined so as to exclude ideas that are already known, obvious or beyond what is justified by the description of the invention in the patent specification. How all this is achieved in relation to a newcomer technology emerges through a process of definition refined by patent offices and courts. This is proving to be as true of biotechnology as of its predecessors, such as organic chemistry and microbiology.

The aggressive policy pursued by some commercial interests in the US to procure patents on genes and gene fragments[21] has roused the gravest suspicions that a deluge of disproportionate and overlapping patent grants is gluing up the research world. In part the US is considered to blame, since examination of applications in its Patent Office is notoriously soft and no formal intervention by third parties can be made by way of early opposition to the grant (in contrast with Europe and elsewhere).

From such practices fears multiply: in relation to public health, that the cost of care will increase; that patients will be deprived of access to new techniques and drugs; that research and testing tools will be withheld; that researchers and carers will not share information; that research will become too complicated to enter upon (perhaps because of the so-called "anti-commons effect" of there being too many right holders); and equally that there could be premature commercialisation in the race to get ahead.

It may well be that some of these fears have been exaggerated by reactions to a mere handful of egregious cases. This is why some patent experts urge that the system should be left to adapt its existing principles so as to eliminate what is unacceptable. Because that may in any case prove to be the only practicable way forward, later stages of this study will investigate what the prospects for this approach are. However, it will do so with a strong awareness that it may be a grindingly slow process to secure these modifications by case law, particularly since it is something that has to be settled on a country-by-country basis.

5 Expansion of patent systems after 1950

In part the present difficulties grow out of the previous, closely related, adaptation of the patent system to fit the post-World War II developments in pharmaceutical and agricultural chemistry. In industrial countries the drive to make patents fit was marked in many ways: in some countries legislation was needed to remove restrictions so as allow patents for chemical and physical interventions in agricultural methods[22], patents for living matter, such as yeasts and later micro-biological material[23]; patents for chemical substances, or pharmaceutical

[21] The most obvious examples of these can be seen in the patent policies being pursued by Celera Genomics and Myriad Genetics.

[22] The UK is not unique in permitting use in agriculture to equate to an industrial application (section 4(3) Patents Act 1977. The introduction of the International Convention on the Protection of New Plant Varieties (UPOV) system of plant variety rights recognises the not inconsiderable scientific investment in agriculture, but creates its own regime for novel characteristics (see UK Plant Variety Rights Act 1997)

[23] In the UK there has never been a specific exclusion of living material from patent protection; accordingly material such as yeasts and micro-organisms have been generally held to be patentable. The situation in the United States was, pre-1980, somewhat different. In the 1948 case *Funk Bros Seed Co v Kalo Inoculant Co* 333 US 127 (1948), the US Supreme Court upheld

substances[24], patent claims for these substances *per se*, which were not tied to the method used to produce them[25].

6 Growth of pharmaceutical patenting

Alongside this, it came to be accepted that the first to discover the practical benefit of one or more members of a class of chemicals could claim the whole class (in the sense of chemical structure), in order not to leave competitors an easy path around the claim[26]; and that intermediates for making beneficial end-products could be claimed for their potentiality even before the end-products were made and their value ascertained or confirmed[27]. The rules of novelty needed to be circumscribed so that purely theoretical references in the prior art to particular alternatives were not readily treated as already disclosing what in reality needed more substantial research, often of a dogged empirical kind, in order to produce a useful result; and the rules on obviousness needed to be limited so as to recognise that laborious and expensive, but broadly predictable, experimentation would not be discounted, at least to the extent of precluding the chance of any patent reward for such successful work from the outset.

7 Methods of medical treatment

In various countries including Britain, there was a long-standing, if somewhat ill-defined, exclusion of methods of medical treatment from what was patentable[28]. The justification for the exclusion appears to be that members of the medical profession should be able to treat patients without fear of infringement proceedings; or to put it another way, that the availability of direct treatment should not be dependent on the ability of the healthcare provider to pay a fee for a licence to carry out the medical procedure. In the EPC, the exception was given explicit form. The following are not patentable: methods of treatment of

---

the rule that a 'product of nature' was not patentable. Therefore, any invention which was based on natural material was excluded from patent protection (the only exception to this was asexually reproducing plants which are protectable under the Plant Patents Act 1930). In 1980 the Supreme Court's decision in *Diamond v Chakrabarty* (65 Law ed. (2d) 144 (1980)) in effect removed the product of nature doctrine, and admitted patent protection for "anything under the sun manufactured by man". This is now the guiding principle behind US policy on the protection of living material, the key to the determination of patentability being whether the material is 'manufactured'.

[24] In Italy, the patent law excluded any form of protection of pharmaceutical inventions. The country accordingly fostered competition via generic imitations until the exclusion in the law was held unconstitutional in the 1970's. Even so, it took time to reach the same level of patent protection for pharmaceuticals in Italy as in the rest of the EPC states.

[25] This can be seen in the UK Patents Act 1949.

[26] The test which is used here is whether the same benefit could, in some measure, be predicted for the whole class. See White *Gene and Compound per se Claims: An Appropriate reward? Part One* The CIPA Journal, February 2002, 89 & *Part Two* The CIPA Journal, March 2002, 134.

[27] See *Smith's Applications* [1971] RPC 31 where it was said that the question of the value of the ultimate products was irrelevant to the assessment of obviousness.

[28] It is clear that, in Europe, the exception is retained for policy reasons. This can be seen in the discussions surrounding the revision of the EPC in 2000 where it was decided that the exclusion should be retained. The underlying policy is based on the continuing belief that the patient-doctor relationship must not be impeded by the time-consuming complexities of acquiring a licence. It is relevant to note that the same concerns can be seen in the US where there is no exclusion of methods of human treatment. In the US, it is possible to obtain a patent over a method of human treatment, but recently an exception to infringement is provided to a medical practitioner performing a medical activity (USC 35, section 287(c)(1)).

the human or animal body by surgery or therapy or diagnostic methods practised on the human or animal body[29].

In turn courts and patent examiners applied a narrow, technical interpretation of this formula because it constituted an exception. Thus the EPO treated diagnosis outside the body as patentable[30]. Claims to novel substances were distinguished from claims to methods of applying known substances in treatment. Where a claim was available on a new substance (including those within a selection), it covered the substance whatever its use, thus avoiding the need to define what would constitute infringement in a claim to a substance for a beneficial purpose[31]. The courts also treated selections of better-performing members of a known class of chemicals as claims to those particular substances and so something distinct from methods of treatment[32]. In time the European Patent Convention would add to this by allowing claims to substances where these substances already had a non-medical use (e.g. as a dyestuff) [33] and were shown to have a first medical use. Case law then added in the patenting of second and subsequent medical uses by way of the so-called "Swiss form" of claim. This is to a medicament compounded for the new treatment which contains the active substance in issue. These extensions of protection, which confine the medical treatment exception more and more, may strike outsiders as barely comprehensible hair-splitting. They have led to a great range of pharmaceutical research being open to patent protection and therefore to development programs (including laborious demonstrations of medical safety) which bring considerable benefits to patients. The hierarchy of property rights which they establish has come about relatively gradually and, by and large, has been considered proportionate to the aims of the system. To say that is not in any way to accept that the same is true for developments of genetic knowledge. It is just this issue which specially concerns patent policy-makers at present.

On another front, legislation from an earlier era of fear about medical provision, provided for the grant of compulsory licences of food and medicine patents as of right, but subject to the setting of terms by the patent office or a court[34]. This special exception was attacked by pharmaceutical industry leaders. In Britain, which had perhaps the leading exemplar of this

---

[29] Article 52(4). According to White a distinction has been drawn between claims to a substance *for* a use of it and claims for a method of treatment. The effect of this is to permit claims over chemical substances *per se* even where their only known application is in the field of medical treatment. White regards this as rendering the prohibition of methods of medical treatment illogical and for that reason recommends its removal *supra* note 26, Part One at 93. For a more detailed discussion see Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology* Chapter 12.

[30] Just what is to count as diagnosis is a matter of controversy. In Decision T 964/99 of 29 June 2001 the Technical Board of Appeal of the European Patent Office stated that "Article 52(4) is meant to exclude from patent protection all methods **practised on the human or animal body** which **relate to diagnosis or which are of value for the purposes of diagnosis**." at 4.4. The application related to a method of iontophoretically sampling a substance from the living human or animal body and was held to be excluded under Article 52(4).

[31] An issue to look at is whether, if a generic manufacturer supplies, a doctor prescribes and a chemist issues a drug which has several uses, there is an infringement of a patent directed to one of those purposes.

[32] To a considerable extent the sophistry which is employed relates to whether the claim was to a medical treatment *as such*. Where the claim is not to a medical treatment as such, then it could be allowed. It should also be noted that the patent law draws a distinction between *in vivo* uses (which are generally held to be unpatentable) and *in vitro* use (which will usually be held to be patentable).

[33] *G5/83 EISAI/Second Medical Indication* OJ EPO 1985, 64, accepted in the UK in *Schering and Wyeth's Applications* [1985] RPC 545 and *Bristol-Myers Squibb v Baker Norton* [2001] RPC (CA).

[34] The legislation was first introduced in 1919 and grew out of fears about the dominance of the German chemical industry.

exception, it was removed by the Patents Act 1977. Today, compulsory licences are available only on relatively specific grounds as the practice has been further limited by TRIPs Art 31[35].

In countries which have an exclusion of methods of medical treatment in their law, there is a groundswell of opinion amongst judges and patent practitioners that it should be removed, and the US system followed. In the US, it is possible to obtain a patent over a method of human treatment, but an exception to infringement is provided to a medical practitioner performing a medical activity (USC 35, section 287(c)(1)). Whether in practice the American approach does anything more than impose financial responsibility on the health authority alone, rather than the medical staff in person, must remain a controversial matter. It would demand, first of all, a clear definition of what the change is meant to achieve and then careful attention to the precise language of any legislation which might set about implementing that policy.

When these developments are listed in a foreshortened history, they may seem striking. Certainly they have served to keep the patent system as a vital reward device for much of the pharmaceutical industry. But their impact was to some degree gradual, and the legal techniques often so arcane that they caused few really major political storms. The chemical and microbiological potentialities open to researchers were such that research-based companies had a great range of opportunities to develop their own territories of expertise. Opportunities for patents on techniques that had multiple uses did not proliferate. Even with patents being granted for very large classes of chemicals, users of the system seemed reasonably content[36]. When one drug company held the 'head patent' and another company a patent for an improvement, an end user would require licences from both. In the past it was not uncommon for the 'head patent' to have expired before the improvement came on stream.

With the rapid developments in genetic information taking place today, and the resulting biotechnological revolution, that position has changed and it is not uncommon for both patents to still be in force. This raises a set of questions about the breadth of biotechnological patents which are still in an early stage of examination. For a valid patent to exist the invention must be shown to be novel and not obvious and the patent specification must describe it in terms which allow skilled workers in the industry to perform it without themselves having to invent anything. (It should be recalled that validity is examined during the application to the EPO or national Patent Office for protection and can be raised again throughout the life of the granted patent before a court.) The invention will be *novel* if no one else across the world has disclosed it to the public or used it so as to make it available. It will not be *obvious* (i.e. it will contain an inventive step) if a skilled worker who lacked any inventive capacity himself would not have thought it so from what he would know in general or could glean from the relevant literature[37].

---

[35] Under TRIPs (see above note 18) the extent to which the Agreement prevents a member state from invoking Crown, (or Government), use provisions, is discussed below..

[36] By way of anecdotal evidence for this, at a meeting of the Human Genetics Commission in February 2002, Andrew Sheard (chair of the Intellectual Property Committee for the British Bioindustry Association) stated that there was general satisfaction with the system in its current form. His members were confident that any problems, perceived or actual, could be addressed through the usual course of things, via case law and developing practice.

[37] In order to judge novelty and "non-obviousness", a "priority date", related to the date of the patent application, is established.

Thus patent law is in principle balanced so as to ensure that rights are only granted in what is new and inventive over and above what is already known. They are only for what is revealed to industry and the public in the patent specification and the scope of the rights, as defined in the patent claims, are proportionate to what the patentee has disclosed as inventive. In principle the balance seems a justifiable approach. Much of the doubt concerns the very considerable cost, both in financial terms and in the deflection of energy from other things, of securing decisions on the various issues. These drawbacks are of course likely to be most apparent where the nature of a science-based industry channels research into relative narrow confines. Genetic research into diagnosis and therapies for humans now grows out of our new knowledge of the structure of the human genome and that necessarily conditions the work which can effectively be undertaken. It is therefore a field in which the existing rules governing the validity and scope of patents need to be applied with a real awareness of the new conditions for research and commercial exploitation in this field. The scope of what is patentable in pharmacology has, as we have sought to suggest, expanded very considerably. It has to be asked at what points there should be some retraction for the biotechnology industry and those who make use of the results of its research.

At least in the UK it can be said that the courts have shown understanding of the relation between scientific research and commercial competition to exploit its medical results. The 1989 *Genentech*[38] case was highly significant. It held invalid a patent claiming all ways of manufacturing the blood-clotting agent, T-Pa by recombinant bioengineering. The patent showed that one already known technique could be successfully used to amplify supplies of T-Pa from a natural source. It was found by standard legal tests, on the one hand of obviousness and on the other of discovery rather than invention, that the patent had been wrongly granted. Several years later, it was held in the *Biogen*[39] case that claims to all ways of expressing the Hepatitis B antigen were too widely based when the specification only showed how to perform one out of two elements in a new procedure for implanting the DNA in a prokaryotic host-cell.

Following the same approach, a claim to a medicament containing rapamycin[40] (whether or not made by recombinant DNA technology) as an immuno-suppressant in transplant surgery could not have claimed its derivative versions with altered side-chains because it was not known which of them would be therapeutically beneficial. It followed that the claim could not be read to cover those derivatives of rapamycin which turned out to work. These leading decisions demonstrate that in the biotechnology field, courts by no means always see eye to eye with patentees about the extent to which they should have exclusive rights that extend to the major variants or to all ways of producing a genetic product. The lesson is evidently that the demands of patentees do not have to be accepted uncritically. They may vigorously assert their entitlement to demand that infringement stop and a licence be taken on what may be

---

[38] *Genentech v Wellcome [1989] RPC 147 (CA).* This case is central to understanding the concepts of inventiveness and contribution in UK Patent Law.

[39] *Biogen Inc. v Medeva* [1993] RPC 475; [1995] RPC 25; [1997] RPC 1. The case concerned a patent acquired over a Hepatitis B vaccine. The possibility of developing such a vaccine was known to all those working in the area but none, save Biogen, were willing to take the financial risk. Biogen succeeded and obtained a patent on the results of the research. Medeva sued to revoke the patent.

[40] *American Home Products v Novartis* [2001] RPC 159, CA. See also *Kirin-Amgen v Roche Diagnostics* [2002] RPC 1 paras 593-638.

very restrictive terms. Once the validity and scope of the patent is critically assessed by experts the situation may come to seem very much less threatening.

8 Limitations and exceptions to patentability

By way of counter-balance to the expansion of patentable subject-matter, there has been some extension (and one categorical contraction) of the limitations upon the exclusive right granted by the patent[41]. First, patent legislation in EPC countries, taking its cue from the CPC, now contains limitations allowing both private, non-commercial use and experimental use (often lumped together as the "research exemption"[42]). Secondly, there are provisions in patent laws (above all, in the UK Act, ss. 48-59), which govern the grant of compulsory licences and Crown use. Thirdly, competition law (or anti-trust law in US parlance) may apply to unduly restrictive licences and even to exceptionally demanding assertions of patent rights by patentees holding a dominant position in the market. Each of these factors calls for brief description at this stage.

(a) Experimental use

In the past most European countries restricted their research exemption to non-commercial activity, i.e., typically, to work in universities and public institutions without industrial backing. Under the present law there are separate provisions which on the one hand exempt use which is private and non-commercial, and, on the other hand, experimental use. In consequence courts across Europe have shown increased willingness to treat experimental research as exempt from patent liability even though it has a commercial purpose[43]. Under this experimental use exception it is permissible to conduct research which may modify or improve the invention patented[44] – and in Germany at least, this includes providing further information about the properties of the invention, for instance through clinical trials[45].

But limits remain. The exemption does not include research using a patented research tool which is not itself the subject of the further experiment (as where Polymerise Chain Reaction (PCR) is used to amplify genetic material). Nor does it cover tests which merely replicate the invention, e.g. where a generic drug company is seeking evidence for permission from a Medicines Authority to market its version of a drug once the patent on it expires. Much of the recent case law in Europe goes to this particular question, though it is only tangential for present purposes. One major ambiguity about the experimental use exception, as it affects biotechnological patents, concerns how far clinical tests can be regarded as experimental, since treatment and the continuing search for further genetic knowledge often enough go

---

[41] These are, in addition to the exclusions of discoveries, inventions the commercial exploitation of which would be contrary to *ordre public* and morality and plant and animal varieties discussed above at page 15.

[42] While the EPC (Art 69 and Protocol) specifies that the scope of the right is determined by the terms of the claims, the acts constituting infringement are found in the CPC (Arts 25-28), the exceptions being specified in Art 27

[43] For the UK, see *Monsanto v. Stauffer* [1985] RPC 515. For recent confirmation of the new approach in France, *Wellcome Foundation v Parexel International & Flamel,* Tribunal de Grande Instance de Paris, 20th February 2001: Intellectual Property News Issue 17, July 2001.

[44] The exception must also cover experiments to discover whether the invention can be made from its description in the patent specification (essential if the patent is to be challenged).

[45] Two decisions of the German Supreme Court treat clinical trials of pharmaceuticals as falling under the exception.

hand in hand. It may well be that they can only be treated as exempt where the latter objective is a dominant motive for the tests but the law remains rather uncertain.

The issue of access to protected material for research purposes is related to situations where test kits are developed within the National Health Service. Where an alternative to a kit supplied by a patentee is developed in-house and routinely used in clinical work this appears not to be experimental use nor private, non-commercial use[46]. Accordingly without a licence the kit and/or its use may well infringe the patent. Of course it is a question whether this should be the legal position, especially in a situation where the infringing 'homebrew' kit is not being used as a complete replacement for the kit and service from the patentee. Not only does a refusal to license the low-cost test kit cut out a basic but efficient service, but it may also impede the development of future diagnostics and therapeutics by anyone other than the patentee.

As things stand, however, patents are private property rights and a patentee may therefore seek to extract maximum value from the exclusive right.

Whatever the precise position, it is hard to see that the rules applicable to genetic pharmacology should differ from those affecting all pharmaceutical invention. In the absence of any direct evidence demonstrating that particular types of information should be treated differently the presumption in patent law is that there should be no differentiation. This in turn makes it the more difficult to suggest that the law on the subject should be substantially revised, as distinct from clarified as to its present meaning[47]. We consider that there is greater scope for striving to draw reasonable boundaries, particularly on the two major issues arising under this head: what constitutes the use of a research tool for unconnected (and therefore not exempt) experimentation? And what in the course of clinical work counts as "experimental purposes"?

While the evolving European position on the research exemption does give rise to ambiguities, at least it can be said that a more coherent dynamic prevails in Europe than in the US. It is commonly thought that research is exempt in the US only if it is strictly non-commercial[48] (though the case-law does show certain signs of moving to a more liberal position, in the manner of the recent trend in Europe). On the other hand, tests to secure marketing authority during the period before the patent expires, are now permitted there by statute. The Department of Health is primarily concerned with what happens in this country under UK law. In so far as we are less restrictive than the US, we create a more open climate for research and that may well be to our advantage (though, of course it will not benefit those British biotech firms or health organisations who thereby lose out as patentees).

[46] Nor could it be "private and non-commercial use" since a government service is most unlikely to be regarded as "private".

[47] The Frascati Manual (Appendix Five) provides descriptions of levels of research and development activity.

[48] The Drug Price Competition and Patent Term Restoration Act 1984 (the Hatch-Waxman Act) permits use for testing that may allow generic firm's version of a patented product to be licensed by the FDA from the moment of the patent's expiry.

(b) Compulsory licensing and Crown Use

From 1883 onwards, UK patent legislation began to acquire provisions under which, the patentee might be subjected to a compulsory licence (with terms settled by the Comptroller-General of Patents or a court) for failure adequately to exploit the patent either directly or through voluntary licences. Only rarely do would-be licensees take matters so far against a resisting patentee, but the threat that they could do so is considered to be a conditioning agent which can help the formation of voluntary arrangements. As the result of World War I scare, a separate provision made compulsory licences available almost as of right for food and drug patents. This became the much-debated Section 41 of the Patents Act 1949. A sustained attack upon it by leading pharmaceutical interests led eventually to its abandonment in the Patents Act 1977; this was the undeniable contraction referred to above.

While the general provisions concerning compulsory licences remain part of UK patent law, they have now been limited (for patentees from WTO states) by the conditions laid down in the TRIPs Agreement, Article 31[49]. Among these is the requirement that first the intending licensee must have made efforts for a reasonable time to obtain a voluntary licence on reasonable terms[50].

In UK law, grounds justifying the grant of a compulsory licence include:

- That UK demand for the patented product is not being met on reasonable terms; or
- That UK exploitation of any other patented invention of importance is being prevented or hindered; or
- That UK commercial or industrial activities are being prejudiced[51].

These factors reflect some tension between securing the incentive effect of the patent system and other public interests. Nonetheless they could in principle be relied upon by an organisation associated with the Department of Health or a competing test or product supplier against a patentee whose refusal to license or whose licensing terms were found to be seriously overbearing. Under the first of these grounds, it would seem relevant to take account of prejudice to the provision of medical services in this country. Arguably it could be held unreasonable to require diagnostic tests to be performed by the patentee abroad, rather than by medical teams here, when it is they who have the responsibility to interpret the results to patients. It is certainly important to understand the scope of the current compulsory licensing provisions, however cumbersome they may appear, because their existence is some answer to the demands of those who seek special powers to intervene in the sphere of genomic patents.

---

[49] To achieve this the Patents Act 1977, s. 48 ff, was substantially amended by SI 1999 No. 1899.
[50] S. 48A(2). For non-WTO proprietors the broader principles of the earlier law still apply: see s. 48B.
[51] S. 48A(1).

The scope of compulsory licensing of all patents between WTO countries is now conditioned by the rigid framework of the TRIPs Agreement, Art. 31. The WTO statement made in Doha in 2001 recognises the problems which can arise over overly rigorous patent practices in respect of access to medicines[52]. In addition to acknowledging that members should be able to take measures to protect public health, the WTO also stated that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences should be granted. However, it is also clear that the Doha statement is primarily aimed at enabling developing countries to have access to medicines and it is not clear to what extent developed countries will be able to rely on the 'public health' exemption in light of their sophisticated pharmaceutical base. The prospects for renegotiating this aspect of TRIPs in ways which affect the practice in developed countries such as the UK (as distinct from developing countries) are, at present, distant.

Ever since the Crown was made subject to patent law obligations, it has had a special power to act in specified ways which would otherwise constitute infringement of the patent. One reason for allowing central government to act in this way is that the compulsory licence procedure would not fit. It would involve one Department applying to another to have the grounds and the terms settled over the head of the patentee. Under Crown use, the Department may operate within the patent without prior licence, subject to a payment of 'compensation for loss of profit' to the patent holder. Accordingly, the status of the provisions in relation to TRIPs Art. 31(a) appears somewhat restricted[53]. Under the present text of the Patents Act 1977 it is clear that the sale of drugs and medicines falls within the Crown use provisions[54] and likewise the offer of services such as diagnostic testing.

(c) Competition (anti-trust) law

Competition law regulates the manner in which companies and businesses compete. Its primary functions are to regulate: takeovers and mergers; agreements between businesses to restrict competition; and the abusive exercise of market dominance by companies which have acquired a large market share or operate from a monopoly position.

Commercial and industrial activity in Britain is affected both by the EC's Rules of Competition and the equivalent national system of "anti-trust" regulation under the Competition Act 1998. The EC Rules of Competition, laid down in the EC Treaty, especially Articles 81 and 82, give the European Commission executive responsibility for action against (i) anti-competitive agreements and concerted practices between undertakings; and (ii) abuses of dominant position by undertakings with market power[55]. In the UK context, similar obligations are now

---

[52] The Declaration on the TRIPS Agreement and public health, made on 14th November 2001, states that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. For the full text of the WTO Statement from Doha see Appendix Four. It can also be found at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[53] Article 31 which deals with forms of use within the patent which are not authorised by the patentee, applies specifically to use by government and third parties authorised by government. It requires that the authorisation of such use "shall be considered on its individual merits". In the UK, the Crown use provisions are subject to Article 31.

[54] See S. 55(1)(a).

[55] EC Treaty, Arts. 81, 82,

placed upon the Director-General of the Office of Fair Trading and in addition the Competition Commission may investigate a monopoly situation. If it finds that a monopoly situation exists which operates or may be expected to operate against the public interest, the Minister to whom the report is made may secure an order from the Comptroller-General of Patents that restrictive terms in patent licences be modified or cancelled; or that the patent be rendered open to licences of right (which will be on terms settled by her if necessary)[56].

These revisionary powers came into UK patent and other IP legislation in the wake of a hotly controversial issue involving the Department of Health. In 1973 the Monopolies Commission reported on a reference to it by the DTI of Roche Products' refusal to lower the price to the NHS of its patented Librium and Valium[57]. The company had refused to participate in the VPRS in protest (so it said) against the then compulsory licensing provisions for drug patents under the 1949 Act, s. 41, already referred to. It was required by the Commission's Report to lower the prices for each drug very significantly. This application of general competition law principles in order to reduce the market power of a patentee in respect of the protected invention represents an interventionist high point. The European Court of Justice in general treats IPRs as allowing their holder to extract monopoly returns from its exploitation of the subject-matter and would find an abuse of dominant position under the EC Competition Rules only if there was additional anti-competitive conduct[58]. It can however be persuaded to depart from this approach in exceptional cases[59]. Whether it would ever tackle the excessive use of market power by a pharmaceutical patentee through this requirement of competition law is hard to predict. Certainly the conduct of the patentee would have to be characterised as egregious. Nonetheless, there is a possibility of using EC or UK competition law to secure some moderation in the demands of patentees which go beyond a proportionate return for their invention.

In addition to this, the terms on which patent and related licenses are granted may be open to attack if they unduly distort competition. Thirty years ago this approach was used by the European Commission vigorously to police restrictive terms in patent and other intellectual property licences between the patentee of an invention and manufacturing licensees who were taking the new technology into other national markets. In particular this could apply where the licence was exclusive, since this rules out competition from the patentee himself as well as other licensees. More recently this policy has been pursued with less vigour. In any case applications of it in relation to the medical and pharmacological sectors do not seem to have caused major difficulties. Nonetheless, if there are today serious restrictions embodied in the manner in which diagnostic and similar tests have to be performed, the possibility of competition law considerations may well arise. This could particularly be so where the constraints aim to place the patentee in a stronger position than the licensee to pursue further research, since it is not the aim of the patent system to provide an incentive for more than the invention actually patented (and thereby published).

---

[56] Patents Act 1977, s.51, as amended by the Copyright, Designs and Patents Act 1988, Sch.5, para. 14.

[57] *Chlordiazepoxide and Diazepam* (H.C. 197, 1973). The Monopolies and Mergers Commission was the forerunner of the present Competition Commission.

[58] See esp *Volvo AB v. Erik Veng* [1988] ECR 6211 (design rights in car spare parts); and *CICRA v. Renault* [1998] E.C.R. 6039.

[59] *RTE and ITP v EC Commission ("Magill")* [1995] I-ECR 743 (copyright in TV listings); but note *IMS Health v. European Commission* [2002] I-E.C.R. 3401

C GENETIC INVENTIONS AND PATENTS

The following sections outline the specific issues which relate to the protection of genetic inventions and their access for research and development. Arguments about the extent to which patents should be available for genetic inventions can be placed under the following heads:

1 General ethical objections

These include:

- A state-sanctioned system for commercialisation of useful knowledge should not be applied to new information about the genetic construction of the human body, which is a common inheritance of all people.

- This information should be shared by research communities freely as part of fundamental knowledge which should be open to all to use as they will.

- Genetic information has profound implications for environmental and social conditions in societies at all stages of development, making it wrong for individual investors to be accorded exclusive rights over commercial exploitation, however significant a factor that may be in securing beneficial developments (such as new diagnostic tools and therapies).

European patent law continues to place an embargo on patents for inventions which are contrary to morality or *ordre public*. Arguments from a variety of ethical perspectives, such as those just listed, have been put to European Patent Office Boards over the past decade, urging that this provision should place severe constraints on patents for genetic engineering in one or other form. The Boards have refused to apply the objection to the cases before them, treating the legal ground as applicable only when public revulsion concerning the invention is marked and when any countervailing value to be had from it would be insufficient to justify it being practised.

The EU Biotechnology Directive in 1998 in effect confirmed this approach. It ruled that, on the one hand, the human body and the simple discovery of one of its elements (including genetic sequences) cannot be patented; yet an element isolated from the human body or otherwise produced by a technological process can be. The distinction is upheld in the European Commission's recent Report on the Directive. For those who suspect the very business of "patents on life", however, the distinction continues to appear casuistic. The Nuffield Discussion Paper suggests some unease that what is being patented is in essence information, rather than technology. But that Report, even though starting from ethical considerations, chooses to see that the way forward lies in deploying the accepted general requirements of patent law. This probably reflects the preponderance of informed opinion on the issue. There is reassurance in the specific cases which the Directive lists as being outside the range of patents: cloning humans, modifying human germ lines, using human embryos for

industrial or commercial purposes, and modifying animal genetic identity without substantial medical benefits. Human stem cells and cell lines obtained from them may be added to that list. The Commission's Report identified the patentability of human stem cells and cell lines obtained from them as one particular area of concern which the Commission intends to investigate further. However, at least in Europe, ethical objections to patenting seem to have receded even in relation to human genetics.

2 The identification of genes and partial sequences are discoveries, rather than inventions

The concern here is that the simple identification of genes and partial fragments does not disclose any requisite industrial application and are therefore discoveries rather than inventions. The concerns engendered by developments in bioscience have been exacerbated by the publication of the results of the Human Genome Project and the race by some companies to patent elements of their results which could have commercial significance, particularly in the US. Patents were often granted for applications for gene fragments whose full sequence and function were unknown. Their utility was often vaguely identified by definitions such as 'scientific probe for the discovery of genes' or expressed sequence tags (ESTs)[60]. This led to a proliferation of patent applications and by the end of 1999 Celera, for instance, had filed for "preliminary patents" on over 6,500 partial human gene sequences. By then the question of the patentability of such claims was increasingly to the fore.

In consequence in 2001, the United States Patent and Trade Mark Office (USPTO) issued new guidelines requiring the patent specification to demonstrate a utility that is specific, substantial and credible, rather than merely speculative. The provision is still somewhat weak, since the utility need only be theoretically possible. For this the new policy is criticised by the Nuffield Discussion Paper. However, at least the EPO through its case law, and the UK Patent Office (UKPO) by its Guidelines, have adopted much the same standard. The UKPO Guidelines refer to the need for different approaches to claims for sequences within genes and within proteins. What is not tackled by these general rules is the question whether use-limited claims alone should be allowed when one function for a gene, protein or receptor has been discovered and then a second function is separately discovered.

3 Diagnostic testing should be distinguished from therapy and treated as discovery without industrial application

Health authorities, at least in the developed world, have been sensitised to the potential dangers of genetic patenting by the storm over Myriad Genetics' policy for administering the breast cancer diagnostic tests which fall within their patents on the BRCA 1 and 2 genes. Their concerns go both to the anticipated requirement that all processing of test samples will be undertaken by Myriad in Salt Lake City at considerable cost, rather than on a simpler, closer-to-home basis; and to the consequence that such testing will provide Myriad and its collaborators with material for further research (e.g. for other genetic causes of the cancer).

[60] European geneticists and the NIH were opposed to the patenting of partial sequences who functions were unknown ensuring that the scope was commensurate with invention.

It is possible that, if these practices come to predominate, proceedings for compulsory licences might succeed in one or more countries or that competition law might be brought into play against the manner in which the dominant position is being misused. Alternatively, it could perhaps be argued that diagnosis should be placed outside the range of what is at present patentable under existing law. In the UK and other European countries which have a specific legal exception for methods of medical treatment that excludes diagnosis as well as therapy, the limitation is not currently interpreted to cover a diagnostic procedure in which tissue is removed from the body and then tested under laboratory conditions. That, however, is a question of interpretation. It could be re-visited.

4 Claims in gene patents show no inventive step

Patent Offices now lay emphasis on the standard requirement of inventive step (non-obviousness) as the requirement which will do most to retain genetic patenting within acceptable bounds. The Nuffield Discussion Paper puts much of its hope in this quarter, and urges the USPTO in particular, to apply the test with proper rigour. With the growth of bioinformatic techniques to achieve automated comparison of gene functions between different species, it becomes increasingly hard to characterise the work as anything other than routine.

5 Given the broad scope of the claims in many patents, the disclosure in the patent specification does not justify such scope

This issue is closely related to questions of industrial applicability and inventive step, but is nonetheless distinct. It is also the most controversial legal-cum-policy issue that is currently outstanding. Our analysis of the history of pharmaceutical patenting reveals two policy-choice rules in current patent law. First, there is the rule that the first person to identify one use for a novel thing or substance should be entitled to a patent over all its uses. Secondly, the rule that subsequent researchers who add inventive knowledge to an earlier invention can claim a selected thing or substance as such, once again on the basis that a newly uncovered use has been revealed. The first patentee's claim "reaches through" to subsequent discoveries as long as his patent continues in operation. Then the rights of the improver patentees could create a pyramid of claimants all seeking licences. The result is likely to be a royalty stack which could well impede new R&D further down the line. A first question is therefore whether each of the patentees should be entitled only to a patent for the use discovered by him.

For example, mutations in the *RET* (*RE*arranged during *T*ransfection) gene are responsible for two strikingly different disorders, Multiple Endocrine Neoplasia, which includes thyroid cancer and Hirschsprung disease, a disorder of the intestinal tract. Differences in the nature and position of the mutation result in two very different phenotypes. A single patent over the sequence would give the patent holder potential control over two very different disorders. Two separate patents, however, might require two sets of negotiations and two different sets of conditions for use. However, the best-known example has become Human Genome Sciences' patent on the CCR5 receptor, subsequently shown to be the entry path of the HIV virus into human cells.

6 The research exception is inadequately defined in law

The particular issue here is that it remains uncertain how far the exception covers clinical treatment which provides research results at the same time as benefiting the patients selected. As has been argued in Section B.8 (a) (and supported in Appendix Seven) the scope of the research exception is uncertain because it has been a matter of case-law development in various European countries. The cases certainly signal a considerable expansion of the concept compared with the interpretations to be found before the 1980s. While it is reasonably clear that it may now apply to research which is commercially funded, it is only in Germany that the senior court has indicated that research can include clinical trials on at least a fairly broad scale (i.e. covering tests at a number of sites). As research on genetic diagnosis and therapy grows in volume and effectiveness the question of clinical testing will become urgent. On balance a health authority appears to have a greater interest in ensuring (preferably by clear legislation) that the exception does apply to all testing that can reasonably be said to have research as one main purpose, provided that the prospects for further knowledge are not fanciful.

D USE OF OTHER INTELLECTUAL PROPERTY RIGHTS (IPR)

1 Introduction

Protection for genetic information is usually discussed in terms of patent protection. However other legal rights are also relevant. The following sections discuss the role of copyright, design right, database rights, confidentiality, utility models, data protection and human rights. It will be seen that whilst these are issues for discussion they are not generally seen as being as critical as patent protection.

One reason for reviewing briefly the role (actual or potential) of other types of intellectual property right and legal protection of individuals in the genetic sphere is the rise in the importance of *in silico* information. Where *in silico* information is only raw data which has been generated by known or obvious methods it would seem not to be readily protectable as such by patents[61]. In any case, there are other genetic techniques, services and products which may not be covered by patents and their developers may be looking for exclusive exploitation through a different right.

Accordingly, among IPRs it is relevant to consider copyright and its derivatives - notably database protection and unregistered design right. In addition breach of confidence and, in future, some form of utility model protection are germane.

Under *Other Issues* reference is made to various types of legal protection for individuals which may impose constraints on exploiters of genetics-based subject-matter: starting with the possible impact of human rights law, mention is also made of consent by patients and other subjects of experiments, as well as the data protection legislation in the relation to patents and other IPR.

2 Types of IPR

(a) Copyright

Copyright arises in the UK under the Copyright Designs and Patents Act 1988, now amended to take account of a succession of EU Directives. Copyright first developed in order to protect the tangible expression of ideas in the form of artistic, literary, dramatic and musical works. Scientific papers, for example, have long been accorded copyright – the works being literary or artistic or a combination of both. It provides long-lasting protection (commonly the life of the author plus 70 years thereafter) to authors of such works against their being *copied* either in permanent form or through performance, including broadcasting and the like. Traditionally, however, copyright did not protect any other use of information contained in a work. Copyright requires no preliminary application to an Office and that is one explanation of why it has become a source for protecting new demands to stop imitation which have grown with modern technology. The result has been the introduction of "related rights" (to

[61] See above, under diagnosis and method of treatment.

those of authors), which are given to investors, for instance those who finance sound recordings and films.

Three elements in this process of expansion deserve particular note:

(i) Copyright for literary works has come to include computer programs - instructions that make machines work rather than inform people or give them pleasure. Copyright gives rights over much programming which would not qualify for a computer program patent. This is novel territory for copyright which could in turn spark annexations further afield, since copyright grows rather readily by analogy.

(ii) Compilations of data have in the past been generously treated under UK copyright. However, by virtue of an EC Directive, this copyright now subsists only if the database involves some personal intellectual contribution (e.g. in ordering the material). By way of compensation a new form of related right – Database Right - has been accorded to investors who set up and maintain databases (see below).

(iii) For 20 years after 1968 copyright in a drawing could be infringed by making industrial products which gave it 3D form. The result was intrusive and illogical, and so it has since been modified. Copyright for designed products has largely been replaced with a more carefully circumscribed protection called Unregistered Design Right (see below).

(b) Analogues of copyright: Database Right

Database Right, introduced in 1998, protects the investment in compilations of independent works, data or other materials which are a) arranged in a systematic or methodical way and b) are individually accessible by electronic or other means[62]. It is accorded to the investor who establishes the database and lasts for fifteen years, but with time extending whenever there are substantial additions to the material. In order for the right to arise it is necessary for the compiler to demonstrate that the selection and arrangement of the database contents is an intellectual contribution and, therefore, 'original'. The right relates to the *compilation* of the information and not necessarily to the information itself. Because the right exists over the compilation it is taken to exist independently of any copyright arising over the contents of that database. It is a right against extraction from the database or re-utilisation of the material, the European Court of Justice has at the moment the unenviable task of deciding what activities by others fall within the right. Because of the nature of database technology the right is in a state of evolution and it is difficult to state its exact ambit in absolute terms[63]. Almost the same permitted acts apply as under Copyright.

---

[62] The UK law which transposes the EC Database Directive is found in the Database Regulations (SI 1997 No 3037). Database right must be distinguished from the protection of personal data provided by the Data Protection Act 1998, for which, see section 3(c)

[63] Not least the duration of the copyright term for databases cannot be stated in general terms as it would appear that a 'running copyright' exists in respect of each - this means that where a compilation is updated then this may serve to extend the copyright term.

An example of its use in respect of genetics would be the protection of database collections of genomic information compiled in a particular research programme. By virtue of the right, competitors would be prevented from extracting any substantial quantities of information from that database without prior authorisation.

In its Fourth Report, published in 2001, the House of Lords Select Committee on Science and Technology[64] concentrated on genetic databases. The House strongly endorsed the position taken by the Wellcome Trust, Sanger Centre and International Human Genome Sequencing Consortium insisting that primary genetic data, notably the analysis of human and other genomes, should be freely available in the public domain. The SNP Consortium is a practical expression of the same public interest viewpoint. As is well-known, certain US interests have actively promoted their opposing belief that such source material should be commodified, by seeking patents on ESTs and searching for other forms of IP protection. So far as the UK (and the rest of the EC) is concerned, Database Right is not available here for US databases. So the position will remain, until the US introduces an equivalent right, which would be open to EC investors in databases. Ironically it has so far refused to do so.

(c) Analogues of copyright: Unregistered Design Right in the structure of molecules

Ten years ago, when the first results of the Human Genome Project were leading to a flurry of concern over the possibility of acquiring patents over parts of the information, there was considerable interest in finding some *via media* through lesser IPRs. The deployment of copyright to protect computer programs was particularly suggestive. Some participants in the debate believed that there could be a modified 'copyright' which would not be an exclusive right but only a right to receive a royalty when data was copied from a given source. To a degree in the EU, this position has since been met by the introduction of Database Right, although the original proposal to reduce this right in certain circumstances to a claim for royalty upon copying was removed from the final version of the right.

The search for other alternatives has not gone away completely. In this country, the unusual development of design copyright and then its re-modelling as Unregistered Design Right ("UDR") is considered by some leading IP experts to be capable of yielding a form of protection which would stretch beyond the taking of information as such (which is what Database Right is about)[65]. It is argued, for instance, that the formulaic representation of complex organic molecules and similar material (whether genetic or not) should be treated like a technical design for a tool i.e. it should be accorded UDR over products consisting of the molecule or material. UDR of this novel kind would normally last for 10 years from first authorised marketing of the material, and would arise simply from copying (there being no requirement that the subject-matter first be registered)[66]. In its last 5 years of life, the UDR would be subject to compulsory licensing which would allow competitors to use the material

[64] www.parliament_the_stationary-office.co.uk/pa/ld200001/ldselect/ldsctech/67/5701.htm
[65] The legislation governing UDR is the Copyright, Designs and Patents Act 1988, Part III.
[66] e.g. Laddie, Prescott, Vitoria, Speck and Lane, *The Modern Law of Copyright and Designs*, 3rd ed. Vol. 2, 2000, Chapter 38.

on payment of a royalty. The proposal turns on technical legal arguments, which will strike the non-specialist as esoteric.

The notion that such an extension could today be introduced in the UK by judicial decision, rather than specific new legislation, seems very unlikely given the current policy-making background. Major initiatives on the scope of IPRs in the EC have, in the past decade, come to be settled at Community level in the form of Directives to harmonise national IP law[67] or Regulations introducing Community IPRs[68]. Since the rest of the EC has the greatest difficulty in accepting the British concept of UDR even for straightforward product design, it is highly unlikely that a campaign at that level for a "pharmaceutical substance UDR" would ever become airborne.

(d) Confidence

Over time English judges have developed a right to the protection of information held in confidence against its unauthorised disclosure or use. When applied to trade and other commercial secrets, its character is close enough to established IPRs for the right to be placed in the same legal sphere[69]. To be protected (i) the information must have the necessary quality of confidence; (ii) it must have been imparted in circumstances importing an obligation of confidence, either because this has been agreed expressly or would be assumed by reasonable people from all the circumstances; and (iii) there must be an unauthorised disclosure or use of the information, actual or impending[70]. Exceptionally a public interest in releasing the information can override this form of protection[71].

Any personal genetic information will be subject to the usual conditions relating to the protection and use of patient information[72]. Clearly any valuable information which the Department of Health has built up in the course of providing treatment or through other research can be the subject of an obligation of confidence, which is best established by express agreements in writing (e.g. in contracts of employment). If the agreement is that the data is not to be used for commercial exploitation without permission, then that exploitation may be halted by court injunction.

However, this is a fragile right, since a) confidence once broken may be actionable only by way of damages; and b) if the developer of the information is responsible for a product or service on the market, then an outsider remains free to buy it and then analyse it and use the information in competition; so the right is not worth much unless reverse engineering is not possible.

---

[67] Literary copyright for computer programs and Database Right being two pertinent examples.

[68] As with the Community Trade Mark and the Community Industrial Design – and in the future perhaps the Community Patent.

[69] Protection of confidential information is essential in relation to patent law procedure as an invention must not have been made public before the patent application being filed. In relation the value of copyright lies in providing a rather wider right of privacy.

[70] Megarry J in *Coco v Clark* [1969] Reports of Patent Cases, 41 at 47.

[71] In healthcare, this has given acute difficulty, for instance, when a medical officer turns out to be HIV positive.

[72] Health Services Guidance HSG(96)18: *The Protection and Use of Patient Information.*

The common law of confidence must be looked at in conjunction with the statutory duties imposed by the Data Protection Act 1998 and the Human Rights Act 1998 (see below).

(e) Utility Model ("UM")[73]

Utility models are a form of IPR designed to protect low level incremental innovation and as such are aimed particularly at small to medium sized enterprises. They can protect ideas for technical developments which have a commercial application since they are usually granted on the basis of a lower standard of inventive step (the standard of novelty is generally the same as for patents). They are made attractive to SMEs by being quicker (the examination process is greatly reduced) and cheaper to acquire (a consequence of the reduced examination).

UM protection is currently not available in the UK, but the European Commission is considering introducing an EU-wide form of the right[74]. The proposed Community UM would involve simple, quick registration with the aim of grant taking place within 6 months from application[75]. Its cost would be low. A lower level of inventive step would suffice than is required under ordinary patent law[76]. There will be no limit on the number of claims which can be made in respect of the invention. Once granted, the rights will be identical to those conferred by a patent, but will last for a maximum of 10, as opposed to 20, years. At present the draft provides exclusions to the protectable subject-matter and these include inventions involving biological material, chemicals, pharmaceutical substances and processes[77]. Surgical or therapeutic treatment procedures applicable to the human body or to the bodies of animals and diagnostic procedures carried out on the human body or the bodies of animals are also excluded on the grounds that they are not considered inventions susceptible of industrial application. The Community UM, under the present draft, would give protection for mechanical devices which could be used in conjunction with genetic material although the right would not, as such, provide protection for the genetic information itself.

There has been considerable concern in the UK, notably from professional circles, about the proposal for a Community UM: First, the level of inventive step in patent law is already sufficiently low to allow protection to be granted over discernible inventions. It is very difficult to envisage a level of inventiveness lower than that currently used which would appropriately delineate a protectable invention. Secondly, utility models would proliferate exclusive rights over basic, obvious technological developments, thus impeding what is currently legitimate practice in R&D. Thirdly, the right granted, equivalent to that under a patent, may substantially outweigh the inventive (incremental) contribution. The proposal appears to ignore the experience which necessitated pre-grant examination of patent

---

[73] This is also sometimes known as second tier protection or as a petty or short-term patent. It should be noted that utility model protection varies from country to country. 12 EU member states currently provide some variety of this protection but nine different types can be identified.

[74] COM(1999)309 final

[75] This can be contrasted with the patent system where it can take between 1-3 years for a grant to be made.

[76] The novelty requirement is expected to remain the same. It is questionable if the requirement for industrial application will alter as the current language used is that in order for an invention to qualify for utility model protection it must be shown to be *susceptible* of industrial application. The requirement in UK patent law is that it must be *capable*.

[77] *supra* note 74, Article 4, see also note 105 below. Of course the exclusions could always be altered during the legislative process.

applications. The utility model, granted without any preliminary comparison with the "prior art", would be of very uncertain validity. Yet it could be used by anyone, including very large corporations as a damaging tactical weapon in business competition against those without the will or ability to fight back: it might easily become an *anti-SME* instrument. The Community project therefore demands careful appraisal by governments at the national level.

3 Other issues

(a) Human rights

The Human Rights Act 1998 (making the European Convention on Human Rights part of UK law) contains a Right to Life in Article 2 and a Right to Private Life in Article 8. Some NGO's, for example the Human Genetics Commission, have raised the question whether these fundamental rights should be taken into account when looking at intellectual property rights and genetic information. To date, these issues have not been discussed in detail. It seems unlikely that Article 2 could be used to broaden the patent exception for methods of medical treatment so as to embrace all pharmacological inventions. The effect would be to make them open to imitation by competitors, since the originator would have no exclusive right. It also seems unlikely that Article 8 will open a way to broader protection of personal information than currently arises under confidence law, or so current judgments interpreting this Article suggest.

(b) Consent

There is currently no requirement in British patent law that consent from a donor has to be obtained in order for a patent to be applied for in respect of an invention arising out of that material. The EU Biotechnological Directive states, in Recital 26, that consent must be obtained when directed by national law. However the UK has yet to introduce such a law and it is unlikely to do so in the near future.

Obviously the removal of tissue for R&D purposes is subject to the usual consent practices set down under the various regulations and guidelines. It is not thought necessary to set these out for the purposes of this Report, since they do not affect proprietary rights in the associated knowledge.

(c) Data protection

Personal information is protected, under statute, by the Data Protection Act 1998 (at common law it is protected under the law of confidence). The Act provides for the secure handling of personal information whether stored electronically or in other filing systems. Information which falls into the category of 'sensitive personal data' (such as genetic information) is subject to stricter controls under the Act. Information may only be kept for as long as the purpose for which it has been processed remains. However, this does not apply to data kept for research purposes, although this is subject to limitations (section 33(1) of the Act). Part 5 and Schedule 1 of the Health and Social Care Act (HSCA) also relate to the control of patient information. For a full understanding of the legal position the HSCA

and Data Protection Act must be read together[78]. The Data Protection Act does not give rise to any property interests in the information as such, its function being primarily to ensure that those who hold such information do not abuse this position.

Article 25 of the EC Data Protection Directive[79] (on which the UK legislation is based) requires that, in order for information protected under EC data protection laws, to be transferred outside the EC the country, or organisation, receiving the information must constitute a 'safe harbour'. This means that they provide an equivalent level of data protection. For example, information may only be transferred to those US companies which comply with this provision.

[78] Section 60(6) of the HSCA states that: Without prejudice to the operation of provisions made under subsection 4(c) regulations made under this section may not make provision for or in connection with the processing of prescribed patient information in a manner inconsistent with any provision made by or under the Data Protection Act 1998."

[79] 95/46/EC - the specific reference is L215 and can be accessed via www.europa.eu.int/eur-lex/en/oj

E GENETIC INVENTIONS AND OTHER IPRS

Our survey of the implications of other forms of IPR for genetic research has been brief. It leads us to the conclusion that the most likely difficulties in the immediate future lie with databases of genetic information. The situation with the SNP consortium and the Syngenta rice genome database[80] are two recent situations that come to mind.

Many scientists believe that single nucleotide polymorphisms (SNPs) predispose individuals either to disease or their response to drugs. Furthermore, SNP maps may be helpful in combating complex disorders such as some forms of cancer and vascular disease where multiple genes are responsible for the disorder. Therefore, access to SNP maps will be of extreme importance to biomedical and pharmaceutical research and development programmes in the search for new products and diagnostics. A consortium of large pharmaceutical companies and the Wellcome Trust have initiated a program to map the 300,000 common SNPs. It is estimated that of these 300,000 SNPs around 10-20 thousand may be of commercial significance. Patent applications will be filed solely to establish the dates of scientific discoveries of the SNPs mapped. The members of The SNP Consortium and the collaborating academic centres have agreed not to allow any patents to issue, and to publish mapped SNPs expeditiously. These steps will ensure the SNP map is free for all biomedical researchers to use without obligation. The SNP Consortium was created precisely to produce a high-quality SNP map that will be publicly available and freely available to researchers, commercial or non-commercial alike. However, this balanced approach is likely to be the exception rather than the rule and access to databases will incur a cost, for example access to the Celera Human Genome Sequence database and more recently Syngenta's rice genome database.

The restrictions placed on downloading the rice sequence data, from Syngenta, are very similar to those covering the human genome data published last year by the US company Celera Genomics. Syngenta is making the data publicly available through its own Web site, rather than through GenBank, a public database. Scientists can use the partially assembled raw genome sequence without strings for research, and Syngenta will permit researchers to publish papers and have Syngenta deposit a gene's worth of DNA data in GenBank without negotiation. (The raw data include minimal notes, an official says, such as labels on DNA likely to be "nonrice in origin.") Larger amounts will require a specific agreement. The company seeks no "reach-through" intellectual property rights, but scientists doing commercial work must negotiate their own data-access agreements. Syngenta are not ready to permit unrestricted access of its data by its competitors as its feels it has a significant commercial advantage. Syngenta feel that the public benefit of bringing this important science out of trade secret status greatly outweighs argument over accessibility.

Sir John Sulston, former director of the Sanger Centre disagrees. He states that bioinformaticians handle very large datasets, and they need to have all their data in one place in order to make sequence comparisons. With Syngenta not depositing the information with Genbank which is the accepted scientific community practise, you will end up with a large

[80] Correct at the time of writing.

number of databases with varying rights of access and the whole area becomes impossible to work in. With the number of databases containing valuable information, such as genomic data, increasing daily, access, and the cost of access, to this data will be of increasing importance. Access to information is also very much about who controls and stores data and where they do it.

In the first instance, barriers to accessing this material are technological, in the form of passwords, encryption and the like. Their prime legal support is through the contracts that are made at the time of permitting access to the databases. So far as the information is recorded anonymously, there will be additional IPRs which could be useful against third parties who acquire the information without direct contact and either record and use it themselves, or make it publicly available or exploit it commercially. First, in any case where the wish to protect the material from free release is stated or would be apparent to any informed person, an action for breach of confidence will lie. In principle it gives the right to stop any revelation or use of the information which is happening or is about to happen, and a right to monetary compensation where damage has already been done.

Secondly, the person who finances the organisation of the database will have database right in it. This right, created by the EC in 1996, is of uncertain scope, above all, because it is not clear that it applies against persons who consult the database for specific information which has (for instance) an application to their research; or whether it only applies against competitors who are seeking to exploit the database, or a substantial part of it, as a database, which, for instance, they supply to others. The question is currently before the European Court of Justice. It can be anticipated that the wider view of the right will prevail. Such a result will enhance the royalty earning prospects of database providers, if they choose so to exploit their results

The issue in relation to genetic research is accordingly whether legal steps should be taken to limit the legal range of this mixture of contract and IP rights, so as to make access more readily available. The IPRs might for instance be reduced to rights to claim compensation for use. Or should the law go even further and positively require that information be made available from given sources: and if so, which sources; under what conditions; and subject to what compensation, if any? The Database Right was originally created in order to protect the investment involved in constructing large compilations of usable data in fields such as the copyright industries (literary, musical, film and TV, etc), financial services, tourism and other leisure fields, where the commercial motivation and value are accepted. The justification for it becomes much more questionable when it is asserted vigorously in the realm of scientific investigation, which relate to basic human needs and which are often funded by way of some public-private collaboration.

F LITERATURE REVIEW

The Selective Bibliography attached in Appendix Two sets out the literature which has provided background for the Report - it will be seen that the issues identified within the project as being of particular importance (subject-matter, scope of protection, the research exemption and role of licensing) are generally in line with those identified elsewhere.

As can be seen from the Bibliography, there is a considerable literature in existence which covers nearly all aspects of gene patenting. It is not proposed to provide a critical analysis of this literature. It is clear from the literature available that the types of concerns which are identified below are shared across a broad section of the academic, scientific and political communities. There is also a clear dynamic for ensuring that the patent system is used appropriately and that patents which restrict access to protected material to an unacceptable extent are to be deplored.

The key issues raised in the literature relate to the following:

1 Should genes be patentable?

The consensus is that genes as such are not, nor should they be, the subject of a patent grant. However, once genetic information has been put to novel and inventive use then patent protection might be appropriate. In respect of the former, it is recognised that merely stating that genes are not patentable might fall on deaf ears given recent patent grants in the US to companies such as Myriad Genetics and HGS. Neither corporation claims the gene as such in their patents; but the scope of the patent granted is such that the effect of the patent is to extend protection over the gene itself – i.e. it cannot be used without the consent of the patent holder. The view is expressed, both in Europe and the US, that patent offices must ensure that there is clear blue water between a discovery (ESTs, etc), unutilised material, and a patentable invention.

2 Breadth of claims versus contribution to genetic knowledge

There is a divergence of view expressed here. While no author supports the notion of overly broad patent protection, there is clearly more support for broader claims from those supporting patent protection than from those who are concerned about the over zealous use of the system. There is equally no agreement on where the appropriate place is for determining the proper boundaries of protection. Strict supporters of patents prefer the *status quo* under which courts act as primary arbiters whereas others would wish to see more restraint during Patent Office examination and opposition.

3 Research

Whilst this is an issue which is raised in most of the literature it is usually only discussed in superficial terms alongside the more fundamental questions such as the patentability of the material itself. There seems to be consensus that without an adequate exception, patents

could adversely affect the ability of researchers to carry on R&D, but that to date there is only limited anecdotal evidence that such an adverse outcome is actually occurring. This seems to be an issue which commentators regard as requiring monitoring, not least to see whether a proliferation of patents directed at essentially the same genetic investigation creates an unduly monopolistic barrier to future research. There seems to be very diverse views on whether a concrete definition of the research exemption[81] will actually help or hinder research and development.

4 Licensing

Again this is an issue which is usually raised alongside research as secondary to questions of patentability and ethical considerations. There is little written on the availability and value of Compulsory Licensing and Crown use.

5 Healthcare issues

These are invariably discussed in the context of developing versus developed countries - and there would seem to be a need to draw attention to the fact that healthcare systems, such as the NHS, could benefit from a broader debate on the impact of IPRs on its ability to deliver effective and appropriate healthcare. It can be seen that the concerns raised in the literature mirror those identified in the Study.

[81] See Appendix Five and Seven

G CONCLUSION

This stage of the study ascertained the legal issues pertinent to the use of genetic information and identifies in outline the issues which will necessitate further attention. These were primarily seen to be:

(a) Determining appropriate material for protection, and in particular, determining the appropriate contribution necessary for protection, factors which follow from the application of patent law tests of novelty, obviousness and adequate disclosure

(b) The scope of the right granted, which turns on the appropriateness of the claims granted to protection in the patent specification

(c) The nature of the research exemption

(d) The role the public interest exemptions and constraints on abuse of a monopoly position can play in curbing over-protectionism.

The study predominantly focused on identifying the various intellectual property issues which arise in respect of genetic material. There are, however, also issues relating to the management of genetic material which arise out of the use of other forms of intellectual property right (most notably copyright, confidentiality and database rights) and the impact of non-IPR laws including data protection and human rights. These issues are evolving and whilst they do not yet have as great an impact on genetic material, it is likely that they will become increasingly important and need careful consideration within a management of genetic material portfolio.

The next section provides some recommendations for policy responses which could be adopted to deal with these issues.

SECTION TWO:
POLICY ISSUES AND RESPONSES

A INTRODUCTION

The function of Section Two is to provide some practical solutions to the problems identified in Section One.[82] Its objective is to provide the Department of Health with suggestions as to how it can establish, amongst other things, early warning mechanisms to prevent inappropriate patent grants, structures for dealing with difficult licensing issues, and frameworks for mutually beneficial partnerships with other providers of healthcare related intellectual property. In making these suggestions the Project Team recognises the potential immensity, as well as diversity, of this task and recommends that advantage should be taken of the work of groups such as the Human Genetics Commission, Intellectual Property Advisory Group and Nuffield Council on Bioethics and make representations to these groups where necessary.

In developing a Department of Health perspective, we have noted that there may be stances which the Department of Health might ideally wish to take, but which it would be unlikely to pursue in the current patenting environment. In light of this we have been, when identifying the options available, mindful of the need for viability in the short as well as long term. Of particular importance to this determination is the Department's dual role as user of externally sourced patented material and as a body interested in acquiring and exploiting rights of its own, either directly or through its regional hubs. As to the former, while the Department, as the country's major user of healthcare products and services is evidently in a strong bargaining position to deal with patent holders, it also comes under considerable pressure to provide high quality healthcare within constrained budgets. Its ability therefore to look after its IP interests may not be as straightforward as might at first be assumed. In understanding what options are available to the Department, it is essential that, in addition to noting the problems which IP is commonly perceived as causing, the Department also appreciates the limits which the law places upon patent rights (these take the form of the requirements for validity and disclosure, various exceptions, compulsory licences etc which have been discussed in Section One). The single most effective option available to the Department is to take a central role in ensuring that these are properly observed in those situations where the Department has an interest.

The Department of Health is in a uniquely strong position regarding its ability to negotiate with holders of intellectual property rights - this strength coming from both its role as main purchaser of healthcare-related intellectual property and, its consequential ability to invoke either compulsory licensing or Crown use in the event of differences over licensing terms. In assuming this role it is vital that the Department should foster mutually beneficial partnerships

[82] The remit given to the Project Team related specifically to genetic material. However, the concerns raised apply to the broad range of patentable subject-matter and the general principles which we have identified can be applied to all intellectual property (whether internally generated or externally sourced).

between itself and the holders of intellectual property, facilitating access to that property for research and development as well as for general healthcare purposes[83].

The new genetics has reached the stage where it seems to promise much for the future of healthcare. Yet large investments of capital are going into experimentation and rewards have so far been very intermittent. Predictions about potential patenting problems are therefore speculative[84]. The UK Patent Office Guidelines suggest that the number of successful patent applications is likely to fall, because of an increasing inability of the applicant to demonstrate an inventive step. These also appear to indicate a cautious response to any concern that the implementation of the EC Biotechnology Directive in the UK might lead to more patents being granted. However, the Guidelines only apply to the UK. There is no such official statement from either the USPTO or EPO. However, because the risk to investors is so great, there could well be cases of very aggressive reliance on patents and the Department needs to be aware of this possibility and prepare for it.

In developing its recommendations the Project Team has relied upon the three key publications: The Nuffield Council on Bioethics Discussion Paper on *The Ethics of Patenting DNA*[85], the European Commission's Report on the *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*[86] and the UK Patent Office's *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office*[87].

These three publications provide a tripartite framework[88] within which it is possible to establish a clear Department of Health policy[89].

In summary:

(i) Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (July 2002). This discussion paper reflects the views of a highly influential range of participants and contains a valuable analysis of the present state of genetic research and its prospects for commercialisation through IPRs. It emphasises the limited extent to which aspects of that research can be said to involve patentable *inventions* (as distinct from discoveries,

---

[83] It is recognised that the notion of 'partnership' might be more appropriate to small to medium pharmaceutical companies or to universities rather than to multi-nationals which might wish to maintain clear competitive lines

[84] For an idea of the numbers which might be involved see Thomas, Hopkins and Brady *Shares in the Human Genome - the Future of Patenting DNA* Nature Biotechnology December 2002, Volume 20, 1185- although it should be noted that in practice very few of these patents, figures provided by Mike Stott of GSK at the February 2003 workshop indicate that the numbers could be as few as only 5-20 per company, might have any practical impact, the others falling by the wayside due to lack of commercial viability, company merger, or other reasons resulting in a lack of interest in protecting the intellectual property.

[85] supra note 5

[86] supra note 6

[87] UK Patent Office, September 2002. http://www.patent.gov.uk/patent/reference/biotechguide/index.htm Another development which it is relevant to note was the announcement, in early December 2002, of the UK Patent Office's consultation exercise, which will lead up to an amendment of the UK Patents Act 1977 possibly as early as 2003/04. Whilst the consultation does not relate specifically to gene patenting it does raise a number of issues relating to novelty, certain exceptions to patentability (in particular the exclusion of methods of treatment) and licences, upon which the Department of Health may wish to express a view.

[88] Hereafter referred to as the 'Tripartite papers'. Whilst we have focused on these three publications it is relevant to note that there continues to be extensive discussion of both the theoretical and practical issues relating to the patenting of genetic material within the academic and scientific press and the subject remains a popular one for conferences.

[89] Each of these publications is discussed in more detail in Appendix Six

straightforward research strategies, etc.) and calls for a more restricted application of the patent system. It argues that patent offices must, in the public interest, take a more critical role in examining applications for genetic patents, it being the very purpose of the examination system to filter out unjustified claims to rights before they become available against industry and academia.

(ii) European Commission: *Report on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (October, 2002). The Report is the first evaluation by the Commission of the EC Directive on the Legal Protection of Biotechnological Inventions of 1998. It summarises the contentions about each Article of the Directive which have arisen since its enactment and introduction into the national patent laws of at least some Member States. Not surprisingly, the Report is in general supportive of what the 1998 Directive achieved after its long gestation. But it makes clear that there should be adjustments at least at the level of administering the law in patent offices. And it marks out for further investigation: (i) the proper scope of genetic patent claims (especially the "reach-through" problem); and (ii) the patentability of human stem cells and cell lines obtained from them.

(iii) UK Patent Office: *Guidelines for Examination of Applications relating to Biotechnological Inventions* (September, 2002). These new Guidelines are intended for examiners in the UK Office who are applying the present law to applications before that Office. (They therefore do not touch practice in the European Patent Office, which provides an alternative route to patents for some 30 European countries, including the UK). The Guidelines show a lively awareness of the need to give meaning to the concepts of patentable subject-matter, industrial application, novelty, obviousness, adequate disclosure and its correlative, proportionate claiming. They consider carefully the impact of decisions by the English courts, which have limited in various ways the operation of the law in relation to biotechnological patents.

B SPECIFIC PATENTING ISSUES AND PROPOSED POLICY RESPONSES

Before looking at the specific issues we would like to make the following observation regarding a review of general patent policy.

Because of the adoption of the EU Biotech Directive and the proposed introduction of a Community Patent many of the decisions relating to the patenting of genetic information (and also those relating to copyright, design right, utility models and database protection) are likely to be concentrated at the European Commission. There the UK Government's principal representatives will continue to be from the UK Patent Office. The same will be true of our representation at the Administrative Council of the EPO, WIPO and WTO. The Patent Office has lately improved greatly its openness to outside consultation, calling regularly for comments from interested parties and the general public on issues being raised in Europe and internationally. It can also call on the expertise of the Intellectual Property Advisory Committee (IPAC) and Human Genetics Commission. Given the Department of Health's considerable interest both as holder and user of patents, it can properly expect to be one of the bodies consulted in these processes. Our advice is given within this framework. Clearly the Department of Health does not, nor should it, wish to adopt the Patent Office's role - but it does need to be in a position to review policy from its own perspective in order to be able to contribute to the formation of the UK Government's position.

Our two main recommendations are:

(i) That the Department of Health should monitor the practice of the Patent Office in those applications which most directly concern healthcare delivery and

(ii) That it should make use of the various provisions within patent law particularly where there is an issue whether an application or patent satisfies the current legal requirements.

Accordingly the Department will need to be in a position to understand how the tests of novelty, inventive step, industrial application, disclosure and claim drafting are being applied to gene and gene-related patents. It should also become aware, at an early stage, of particular applications and patents which may present difficulties. In other words, the Department of Health should act in the same way as a prudent firm in industry. We are not suggesting that any new powers should be introduced nor that there should be any special extension of these powers just to the field of genetics. This means that the Department is in the same position as any other user of patented material - save in respect of Crown use.

The following sections outline specific issues surrounding the patenting of genetic material. The aim is to characterise (but not to provide an exhaustive analysis of) the types of objection to patenting which are being voiced today with growing insistence and to suggest the types of solution which could be investigated by the Department of Health as well as other healthcare providers in Europe.

1 Background to the recommendations

The Project Team were asked to evaluate (a) the likely extent of patent problems arising in respect of any given type of genetic invention and (b) the risks and benefits for the Department in taking, or not taking, action against a specific patent or monopoly position supported by the presence of a patent (e.g. service provision tie-ins related to a specific test).

In respect of the first, as has already been stated, it is difficult to determine the size or extent of patent problems that might arise. In terms of ascertaining the future extent of patent activity within Europe, the tone of the Commission's Report implies an expectation of an *increase* in patenting activity in order to bring Europe closer to the United States and Japan in the number of patents granted in the bioscience area. The Report does not discuss the threshold for protection nor whether the on-going developments in the science are likely to make the goal of increased activity difficult to secure. Because of this it is hard to predict whether there will be a proliferation of those concerns which have arisen in respect of *Myriad*-type patents or if, as the jurisprudence of the granting office develops, these concerns will be alleviated.

With regard to the second it is equally difficult to state what the risks could be in any given context or which particular course of action the Department should follow. The reasons for this are several.

First, within a UK context, there is a need to allow the Patent Office Guidelines to bed in, and to assess whether the practice set out in the Guidelines has the effect of reducing inappropriate grants. If the Guidelines do have this effect then fewer challenges are likely to be required and those that do take place could (provided that they are not based on ill-considered argument) have a greater likelihood of success. This is one of the reasons why we stress below the need for constant monitoring of Patent Office activity.

Second, the decision to undertake a challenge will not be one purely based on strength of legal argument. It will depend on the policy adopted by the Department of Health [90].

Third, any decision to challenge (whether by the Department itself or by hubs) will need to be looked at in the context of the legal environment at the time of challenge. It could be the case that similar challenges in future will not succeed. This does not mean that the specific challenge of concern to the Department will automatically fail, but the likelihood of a receptive judiciary needs to be considered. There needs to be a careful evaluation of when challenges will be in the Department of Health's best interests. In making this evaluation the Department will not wish to be seen to be 'soft' when it comes to deciding whether or not to challenge. In other words, the mere fact that the challenge may fail (and such a possibility exists in any litigation) should not be over-valued in decision-making. The Department (and, if

[90] If litigation is to be undertaken by the hubs then, presumably, it will be for the hubs to determine for themselves an appropriate risk assessment strategy. Such a strategy might involve alternative resolutions worked out between the Department and the patent holder.

relevant, the hubs) will need to be seen to be robust in this matter and not afraid to go to law to protect their interests.

It is recognised that priorities will shift and that financial and political considerations could be the ultimate determinants. Their effect on the ability of the Department to delivery healthcare utilising the best of genomic innovation will need to be carefully assessed.

2 The issues

We preface our comments by stating that the Department of Health should support the granting of patents over genetic subject-matter, while insisting that the general criteria of patentability be properly applied during the examination process. This will be discussed further below.

We have been considerably helped in our attempts to identify the issues for further assessment by the analysis in the Nuffield Discussion Paper, which divides the problems under the broad heads of:

- Diagnostic testing
- Research tools
- Gene therapy
- Therapeutic proteins

In addition to these we would add the two issues identified by the European Commission as requiring specific attention:

- The scope conferred by a patent on human gene sequences
- The patentability of human stem cells and cell lines obtained from them

There are other issues which are either not discussed in the Nuffield discussion paper or the Commission's report, or which are only mentioned in passing. We feel these merit further attention. In addressing these, the central question is whether a predominantly publicly funded health service system (as in the UK) engaged in a broad range of healthcare delivery, should be able to:

- Claim increased reliance on public interest exclusions or limitations (such as public policy and research use) and
- Make greater use of Crown/government use provisions to enable wider public access

It can be argued that more weight could be given to the use of these devices where the health service is predominantly public rather than private. Taking these considerations into account, we have redefined the categories for attention and make the following recommendations:

(a) Patent law application and interpretation issues

- Patentable subject-matter (including general issues, stem cells and cell lines, diagnostic tests, research tools, gene therapy, therapeutic proteins)
- Scope of claims (including reach-through claims)

We recommend that the Department should actively monitor the activity of the EPO[91] and UK Patent Office to ensure that:
(i) Patents are granted only over inventions which meet the threshold for protection and
(ii) Patents granted are not inappropriately broad in scope

(b) Access issues

- Experimental/Research Use
- Licensing (both in and out)
- Compulsory Licensing
- Crown Use
- Competition law

We recommend that the Department should seek to establish a positive working relationship with the holders of intellectual property rights to ensure mutually acceptable access terms. However, in the event that such terms are not forthcoming, the Department should be prepared to draw attention to the scope and extent of compulsory licensing procedures as a factor to be considered in licensing negotiations; and that it should weigh up the desirability of relying on its powers under the Crown use provisions of the UK Patents Act. However, the Department of Health should consider the invocation of either UK or EC competition law in circumstances where a patent holder(s) is abusing a monopoly position in order to dictate the terms of licence/access agreement which go beyond the mere assertion of the exclusive right adhering to any IP.

(c) Other issues

- Public Policy
- Morality
- Methods of Treatment & Diagnosis

3 Prioritisation of issues

In addition to setting out recommendations for the Department of Health we also indicate whether we think a particular issue is of high or low priority.

- High priority issues require immediate action
- Low priority issues are those which the Department simply needs to monitor but which are not, at present, thought to cause great concern.

[91] It is worth reminding that the EPC (which established the EPO) was set up by its Contracting States under the auspices of the Council of Europe. It is autonomous and not subject to any external review or appeal. It is also not subject to EU legislation although the EPO has adopted certain provisions of the EC Biotech patenting directive for the purposes of supplementary interpretation.

We identify the first category, application and interpretation issues, as high priority. We do so because we believe that the Department of Health should, as a matter of urgency, establish a central patent policy which will apply to any given patent situation. Once that policy is established the question of whether the action to be taken in respect of the specific patent in hand should be high, medium or low priority can be determined.

In respect of each of the prioritisations outlined below we would stress that once the policies and practices of the UK Patent Office and EPO in terms of grant, and the Department of Health in terms of responses to those granting practices become established, some actions could be stepped down to medium or low priority.

4 Options for the Department of Health

The options for various actions available to the Department of Health are:

(a) To monitor applications made to the EPO and UK Patent Offices and, where it is thought that an application might cause concern, to consider presenting information to the granting office which might assist its decision making.

(It is worth observing that no company will want the potential disrepute which comes from making questionable patent applications and the fact of the monitoring by the Department of Health could act as an additional deterrent.)

This information might, for example, concern the novelty or inventiveness of the invention particularly in respect of prior uses of genetic information or products. This form of intervention is possible *before* a grant has been made.

Where a doubtful grant has been made, and this is affecting the ability of the Department of Health to use the invention protected by that grant, we would urge that the Department of Health should first endeavour to enter into amicable discussions with the patent holder to agree favourable access terms.

It is important to remember that a patent holder is more likely to wish to negotiate favourable terms if the alternative is a costly challenge to the patent. Equally the negotiation of favourable terms, undertaken against the backdrop of the various options outlined below, to the Department than litigation even where there is doubt over the validity of the patent concerned could prove more advantageous (in terms of cost, time and relationships with the holders on healthcare related intellectual property). For one thing, if the Department of Health is seen to be more litigious then conciliatory then this could have the effect of rendering its own patents more open to scrutiny and challenge.

It is only in the event that amicable overtures from the Department of Health are rejected that we would recommend the following courses of action:

(i) To attack the validity of the patent after grant, where it has not been possible or practicable, (for instance, by producing prior publications which show that the claimed

invention is not novel or is obvious), to bring such information to the attention of the granting office before grant.

In the European Patent Office this action can take the form of an opposition, which must be launched within 9 months of grant. Its effect, if successful, will be to invalidate wholly or partly the Euro patent for each country applied for. The Euro patent (UK) or a patent granted by the UK Patent Office may be the subject of revocation proceedings in UK tribunals or courts, again on grounds such as that the invention is not novel or inventive. These proceedings may be brought at any time during the life of the patent.

(ii) To use the patented invention without payment of a licence fee - in other words to treat the invention as if it were not patented but in the public domain.

Any litigation brought by the patent holder in the courts for infringement of its patent may be countered by a defence that the Department is not acting within the scope of the claims in the patent specification, in other words that it is not performing the invention; or by a counterclaim of invalidity. The Department would risk the upholding of the patent by the courts and a finding that it was infringing. It would become liable to an injunction against any further use and (in many cases) to damages for its use in the past. It would then have to pay its own costs and a considerable proportion of those of the successful patentee. The bill is likely to be very large and we would suggest that this option is only used in exceptional circumstances where it is clear that the likelihood that liability can be avoided is high.

(iii) To raise doubts over the validity of a patent during the negotiation of a licence to use the patented invention.

This could act to the Department's advantage since it could then negotiate more favourable terms. It would be to the advantage of both sides in most situations not to engage in litigation. As stated already the fact of the Department of Health's unique position as primary purchaser of intellectual property related to healthcare, together with the desirability of working in amicable partnership with the holders of that intellectual property, places the Department in a strong position during negotiations. In such discussions it will be worth mentioning that by the start of 2003, the UK courts have yet to uphold a biotechnology patent[92].

(b) Where a patent has been granted (and appears valid) but the patent holder is either refusing to licence the invention or the terms of the licence are not acceptable, the options available to the Department of Health would be:

(i) To consider obtaining a compulsory licence

Discussion of this prospect during negotiations may bring the patent holder to modify its position. If this pressure does not work then the Department may seek a

[92] It is likely that this will change and this underlines the need for a monitoring of UK biotech patent cases.

compulsory licence for itself or another, bearing in mind that a licence will not necessarily be granted by the Patent Office. A number of conditions have to be met before a compulsory licence can be sought. The first is that it is only possible to seek a compulsory licence *after* a patent has been granted. The second is that three years must have elapsed from grant before a compulsory licence can be sought (this is to provide the patent holder the opportunity to exploit the potential for a market lead). The third is that the Patent Office has to be convinced that a ground exists within the Patents Act which justifies the licence in principle and a range of other conditions has to be satisfied, including a prior effort to secure a licence voluntarily. The Office then sets the licence terms (as to royalty, scope, etc.) which it judges to be reasonable. The EPO does not concern itself with such licensing, which is dealt with at the local level by national granting offices). Any licence or refusal of a licence may be reviewed on appeal by the Patents Court of the High Court.

In many respects the existing compulsory licensing system is cumbersome and difficult to navigate. Because of this, together with the need to have a workable compulsory licensing system, there might be room for the Department, should it wish, to instigate a reassessment of the current provision. In making this assessment it should be borne in mind that many of the limits upon granting compulsory licences come from the UK's obligations under TRIPs. These limits have yet to be tested under UK law.

(ii) To invoke Crown use to ensure access

As noted in Section One, this provision of the Patents Act 1977 specifically provides for the manufacture and sale of medicines and drugs (although it does not specify tests). This does not require any prior authorisation from the Patent Office, but only payment of a reasonable compensation for the use. The UK Patent Office considers the Crown use provisions to fall within the scope of Article 31 of the TRIPs Agreement. In assessing the circumstances when Crown use could be invoked it will be necessary to refer to the provision within TRIPs. There is also the possibility that there could be a challenge to this power of the Crown brought by another government under the WTO dispute settlement procedure, claiming that the UK was not complying with TRIPs, Article 31. This would not affect reliance on the powers given by the Patents Act to the Crown until the law was changed as a result of the challenge.

Potentially this provision could be valuable to the Department of Health. There is a problem with using this provision. It is possible that an argument could be made that there is a conflict of interest between the use of the Crown use provision in respect of licensing patented products and processes into the UK healthcare system and the market driven licensing out terms which are likely to be adopted by the Department and/or the hubs.

(iii) To consider a referral to the Office of Fair Trading (OFT)

Where there is doubt over the efficiency of using either compulsory licensing or Crown use, but a patent holder is abusing a dominant position which results from a patent held, then the Department of Health should consider a referral to the OFT Commission. This is useful weapon, but a caveat to its use is that once the referral is made then the matter is removed from the control of the Department of Health. Any determinations as to terms, royalty rates etc. will be a matter for OFT.

We would stress once again that the main value in each of the provisions outlined in (i) to (iii) above lies in its role within negotiations and that we would anticipate that actual resort of litigation or compulsion to license will be rare. But the desire to do so when necessary should be real. It is to be hoped that a clear policy statement relating to the Department of Health's determination to make use of these different courses of action will deter patent holders from asserting speculative patents and from taking unreasonable licensing positions.

C PATENT LAW ISSUES

1 Patent law application and interpretation issues[93]

(a) General position[94]

It was initially thought that the question of whether patent protection should extend to living material might be one which the Department of Health would wish to consider. However, it has become clear that there appear to be few problems with the notion of patenting genes, animals and plants, provided that *the granting criteria are properly applied*[95]. The reality is that patent protection has been extended to this material, and this extension has been sanctioned at the EU, EPO and UK political levels. It is unlikely that the policy underlying this legislative position will change. Evidence of this can be gleaned from the language used in the UKPO Guidelines where it is stated categorically that recent UK legislative initiatives (specifically the Patent Regulations 2000 and 2001 which implement the EU Biotechnology Directive) establish "beyond doubt the legitimacy of biotechnology patents in the UK". The Nuffield Discussion Paper implicitly agrees with this stance in that it focuses on the *application* of patent law to inventions concerning genetic material. It takes the view that the test of protectability lies in the ability to meet appropriately determined granting criteria rather then on any special quality attaching to the material involved. Reassuringly the European Commission's Report also supports this view, making the additional point that the language used in the EC Directive permits flexibility at the national level in applying the granting criteria.[96]

However, the fact of the policy position should not be taken to mean that there will be an ever-increasing surge of patent activity over inventions concerning genetic material. Here a contrast can be drawn between the positions taken within the Tripartite papers. The Nuffield Discussion Paper and Guidelines consider it likely that there will be a decrease in gene patents as levels of understanding over genetic information increase. The Commission Report does not make any direct reference to this likelihood. However the Report does seem to proceed upon an assumption that there will be an increase in the levels of gene patenting activity. Thus the Commission's Report sets out comparators between Europe, the USA and Japan in terms of both bioscience investment and patent activity. The implication is that patenting will stimulate innovation in this field and that Europe must be in a position to keep up with its leading competitors. The Report does not, however, discuss the extent to which patents will be available in the context of the ability of inventions to meet the granting criteria, which is arguably the more important issue.

---

[93] The discussion of these issues is taken from the perspective of the Department of Health as receiver, or potential recipient, of products and processes any patent over which is not held by the Department, NHS or any of the hubs. These are the issues, therefore, which could form the basis of a challenge to the patent or found the basis for negotiations over licences etc.

[94] A more detailed discussion can be found in Section One-C.

[95] See Appendix Nine for the Patent Office's forthright statement on the patentability of human stem cells.

[96] It has, however, to be noted that, since the Directive is EC law, its interpretation can be the subject of a reference for interpretation from the courts of any EC State to the European Court of Justice in Luxembourg.

In contrast this is dealt with by both Nuffield Discussion Paper and the UKPO Guidelines. Between them there is a certain synergy[97]. The Nuffield Discussion Paper presents a specific policy stance that patents over genetic inventions should be the exception rather than the norm, the paper making specific reference to the patenting of DNA sequences. The Patent Office Guidelines state that developments in the scientific understanding of genes means increasingly that the level of inventive step (or non-obviousness) necessary for a patent grant is unlikely to be met in many instances and therefore even where there might be a *de facto* invention, *de jure* it will not be patentable (the specific instances where the guidelines state that this is most likely to happen are identified below when looking at particular categories of patentable subject-matter). In the Commission's Report the issue is one of whether the material concerned is capable of being used on an industrial basis and it is this industrial capacity requirement which, the Report argues, renders discoveries unpatentable.

The inability to meet the granting criteria could result in gene patents becoming the exceptions that Nuffield Discussion Paper advocates without necessitating any new policy statement. It remains to be seen how far Patent Office granting practice provides the result which Nuffield recommends.

One point of caution arises regarding any elision of the positions of Nuffield and the Patent Office. The former appears to indicate that any overarching presumption should favour exclusion from grant where there is a doubt over the validity of the application, whereas the latter operates on a presumption of inclusion, in other words that any doubt over validity will operate in favour of the applicant, since the issue can be more intensively investigated and tested in the courts after grant[98].

It is the view of the Project Team that if the Department of Health were to state a particular preference then the Nuffield position is the more appropriate. Patent offices do not have an examination procedure in order to grant patents, though sometimes they like to say so to customers. They are there to see that legal requirements are satisfied.

Recommended DH Position

Priority for developing DH policy and practice - High

In Section One the Project Team drew attention to specific issues relating to different types of genetic innovation. In so doing we focused on those genetic innovations which have caused particular problems, such as ESTs or research tools. However, advances in bioscience make it increasingly difficult to establish and maintain concrete distinctions between types of genetic innovation. Because of this we recommend that the Department:

[97] The Nuffield Council on Bioethics has not publicly commented on the Guidelines so we do not know if they alleviate the concerns set out in the Discussion paper. As will be noted later in this Report, the most readily identifiable point of convergence between Nuffield and the Guidelines could come in respect of the interpretation and application of the industrial application/utility requirement where similar language is used by the UKPO and the USPTO. The results may still differ. Nuffield has strongly criticised the US approach.

[98] Or in the case of a European Patent in EPO opposition proceedings.

(i) should focus its attention not on the type of material being patented but on the way in which the UK Patent Office applies the new guidelines on applications involving biological material, and on equivalent decisions in the EPO; and endorse the position taken by the Nuffield Council regarding the application of the granting criteria.

In terms of adopting a general position with regard to the patenting of genetic material per se, we would suggest:

(ii) support in principle for the UK position and the adoption of a process to monitor the practice of Patent Office in order to ensure appropriate levels of grant are attained and maintained.

The tone of the Guidelines would indicate that the UK Patent Office is aware of criticisms made with regard to past patenting practice and is paying heed to them. The actual results will take time to establish. However, whilst there appears to be possible convergence at the UK level, it is not possible to state that there will be parity between the policy suggested by Nuffield, the practice framework set out by the Guidelines and the policy and practice of (a) the European Patent Office, (b) the practice demanded by the European Commission and (c) non-European granting offices, most notably the USPTO. If it is accepted that the UK position is, for want of a better phrase, 'as good as it can get' in the current patent law environment and that it merits serving as a model, then action will need to be taken to protect and publicise this position[99]. We suggest that:

(iii) this issue should be taken up by whoever is charged with responsibility for the Department of Health IPR policy in conjunction with other relevant bodies such as the UK Patent Office. Due attention should be given to the work of other monitoring bodies such as the Human Genetics Commission and Intellectual Property Advisory Group.

If the Department wishes to adopt an active precautionary stance, it is worth noting that Canada[100], for example, has taken a harder line than the United States, the EU, the EPO and the UK over the patenting of inventions involving genetic material[101]. However, it is the view of the Project Team that it is easier to negotiate for change within the existing legal framework than to attempt to change the law altogether. In the absence of a UK decision comparable to that provided by the Canadian Supreme Court we recommend that:

---

[99] It is possible, for example, that whilst the UK Patent Office might decline to award a patent over an invention which fails to show an inventive step, other granting offices might take the view that where the commercial utility or industrial application of that invention is considerable then a grant is nonetheless justifiable.

[100] In general terms the Canadian Biotechnology Advisory Committee Steering Group's *Patenting of Higher Life Forms and Related Issues - Interim Report* (www.cbac.gc.ca/documents/ip_biotech_en.pdf) deals comprehensively with all aspects of gene patenting. The Report recognises that scientific developments puts pressure on legal frameworks and that there is a need to ensure that the science does not drive any adjustment of those frameworks without appropriate reflection. The Report recognises that used appropriately patents can serve to benefit society greatly but that the *status quo* does not protect against any risks which could result from gene patenting. The view is that gene patents require special treatment within the patent system and that the Federal Government and Intellectual Property Offices have a key role to play in ensuring that this is achieved. Key in all this is the ability of Canada to continue to play a leading role in gene research and for Canadians to reap the healthcare rewards. There is a recognition of the various international obligations which exist, but the report states that whilst Canada must be mindful of these obligations, its own internal interests, through the use of safeguards and transparency, are central.

[101] The Canadian Supreme Court, in December 2002, ruled that the Harvard Onco-Mouse patent (which related to mouse eggs, and the resulting mice, injected with a cancer promoting onco-gene) was not permitted under the Canadian Patent Act 1985, as higher life forms did not constitute either a manufacture or a composition of matter within the meaning of invention within s.2 of the Patent Act. This ruling is clearly at odds with that adopted by the US, European and UK Patent Offices. Notwithstanding the existing jurisprudence of these offices, the Canadian decision is an important one, not least, as it signals the role of courts in determining the *actual* scope of patentable subject-matter. As to date there has been no UK litigation relating to the patentability of higher life forms, the Supreme Court could provide an important, albeit non-binding, precedent. The ruling can be found at www.lexum.umontreal.ca/csc-scc/en/rec/html/harvard.en.html
The situation regarding the Myriad Genetics patents over BRCA1 and 2 and the Ottawa government is discussed in Appendix Seven.

(iv) the Department should take a cautiously pro-patenting stance, that position being founded on a robust application of patent granting criteria (as outlined earlier in this document).

The burden of proof should rest with the applicant. Where that burden of proof is not discharged no grant should result.

If it is agreed that there is in principle no fundamental objection to patents being granted over inventions concerning genetic material, then logically, the primary issue is the capacity of such inventions to meet the requisite threshold for protection. It is at this point that it becomes difficult (a) to stick rigidly to specific classifications of types of inventions and (b) to draw direct comparisons between the tripartite papers as the terminology and focus differs in all three. It is also recognised that there are other types of genetic invention which may not be specifically identified in the headings below. This does not mean that the underlying principle is not applicable, but rather that an extension of the principle may be required. In respect of each it can be seen that the issue is whether the appropriate level of novelty, inventive step and industrial application has been met. Because of this the Project Team considers it appropriate at this juncture to provide some detail of the Patent Office Guidelines on the granting criteria[102].

(b) The granting criteria[103]

i Novelty

The general patent law requirement is that an invention must not itself have been made previously available prior to the patent application being filed. The test is a comparison between the invention claimed and material comprising the state of the art. Where genetic information has been isolated from a natural source for the first time then it will not lack novelty simply because it previously existed in nature. The key factor is that it must be a *first* isolation. Where it is argued that the claimed gene is not novel then the issue for consideration by the Patent Office is whether the information previously existing was sufficient to be considered *an enabling disclosure*[104].

The Guidelines affirm that a patent over a process will extend to the product produced by that process or method. In respect of gene sequences the Guidelines state that relevance must be given to the *context* within which the sequence has been published, in order to assess whether an earlier publication will destroy novelty of the sequence now being claimed. Where the prior publication did not cover the sequence in the context which is the subject-matter of the patent, (for example if a new application has been identified), then a claim to the sequence for that application is likely to be held novel.

ii Inventive step

Inventive step is shown where it would not have been obvious to another skilled in the art to follow a particular research route. The function of the criterion is to prevent rights being granted over low level or merely incremental innovation. The Guidelines identify a number of concepts which relate to inventive step. These involve circumstances where the goal is

[102] These are discussed in more detail in Appendix Six.

[103] More information on the granting criteria can be found in Appendix One.

[104] This means that sufficient information about the gene must have been made previously available to enable a person skilled in the art to reproduce the invention claimed in the application.

known, where the invention fulfils a need, and where the invention is an obvious replacement. In addition they provide information about how to conceive the person skilled in the art against whose notional skill and knowledge the question whether the invention is obvious or not is tested.

The Guidelines note that the inventiveness of any claimed subject-matter will be determined by the context within which the decision to pursue a line of inquiry was taken. This could involve many different considerations. Where a goal is known but the route to that goal is not known, a key issue is whether the result would have been arrived at if others working in that area had merely carried on with their routine research and development. If this would have happened then, in the absence of any unexpected leap forward leading to the development, it is likely that this would not meet the inventive step requirement. Equally where all the steps leading up to achieving a particular goal are known then following these steps cannot contribute to any finding of inventive step. Everything will depend on how the additional step is characterised. Where there is a reasonable expectation of success then the fact of attempting may not be sufficient to demonstrate that it was inventive to try. The main exception to this arises where the field of study is so new that the extent of certainty over the likelihood of success is necessarily curbed. In this instance it may be possible to show that deciding to carry out the research despite the uncertainty of outcome can involve an inventive step.

The most important statement made in the Guidelines is that, as developments in bioscience continue, it will become increasingly difficult to demonstrate an inventive step[105].

(Obvious research developments are not patentable as they fail for a lack of contribution to the technology. As indicated in Section One-D (Use of Other Intellectual Property Rights), there is the possibility of a utility model right being available in the future which will protect low level, incremental innovation. However, under the current text proposed by the European Commission, such protection will not be available to low level inventions involving biological material[106].)

iii Industrial application

All patentable inventions must be capable of industrial application. This means that the invention must be a completed form (and require no further development) and therefore capable of being used industrially. The Guidelines focus primarily on the identification of genetic sequences. They draw a distinction between inventions which reside in a sequence or partial sequence of a *gene* and inventions which reside within a sequence or partial sequence

[105] This mirrors the views of many patent practitioners. Andrew Sheard stated at a meeting of the Human Genetics Commission in March 2002 and at a conference on Law and Genetics held in November 2002, that in his view the concerns expressed over a proliferation of gene patents will not be realised as the majority of the applications will fail for a lack of inventiveness.

[106] Article 4 of the proposal for a European Parliament and Council Directive approximating the legal arrangements for the protection of inventions by utility model (COM(1999)309 final) states "Utility models shall not be granted in respect of ... (b) inventions relating to biological material; (c) inventions relating to chemical or pharmaceutical substances or processes." Recital 13 says that the reason for these exclusions is to "meet the needs of the industries concerned." No further explanation is given.

of a *protein.* Where the invention resides in a sequence or partial sequence of a gene, then paragraph 6 of Schedule A2 to the 1977 Act also requires that the application must disclose the industrial application of the gene itself. This appears to mean that the applicant must disclose both the industrial application of the sequence or partial sequence within which the invention resides *and* the industrial application of the gene from which the sequence comes. A two-fold disclosure is, therefore, required. This additional disclosure requirement does not apply to applications filed which concern a sequence or partial sequence of a protein. Here the simple test is whether the invention involving the sequence or partial sequence is capable of industrial application. There is no requirement to additionally demonstrate an industrial application for the protein itself. The capacity for industrial applicability is assessed by reference to whether it is specific, substantial and credible.

Both the US and the European systems now require a gene-related patent application to disclose a function or industrial application which is *specific, substantial and credible*. In using this terminology the Guidelines reflect the USPTO Guidelines for examination adopted in January 2001[107]. Whilst the USPTO Guidelines do not have any official status under the EPC, the language used mirrors the practice of the UK Office. This approach has also been followed by the EPO in recent decisions. The Guidelines do not discuss what would constitute a specific, substantial and credible use and indeed they specifically recognise that this approach is one which has yet to be tested in the courts. The Guidelines do not discuss whether the patent application must only refer to one function or application, which must be specific, substantive and credible, of the claimed genetic material; or whether it is possible to claim a number of functions, only one of which must be shown to be specific, substantive and credible.

iv Sufficiency of disclosure and enabling disclosure

The Guidelines discuss the related concepts of sufficiency of disclosure and the requirement that the description of the invention must support the claims made. These issues are important as they do much to determine the scope of the grant made.

An applicant is required to both provide a technical description of the invention and disclose the invention, and the claims relating to it, in sufficient detail to enable a person skilled in the art to perform it. The level of sufficiency of the disclosure can vary and, in some instances, it has been accepted that not every product or process covered by the invention has to be disclosed[108]. However, the description, by providing the relevant technical information, must

---

[107] The operation of this concept in practice was explained by Karen Hauda, from the Office of Legislative & International Affairs within the USPTO, at a conference held in Thailand in September 2002. Utility is demonstrated via a 'real world' use. Any uses which require further research, for example, are not 'real world' uses. Equally a "throw away" utility (e.g. not realistic) or a utility which is not sufficiently specific will fail to meet the threshold. The example she gave was of a claim to the use of transgenic mice for snake food. The claim is neither specific (any type of mouse and not only the transgenic mouse could serve as snake food) nor is it substantial (it is commercially unrealistic, not 'real world' as a trangenic mouse would cost far more than a non transgenic mouse). Where the claim to the transgenic mouse specifically identified the generation of a particular protein profile which was specifically directed to enhancing animal food then the test for specific and substantial utility will probably be met. With regard to the utility being credible she indicated that there is a presumption that the use stated is a credible one *unless* "the logic underlying the asserted use is seriously flawed or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion".

[108] *Biogen v Medeva* [1997] RPC 1 at 48 (HL)

provide for support for the territory being claimed by the applicant. As can be seen the requirements can overlap. The Guidelines provide two examples of the balancing act which has to be achieved between rewarding the inventor and giving rights where no reward is due. Where a broad and speculative claim is made then it might not be clear whether any objection should be on the grounds of incomplete disclosure or lack of support within the description. Here the general practice would be that the application should fail for lack of support. Where the description is clearly insufficient then the objection should be on grounds of lack of sufficiency. This is primarily a conundrum for the application process as lack of support is not a grounds for revocation post-grant.

In a key paragraph, the Guidelines state that *care is needed not to stifle further research and healthy competition by allowing the first person who had found a way of achieving an obviously desirable goal to monopolise every other way of doing so.* This constitutes a welcome acknowledgement of a matter first emphasised for biotechnology by the Court of Appeal in *Genentech v. Wellcome*[109]. There is always a need to maintain a proper public interest balance between rewarding dramatically new initiatives in new fields of technology and preventing over-extensive monopolies.

(c) Specific issues relating to patentable subject-matter[110]

i Research tools[111]

Should patents be available for research tools? It is important first to distinguish between the two things which are sometimes labelled research tools. The first comprises distinct devices used generally in experimentation. The second relates to the identification of specific things (ESTs, SNPs, Genes, receptors, etc) which look promising intermediates for practical results but those results are not part of the invention. In respect of the first type of 'research tool', which act as a 'machine', these can be of immense value and are currently patentable, for example the polymerase chain reaction (PCR). In addition, the identification of these tools does require intellectual endeavour which might warrant the granting of a patent. However, it is recognised that there is an argument that, notwithstanding their value, they are basic tools, and any person operating in a given area will need to use that applicable research tool which does provide the rights holder with a virtually absolute monopoly. This needs to be considered when deciding if a grant is justified. An additional issue is the fact that there are only a limited number of research tools and granting monopoly rights might not be wholly appropriate.

In respect of the second group, ESTs etc, these are partial gene sequences, which are used to identify genes or look at what genes are expressed under certain conditions. ESTs are

---

[109] *Genentech v Wellcome [1989] RPC 147 (CA).* This case is central to understanding the concepts of inventiveness and contribution in UK Patent Law

[110] In identifying these we have been greatly assisted by the Nuffield Discussion Paper. This list is non-exhaustive. It should be recognised that as the science develop new categories of genetic material will be identified which may fall outside the Nuffield groupings. It is possible that different patenting issues will arise in respect of these and these will need to be considered.

[111] "Research tools" is not a term of art in patent law. No legal consequences flow from designating a particular discovery as a research tool. Research tools are not categorically excluded from patent protection (except insofar as they lack patentable utility), nor is the use of patented inventions in research categorically exempted from infringement liability.

relatively easy to sequence, such sequencing requiring only a small inventive step. It appears to be general policy that ESTs and sub-genes are not patentable as they cannot be regarded as inventions – they lack both inventiveness and industrial application. However, the situation does not appear so clear in respect of SNPs. On the face of it, it would seem that the same reasoning ought to apply, save in exceptional cases. However it has proved less easy to obtain a definite statement that SNPs are normally unpatentable and there appears to be a presumption operating in patent circles that they are patentable[112].

The Nuffield Discussion Paper looks at the patentability of research tools (and they specifically identify ESTs and SNPs as two types of research tool) in some depth. It is noted that there is considerable patenting activity in respect of research tools, not least because these are so valuable in bioscience research. The concern raised by Nuffield is that "the granting of patents relating to DNA sequences for use in research...[provides] a level of protection which...is not reflected in the extent of the contribution." The recommendation is that the granting of patents over research tools should be "discouraged" primarily on the grounds that such applications will lack to requisite utility. The Paper also urges the EPO, USPTO and Japanese Patent Offices to work together to ensure that there is parity of practice in the application of the utility criterion.

The Nuffield Council discussion on ESTs notes that whilst there have been some patents granted on ESTs in the past, these have been few and it is unlikely that any more will be granted as they will not be able to meet the granting criteria. In respect of SNPs, Nuffield concurs that the same types of concerns as arise in respect of ESTs can apply to SNPs. The Nuffield Discussion Paper does not make any specific recommendation or statement regarding the patentability of SNPs but it does note that there is a possibility that patent applications involving SNPs will be made, most likely in the US. The Paper goes on to state that whilst DNA sequences (which presumably includes ESTs and SNPs) might be capable of meeting the novelty requirement, there is a more serious issue relating to inventive step and industrial application. The Paper recommends that the use of computational databases renders it difficult to prove an inventive step and that "the standard of credibility required for a claimed utility needs to be set higher than the mere theoretical possibility of this utility"; some positive evidence that the DNA sequence has the claimed utility should be required. The Paper was primarily addressing the US Guidelines, but given the language used in the UKPO Guidelines it might be apposite to apply the views to both.

The Commission's Report only contains an indirect reference to research tools (its refers specifically to ESTs and SNPs but does not call them research tools as such) and this reference does not relate to the patentability of these but merely refers to a need to consider the scope of the patent conferred. The clear inference is that the Commission regard ESTs *and* SNPs as patentable subject-matter. The only issue relating to ESTs and SNPs which the Commission thinks could be a cause for concern is the scope of protection conferred over them by a patent (this is detailed below). The UKPO Guidelines do not refer to research

[112] The USPTO has granted patents on around 20 SNPs to date. Furthermore, Genetic Technologies of Melbourne owns a slew of patents, registered in the name of GeneType of Switzerland, covering the very SNP analysis of the non-coding regions of genes.

tools as such. It would appear therefore that the issue is simply whether these can be shown to meet the granting criteria and in particular the utility requirement.

Recommended DH Position

Priority for developing DH policy and practice - High

Given the fast pace of genomic innovation we recommend that the Department of Health should not adopt a hard and fast rule regarding the patentability of research tools.

There is a strongly held view in many circles, including the UKPO, that ESTs do not meet the requisite level of inventiveness and industrial application for the reasons identified by the Nuffield Council and are therefore not patentable. In general the Project Team suggest that the Department of Health should urge the Patent Office to adopt the same approach to SNPs as it does for ESTs. However, it is recognised that SNPs can be used in a number of inventive ways and the Project Team recommend supporting the patenting of SNPs where a clear inventive step has been demonstrated.

ii Use of genetic information for diagnosis and in diagnostic tests[113]

The issue of the patentability of diagnostic tests is one raised in the Nuffield Discussion Paper, however it is not raised as an issue as such in either the Commission's Report or the Guidelines.

The concerns raised by Nuffield relate to the use of DNA sequences for the purposes of diagnosis. Clearly there is great value in this usage, however, Nuffield contends that once a gene has been identified together with its relevance to a particular disease or trait then it become obvious to use that gene for the purposes of testing for that disease or trait. The paper appears to accept that there is a possible argument for holding the isolation of the BRCA1 gene to be inventive (although the paper does not subscribe to this view), but it argues that in the modern biotech environment it is less plausible to regard the isolation of a gene and identification of its association with a particular disease as an invention. Nuffield recommends, therefore, that any *in silico* identification and characterisation of DNA sequence be held unpatentable as lacking an inventive step. Nuffield also addresses this issue from a public policy basis and convincingly argues that the incentive of a patent might assist in the development of more, and better, tests. However, to ensure that the freedom to "invent around" i.e. find improvements and alternatives outside the patent claims is retained Nuffield recommends that any patent granted over the gene should be restricted to that use, and *that use only*. This would serve to mitigate any blocking of third party research. In the event of an inappropriate restriction on access to the gene, Nuffield recommends the use of compulsory licensing.

A note of caution, however, needs to be added regarding an absolutist approach to the patentability of uses of genetic information for diagnostic purposes (or indeed for gene therapy). If there is an overly strict policy, rendering patent protection unobtainable, the consequence could be that there would be no incentive for companies to carry out the research development necessary to develop the evidently useful application. Equally, too

[113] A more detailed discussion can be found in Section One-C.

liberal a policy, which would permit patents for any or all uses could result in patent thickets making access to the developed material difficult.

Recommended DH Position

Priority for developing DH policy and practice - High

We recommend that the Department of Health supports, in principle, the Nuffield position, but this is subject to the caveats mentioned above and those relating to the practicalities of obtaining a compulsory licence. The Department should actively monitor the granting practice of the EPO and UK Patent Office with a view ultimately to ensuring that, irrespective of the commercial value of the use of genetic information in testing, grants are not made to non-inventive applications.

iii Gene therapy

The issue of gene therapy and the implications for the development of gene therapies if the genes involved have been patented has not been previously discussed in this Project. However, the concerns raised in the Nuffield Discussion Paper are recognised as legitimate and necessitate a comment here. Primarily the argument is the same as that already set down in respect of diagnostic tests. If a patent is granted over a gene sequence and that sequence claims a potential application in a therapeutic context the patent could then hinder or restrict the development by others of that therapy or access to it once developed. The Nuffield Discussion Paper reaches the same conclusion as for diagnostic tests. It argues that once an association has been made between a gene and a disease then it becomes obvious to use that gene for therapeutic purposes relating to that disease. We would reiterate our concerns voiced above in respect of diagnostics.

The Commission's Report does not discuss gene therapy in general terms as such. It simply makes reference to the exclusion of germ-line gene therapy on the basis of the need to respect the "physical integrity of descendants". It does not discuss somatic gene therapy. As the Commission does not make any reference it is not surprising that the Guidelines equally make no reference as such. Again how far patents should be available will be an issue relating to the interpretation and application of the granting criteria.

Recommended DH Position

Priority for developing DH policy and practice - High

We recommend that the Department of Health supports the Nuffield position, subject to the caveat outlined in respect of diagnostics, and actively monitors the granting practice of the EPO and UK Patent Office to ensure that, irrespective of the commercial value of the use of genetic information in gene therapies, grants are not made to non-inventive applications.

iv Therapeutic proteins [114]

Again this is an issue raised in the Nuffield Discussion Paper. Therapeutic proteins can be used to alleviate a particular genetic disorder and as such they are clearly valuable. As with diagnostic tests there is an issue about ensuring access to the patented material for third parties so that they can use the genetic information in further research and development. It is the view of Nuffield that this problem can be resolved by limiting the scope of the claims.

There is no mention made of therapeutic proteins in the Commission's Report. The issue is clearly one relating to the application of the granting criteria. Likewise the Guidelines also do not mention therapeutic proteins as such, and it can be assumed therefore that the issue for the Patent Office will be whether it meets the granting criteria. The Guidelines do provide guidance on scope and this will be discussed below.

Recommended DH Position

Priority for developing DH policy and practice - High

We recommend that the Department of Health support the patenting of therapeutic proteins where a new and inventive application has been demonstrated; that it actively monitors the granting practice of the EPO and UK Patent Office to ensure that, irrespective of the commercial value of therapeutic proteins, grants are not made to non-inventive applications; and that, in concurrence with Nuffield, any patents granted over therapeutic proteins should be limited in their scope. The general issues relating to scope will be dealt with below under (d).

v Stem cells and cell lines[115]

Recent advances in human stem cells have shown a promise for future cures, especially in the area of degenerative diseases such as Parkinsons. The European Commission has stated that the granting of patents for stem cells and cell lines obtained from them may be one way of encouraging companies to carry out research and development in this field to ensure the potential is fulfilled. Furthermore, recent advances in the use of adult bone marrow stem cells may reduce the need for embryonic stem cells, which is ethically a contentious issue, as human embryos have to be used to produce them. In addition, the prospect of being able to devise cells created by the technique known as parthenogenesis[116] appears to open up new and as yet unknown paths which may well cut short the controversy about therapeutic cloning[117].

---

[114] Therapeutic proteins are often high-value complex proteins with high costs of production. They can be used in a variety of applications including surgery, trauma, cancer therapy, cosmetic reconstruction, and chronic diseases. They include structural proteins such as human serum albumen, blood products such as Factor IX, complex proteins including interferon and EPO and protein vaccines. The demand for therapeutic proteins is growing rapidly.

[115] A more detailed discussion can be found in Appendix Six.

[116] Parthenogenesis is defined as the development of an ovule without there having been any fertilisation by a spermatozoid. Parthenogenesis is uniparental sexual reproduction.

[117] There are discussions at the UN with regard to the banning of all aspects of human cloning, whether reproductive or therapeutic. However, due to disagreements between the US and Europe, discussions have been postponed until the end of 2003.

The Commission states that there is a need to avoid broad patents in this area and that applications should relate to precisely described industrial applications, and not to a wide range of potential applications which cannot be described.

The issues of the patentability of human stem cells, and the scope of any patent granted over them are the only matter which the Commission's Report identifies for further consideration. It is clear from the context within which the recommendation for further deliberation is made that the Commission considers that the therapeutic value of stem cells will be more fully realised if patent protection is available. It is less easy to discern a Commission view in respect of the scope.

In March 2003, the European Parliament voted to ban all stem cell research - whilst this has to be approved by all member states before it can be implemented (and as the UK in particular is at the forefront of this research it is unlikely to have UK support), it is worth noting that the views expressed by the Commission in its Report clearly are at variance with those of the European Parliament.

In April 2003, the UK Patent Office published a practice notice (see Appendix Nine), which sets out the general practice of the Patent Office with regard to the patentability of inventions involving human stem cells. The Practice Notice identifies three categories of inventions which could involve human stem cells:

(i) *Processes for obtaining stem cells from human embryos*. These will not be patentable on the basis of Paragraph 3(d) of Schedule A2 to the Patents Act 1977 which states that uses of human embryos for industrial or commercial purposes are not patentable inventions.

(ii) *Human totipotent cells*. As these are capable of developing into an entire human body they are not patentable by virtue of Paragraph 3(a) of Schedule A2 to the Patents Act 1977 which excludes the human body at the various stages of its formation and development from patentability.

(iii) *Human embryonic pluripotent stem cells*. As these are not capable of developing into an entire human body these are not excluded under Paragraph 3(a) and, therefore, provided that the normal requirements for patentability have been met, these are patentable. The Practice Notice makes it clear that the primary justification for permitting inventions involving human embryonic pluripotent stem cells is because of the immense potential they have for providing treatments for serious diseases. In the view of the Patent Office, providing patent protection for this type of stem cell would not contravene either public policy or morality.

Recommended DH Position

Priority for developing DH policy and practice - High

In monitoring developments over the patenting of stem cell inventions, the Department should adopt and support the cautious approach already indicated above for related matters and it should monitor the practice of the European Patent Office (which will not be affected by the April 2003 Practice Notice) and the UK Patent Office (which will be). It will be particularly important to disentangle objections to the pursuit of any experimentation involving embryonic stem-cells, where arguably the public policy decision should be left to bodies such as the Human Fertilisation and Embryology Authority which are already charged with making decisions about the legal/ethical status of living tissue etc, from objections to offering the stimulus to medical research which is the objective of the patent system. We also recommend that the Department of Health should liaise with the HFEA to ensure a common approach. It should take full account of work on stem cells and cell lines that is being undertaken by groups such as the Human Genetics Commission.

(d) Scope of the claims [118]

The issues here is how much patent holders can claim to be their inventions and therefore covered by the patent. The claims in a patent specification identify the contribution made by the inventor and determine the scope of the protection conveyed by a patent. Infringement is assessed by reference to the claims.

The Nuffield Discussion Paper raises some serious concerns over the way in which claims to biotechnology patents have a) been drafted and b) interpreted, giving rise to situations where it is felt that an overly broad monopoly has been granted. The view expressed is that many patent systems have been too generous in the scope of rights granted and that this practice, together with the likely decrease in inventive activity as genetic knowledge increases, has encouraged the seeking of broad patents as early as possible.

The Nuffield Discussion Paper recognises that the effect of its recommendations in respect of specific types of genetic invention will be to reduce the number of patents granted. If these recommendations are not taken up then even greater weight should be given to their recommendation that the scope should also be limited. Nuffield would prefer to see both a reduction in patents granted and a restriction on the scope of these patents. Their recommendation is that the three main granting offices (EPO, USPTO and JPO) should work together to ensure parity in respect of the scope of rights granted. In terms of the form of this parity, Nuffield recommends that consideration should be given to "limiting the scope of product patents that assert rights over naturally occurring DNA sequences to the uses referred to in the patent claims, where the grounds for inventiveness concern the use of the sequence only and not the derivation or elucidation of the sequence itself." The restriction

[118] A more detailed discussion can be found in Section One-B. Sir John Enderby speaking about the Report of the Royal Society published in April 2003 said that "The current intellectual property system needs to be tightened for the sake of both science and society." Researchers should be rewarded for the contribution that they make and the system should provide incentives for carrying out research and development. However some patents are slipping through the net, which give some researchers far greater reward than they actually deserve. " This affects all of us. If patents are granted which are too broad in scope, they block other researchers from carrying out related work and so hold up the development of medicines and treatments. This is tremendously bad for science, but the ultimate losers are the patients who wait longer for beneficial drugs to reach their hospitals and pharmacies."

to the uses referred to in the application presumably means demonstrable, rather than theoretical, uses.

The Commission's Report also discusses the issue of scope, but purely in the context of elements isolated from the human body. The Report states that the granting criteria, and in particular the requirement of sufficiency of disclosure and support, should be enough to enable an examiner to reject any application the claims of which are too broad. As already stated, particular consideration needs to be given to the scope of claims relating to inventions involving DNA sequences, proteins derived from those sequences, ESTs and SNPs.

The Guidelines also provide useful information as to how the scope of claims is to be interpreted. They remind the reader that the function of the claims is to determine the width of the claimed invention. The Guidelines make clear that the issue is primarily one of support within the claims. Where the information contained within the claims does not support an assertion that a particular activity falls within those claims then the alleged infringing activity is likely to fall outside the scope of the patent. The Guidelines also make the point that if the claims do not describe the invention in a sufficient and supported manner it is unlikely that the requirement of industrial application of the invention will be met.

The Guidelines are also the only one of the three publications to discuss "reach through" claims (RTC). These are claims which seek to either prevent further research or claim material produced as a result of that research. There are three issues to be considered here:

The first is where the claims reach through, as in the Myriad Genetics' patents over BRCA and Human Genetic Sciences' patent over CCR5, to any use of the patented 'invention' – a breadth of claims argument.

The second is where the patented genetic material is placed into an alternative host for a specific purpose. Article 8 and 9 of the EC Biotechnology Directive make it clear that the material into which the patented invention has been placed now becomes subject to the patent. There is, however, a distinction between the two Articles. Article 9 requires the patented material to perform its patented function within the new host material whereas Article 8 merely requires the new host material to possess the specific characteristics of the patented material. There is concern over the impact of this where the incorporated material does not have any material effect on the new host. This is something which patent lawyers are looking at very carefully and it is again an issue of the contribution that invention makes to the material in which it is placed (although the Directive makes no reference, in either the Recitals or the Articles, to any contribution as such). If concern over extending rights to material within which the patented material does little other than merely exist is founded, then one solution could be to beef up the function requirement. At present Article 9 simply states that the patented material has to perform its function, it does not states what effect that function must have on the new host material - in other words it does not say whether the function has to make a significant or non-significant contribution. The current wording would indicate that minimal functional effect within the new host would be sufficient to extend the patent right Requiring the function to be significant to the technical working of the new host could be sufficient to minimise any potential abuse of these provisions.

The third is where a licence permits the patent holder to claim rights over anything which results from the use of the patented material, not necessarily only where the resulting product comprises the patent material. This is an issue for contract negotiation and up to the parties to the negotiations to decide how robust they wish to be.

The spectre of so-called "reach through" claims appears whenever it can be said that a patentee's contribution to a stage in research is being extended to cover later advances made by others.[119] In obvious cases, it is unlikely that such claims will be allowed. Any that are granted will not survive a later invalidity attack. The patentees of PCR would not have been allowed to claim an exclusive right over all the inventions which used their invention to amplify genetic samples. The troubling cases are those where the connection between the earlier and the later work has greater continuity.

The situation raises that classic dilemma in patent law of deciding which instances warrant giving both contributors patents in a final product or procedure. When should it be found that each has made a significant intellectual contribution to that outcome and should therefore have a patent from which a share can be claimed in any exploitation? A balanced answer will only emerge if the same factors as were mentioned previously are given serious attention: the need first to show industrial application, then inventive step, in the particular circumstances; there should be a limitation of claims to demonstrated uses unless there really is a general principle uncovered which warrants a claim to all consequent deployments of the principle.

In a short paragraph the Guidelines simply state that speculative claims will fail unless they are specifically defined. In other words a claim to a speculative use will not be allowed because it is not supported by the information provided in the patent.

Recommended DH Position

Priority for developing DH policy and practice - High

We recommend that the Department of Health actively monitors the granting practice of the EPO and UK Patent Office so as to ensure that inappropriately broad patents are not granted.

2 Access issues

(a) Experimental/research use

The European exception for experimental purposes concerns its restriction to research which builds upon the knowledge provided by the patent, and aims to discover something unknown about the subject-matter of the patent or to test a hypothesis about it.[120] This does not cover any use without a licence of a patented research tool or medium which is needed for the research but is not being experimented upon for its own sake. The classic example in genetics has been provided by Hoffmann-La Roche's patent on PCR, needed for the

[119] Claims to substances, discussed under the previous head, may equally be regarded as RTCs.
[120] See Aldous L.J., Auchinloss v. Agricultural & Veterinary Supplies [1999] R.P.C. 397 at 406.

amplification of genetic material. Work to provide an improved PCR would count as an experimental use, but not work which simply used PCR as a standard procedural step. Of course the result may be that, because of general demand, for the patented material the patentee will earn very considerable royalties and other licence fees. The PCR example also serves to demonstrate the value in having model agreement, or *de facto* agreement in the sense that its use is not mandatory but it ends up being used by all Trusts/hubs.

The Nuffield Discussion Paper recommends that the research exemption be clarified within Europe and the US. It also recommends that companies should work together to extend the concept of the exemption through-out the industry. The Paper does not discuss the issues raised by the Project Team above.

The Commission's Report makes a reference to the research exemption only in passing when discussing the Myriad patent. The Report simply acknowledges that the issue of research access has been raised by others and states that the EC Directive is not intended to "call into question the freedom of research in Europe". No attempt is made to address the issue of what does constitute research use.

As research use is a post-grant issue relating to potential infringement, the UKPO Guidelines make no reference to it

Recommended DH Position

Priority for developing DH policy and practice - High

We recommend that the Department should support the work currently being undertaken to clarify the concept of research use at the UK, EU, and International levels It should seek specific clarification with regard to use in clinical trials It should adopt its own definition of research use and utilises this definition when licensing in patented inventions from outside. We recommend that this definition be sufficiently flexible to give the Department room for manoeuvre within negotiations since different approaches likely to be taken towards research use by SMEs/Universities and multi-national companies. If, as has been suggested[121], the Department of Health enters into a partnership arrangement with the patent holder then it would be feasible to describe the expectations of that partnership and include a definition of research use.

It is feasible to incorporate terms relating use in clinical trials within this definition. A patent holder may of course object to inclusion of the definition, or may seek amendment of it during negotiations. But once it is agreed, it will govern the arrangement between licensor and the Department.

The Department of Health should also consider offering advice on good practice concerning the use of patented material and procedures in the course of research conducted by or in relation to its services.

(b) Licensing (in and out)

With regard to the issue of licensing the Project Team has focused on both the specific and general licensing issues including, but not limited to, compulsory licensing. This approach can be contrasted to the Nuffield Council which only discusses the issue of compulsory licensing

[121] See above page 45.

and not within the context of the recent structural changes within the DH/NHS. Neither the Patent Office Guidelines nor the Commission's Report deal with this issue at all as they are only concerned with the grant, not use of patents. In addition the Project Team has looked at the particular problems which have arisen in respect of licensing in gene testing kits and at the status of clinical trials *vis-à-vis* experimental use.

Our starting point is the recently published NHS guidance on licensing out[122]. Notwithstanding the level of involvement which the Department of Health might wish to have in terms of directing intellectual property policy and management, it is clear from the discussions held with those involved in the hubs that they, at present, expect to have control over licensing out and that some also expect a degree of involvement in licensing in. If this remains the position then the Department will probably have to draw a distinction between licensing in and licensing out taking into account any overarching public health interests. However, there are some issues which cause concern.

The first is the level of negotiating power which any individual hub can wield. Clearly the Department of Health as a government department carries greater clout than an individual hub and there is an argument that for licensing in, at least, this should be undertaken centrally. There is also an issue about the level of expertise relating to negotiating licences. Whilst one hub may have broad licensing experience which can be effectively applied to a diversity of intellectual property rights other hubs may not. There are also the issues of who can or should control local licensing policy and practice and the need for equivalence in the agreements reached.

The project team recommends that, in so far as the Department of Health thinks desirable and practical, it should adopt a largely central approach to directing intellectual property strategy. The Department should always seek as cooperative an outcome as possible including, where appropriate, a framework for partnership between the Department of Health and the providers of intellectual property (e.g. pharmaceutical companies and universities). In addition, and where appropriate, the Department should provide model agreements for use by hubs and Trusts.

(i) Licensing in

Where the use is purely local and that use is less than a specified number (10 has been mentioned for testing kits) then hubs should be left to negotiate licences locally. Where there is more extensive use (either by a single hub or several) then the negotiations should take place centrally with the Department acting for the hubs. In a few cases, there may be a need for a robust line, with a view, if necessary, to:

- Challenging the validity of a patent in the courts
- Threatening compulsory licensing and/or
- Taking action under anticompetition (anti-trust) laws

[122] http://www.innovations.nhs.uk/nhs_ip_guidance.htm

If an overly broad patent has been granted and the patent holder is pursuing an aggressive licensing policy in negotiations, it is worth remembering that broad claims may well be thrown out in the event of litigation. Litigation of this type is inherently expensive and it becomes harder for a patentee to handle if it is instituted in a number of countries – a factor which argues for co-ordination with health authorities in other European countries in particular. These considerations place the Department of Health in a strong position, provided that there is a commitment to pursuing such litigation in the event that the negotiations fail.

Where the issue is one of obtaining the grant of a compulsory licence from the UKPO or Patents Court, or of resorting to Crown use procedures, then further attention will need to be given to the concept of 'public health' and what that means for the application of Article 31 of TRIPs since the WTO meeting in Doha in November 2001[123].

In brief the Doha Statement says that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. The Statement reaffirms the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. It states that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. Member states also have the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. However, it is clear from the language used in the Statement that it is primarily directed at developing countries and it is unclear as to the extent to which developed countries will be able to rely on Article 31 to provide healthcare in non-emergency situations.

It is also worth noting that the primary purpose of the Compulsory Licensing scheme is to force an unwilling licensor to the negotiating table and the threat of resort to the Crown use provisions may assist in ensuring an acceptable result from those negotiations. In addition, if the patent grant precludes access to too broad an area of information to such an abnormal degree that the patent holder is 'abusing' the monopoly granted, then there is a small chance that the Office of Fair Trading or the European Commission would be persuaded to intervene on the grounds of anti-competitive practices.

The action taken by the Ontario Government [124] and the Dutch[125] Government in respect of the Myriad Genetics patent would indicate that a strong government line would be by no

---

[123] For the full text of the Doha Statement see Appendix Four

[124] The Government of Ontario, Canada is currently taking action against Myriad's BRCA 1 and BRCA 2 patents on grounds including breadth of claim, reach through claims and access to healthcare. For a comprehensive discussion of the *Myriad* patent see Rimmer *Myriad Genetics: Patent Law and Genetic Testing* [2003] European Intellectual Property Review 20.

[125] The Dutch Government is lending support to the opposition to Myriad Genetics' BRCA 1 patent currently being led by the Dutch Association of Clinical Genetics. In respect of the BRCA 2 patent, the Dutch Government is itself the opponent. The

means unprecedented. Furthermore, The Curie Institute in France is leading the opposition to Myriad BRCA patents at the EPO[126].

Recommended DH Position

Priority for developing DH policy and practice - High

The Department of Health should oppose patent licensing agreements that inappropriately limit clinical care, medical training, and medical research. Patents on genes with clinical implications should in general be licensed to all comers on a non-exclusive basis. This is particularly desirable in the case of diagnostic tests which are covered by a patent or patents. The Department might wish to look at possibility of introducing different licensing in policies according to the type of disorder covered by the patented invention. For example, where it relates to a single genetic disorder, which affects a vast range of people, then the Department might wish to have an assertive policy as the Department will need to acquire more of the patented invention. Where the invention relates to a pharmaco-genetic disorder, which affects fewer people, the Department might decide requires a less assertive licensing in policy.

Licence agreements should be free of any terms that dictate specific methods of testing, methods of reporting results, or clinical uses of the test.

Licence agreements should not limit access through excessive[127] royalties and other unreasonable terms[128].

(ii) Licensing out

As the hubs are primarily going to be income generators they may wish to have a high degree of autonomy with respect to licensing out protected material. However, where that material has an overall value for the Department then central guidance will be needed to ensure that access to that material by other hubs and the NHS is not unduly constrained. This could raise issues of differential pricing (e.g. potentially resulting in differences in local pricing between regions resulting in potential issues of public access being determined by postcode) which will need to be taken into account when looking at the extent of control to be devolved to the hubs.

There also needs to be a degree of consistency in the licensing approaches taken by the hubs. The issue here is one hub autonomy vis-à-vis licensing between a hub and DH/NHS and licensing between hubs. The hubs are intended to be independent income generators and this will necessarily mean they will rightly expect to be able to generate revenue from the exclusive rights which their patents will accord them. It is envisaged that there will be a number of shareholders, of which the Department will be only one. The extent to which the

---

Dutch Government is also considering an opposition to the grant of a third breast cancer patent to Myriad and is conducting a broad study of gene patenting.

[126] The Institute is part of a coalition of 17 French research and clinical agencies, challenging the impact of the BRCA 1 patent through the European Patent Office.

[127] It is not possible to provide a specific example of what might be regarded as an excessive royalty. This will depend on the particular patent at issue.

[128] An example which has recently come to the attention of the Project Team involves a agreement permitting a Trust to use a patented test in clinical trials, subject to the condition that all data be kept confidential and returned to the patent holder. This potentially could reduce the value of the information to the Trust carrying out the trial.

Department can and should exert control over the ability of hubs to generate income through licensing IP will need to be carefully considered and will require a continued Department presence within the hubs.

Recommended DH Position

Priority for developing DH policy and practice - High

None of the three publications deals with the issue of ordinary licensing. In the absence of any steer from these quarters it is the view of the Project Team that:

The Department should adopt a balanced approach to determining policy for the hubs, particularly over the question of exclusivity and focus on ensuring an optimal result for IP generators. We also recommend that the Department should, where possible, offer exemplars of good practice, for example in the form of model agreements, for use by the hubs. It is to be hoped that this will encourage parity of good practice within the hubs.

The majority of situations involving the licensing in and licensing out of patented inventions will be uncontroversial and agreement will be reached between the parties. However, in respect of licensing in, it is possible that a situation could arise where the Department is unable to achieve an appropriate agreement (for example the terms of the agreement might involve uneconomical costs or contain tie-in clauses, such as requiring the mandatory use of a particular service in connection with a patented test). It is also possible that there might not be any alternative supplier. In these instances the Department might wish to consider the threat, or actual use, of either a compulsory licence or Crown use. Both of these options are, however, likely to be used only as a last resort.

(c) Compulsory licensing

As with the Crown use provision (discussed below), little use has been made of compulsory licensing under the 1977 Act. The reasons for this are:

(i) that the value in the provision lies in the threat of the imposition of compulsory licence; in other words its usual purpose is to act as a spur in negotiating acceptable terms, and
(ii) that, if used, they substantially qualify the exclusive rights of the patent holder.

The Nuffield Discussion Paper provides a comprehensive evaluation of the issues surrounding the use of compulsory licensing. There is a recognition of the fact that the TRIPs Agreement has served to narrow the situations when such a licence might be granted. Nonetheless the Paper recommends that such licences should be available in particular circumstances - these primarily relate to uses for diagnostic purposes. Neither the Commission's Report nor the Guidelines discuss compulsory licensing, although the Commission's Report does mention the possibility of a compulsory licence being granted where a patent holder acts unreasonably.

Recommended DH Position

Priority for developing DH policy and practice - High

Compulsory licences can be sought by any individual or organisation (including hubs and individual Trusts). It would be useful, however, for the Department of Health to take a lead on this and to demonstrate that it would support the seeking of a compulsory licence for healthcare purposes. We suggest that the Department should be prepared to draw the attention of private suppliers of test services and products and of local health authorities to the scope and extent of compulsory licensing procedures as a factor to be considered in licensing negotiations. This recommendation is subject to the caveat made previously regarding the problems with the existing compulsory licensing system.

(d) Crown use

The Crown use provision, which permits the UK Government to carry out or authorise third parties to carry out certain acts relating to a patented invention without prior approval from the patent holder, provided that adequate compensation is paid to the patentee, is rarely invoked. Section 55(1)(a)(ii) of the UK Patents Act 1977 makes specific reference to the production/manufacture and disposal (including sale) of patented drugs and medicines. This section thus allows the Government to override the patentee's exclusive right where it is necessary to do so in the interests of public health.

Reliance on the UK Crown use provision is now dependent on the use falling within the scope of Article 31 of the TRIPs Agreement. Article 31 is expressed to cover use of the subject-matter of a patent "by the government or third parties authorised by the government." It then requires that "any authorisation of such use shall be considered on its individual merits" (which for Crown use applies only to the setting of the royalty). However, the general provisions on compulsory licensing, while they allow for application to be made by a government department on its own behalf or for a third party, necessarily result in one branch of government applying for an advantage to another, against the patentee. Once this is appreciated, the case for allowing the present Crown use provisions to stand becomes stronger. The precise ambit of Article 31 is the subject of current discussions in the TRIPs Council of the WTO and it is not therefore possible to draw any final conclusion about whether the UK Crown use provision meets the UK's Treaty obligations under TRIPs.

Subject to the caveat regarding its use mentioned above, Crown use can be invoked by any government department or any individual authorised by a government department, for example a hub, a Trust or a NHS practitioner in respect of Crown services

Recommended DH Position

Priority for developing DH policy and practice - High

None of the three publications makes reference to Crown use. In the absence of any steer from these quarters it is the view of the Project Team that the Department of Health should for the present be prepared, if necessary, to rely upon the Crown use provisions in the Patents Act 1977 as its most direct means of curbing undue demands from patentees regarding genetic health services.

It is not possible to discuss the Department of Health's options in respect of compulsory licensing and Crown use in the absence of any mention of more general issues, particularly those relating to the international legal environment. As stated previously, the recommendation to invoke Crown use is subject to the caveat regarding the problems with using the existing system.

(e) General issues relating to compulsory licensing/Crown use

Given the WTO Doha Declaration and the public healthcare basis of the UK healthcare system, the Department should consider calling for an extension of the Doha Agreement to permit countries which operate a public healthcare system to make greater use of compulsory licences and government/Crown use for that system. (It is relevant perhaps to note that the issue of the extent of the Doha statement is being looked at by the European Commission. It was also examined by the Commission on Intellectual Property Rights[129]). However, whilst there is merit in calling for such an extension there appears little likelihood of success in the short-term.

In December 2002, the WTO failed to reach agreement on proposals to permit special and differential treatment for developing countries in respect of access to essential medicines. The proposal had been to permit member states each to determine which diseases and medicines should be subject to the special treatment. However, resistance from the USA led to agreement only in respect of tuberculosis, HIV/AIDS, malaria, and other types of infectious epidemics. No agreement was reached on the ability of developing countries without national capacity to produce medicines to grant compulsory licences for the importation of the requisite drugs from other countries. The discussions are to resume on 10/11th February 2003. It is worth noting that subsequent to the December 2002 statement, the US has committed itself to making AIDS drugs etc more accessible to developing countries. This unilateral decision does not affect the status of either the Doha statement or the meaning/application of Article 31 TRIPs.

It is clear from the announcements made by WTO and USA that the focus of attention is on *developing* countries and on epidemics. It is unlikely, therefore, in the current political climate that developed countries will be able to rely on the Doha Agreement in order to justify government health policies in respect of non-population-endemic diseases. There may however be a shift in perceptions and sympathies at the national level which would make reliance on existing legal powers acceptable at the bar of public opinion.

(f) Competition law

Competition Law is also a weapon which the Department of Health can utilise to counter abuse of a monopoly position. As noted previously, this is a useful weapon but once the referral is made then the matter is removed from the control of the Department of Health. Any determination of royalty rates etc. will be subject to the decision of OFT and above it the Competition Appeal Tribunal.

The UK Competition Act 1998[130] could be used to secure some moderation in the demands of patentees which go beyond a proportionate return for their invention. In addition there is an EU competition law avenue when trade between Member States is being affected. The law

---

[129] Chapter 2, Integrating Intellectual Property Rights and Development(al) ? Policy, Commission on Intellectual Property Rights 2002.

[130] Using the new powers given to the Competition Commission, the Office of Fair Trading and Secretary of State, as set out in the Enterprise Act 2002.

applies to both anticompetitive agreements (in effect agreements which give rise to a cartel) and to abuses of a dominant position. The 1998 Act makes reference to a number of instances which could give rise to an allegation of an abuse of dominant position. These include imposing unfair selling or purchasing prices, limiting production or markets, applying different trading conditions in equivalent transactions and attaching unrelated supplementary conditions. As noted in Section One, a necessary opposition arises between IPR policies and the objectives of competition law. IPRs are granted where there is sufficient justification for eliminating production and distribution by competitors. Accordingly competition law authorities can be persuaded to require changes in licensing terms only where there is anti-competitive conduct by an IPR owner or owners that is in some way quite exceptional – something which goes beyond merely refusing to grant another a licence on the licensor's terms. Nevertheless, there may be such conduct in licensing genetic IPRs.

If the situation is one where it is the actions of a single patentee that are in issue, it will be necessary to show that there is an abuse of a dominant position. The dominance will have to be measured in relation to the market for the patented product or process. A case could be made upon a refusal to license the conduct of genetic tests where a major purpose is not to make monopoly profits simply as the reward for the actual invention, but is as much to gain privileged access to genetic material in order to make other genetic discoveries. It may be that, as patents on proteins, receptors and related procedures build towards effective forms of diagnosis and gene therapy, collaborations between the different right owners arise which amount to a pool of patents against users which has a cumulative monopoly effect. Conduct of this kind could well amount to an unlawful restrictive practice between firms, which could not be justified and therefore exempted for the countervailing benefits which could be said to stem from that conduct.

Recommended DH Position

Priority for developing DH policy and practice - High

The assessment of the need to make a referral to the Competition Commission is something the project team would expect to remain a top priority for the Department of Health.

None of the three publications makes reference to the use of competition law. In the absence of any steer from these quarters it is the view of the Project Team that the Department of Health should consider the invocation of either UK or EC competition law as a threat in circumstances where a patent holder or holders is abusing their monopoly position to dictate the terms of licence/access agreement which goes beyond the mere assertion of the exclusive right adhering to any one piece of IP.

3 Other issues

(a) Public policy

The patent system contains a number of exclusions which operate to protect the public from the over-monopolisation of information. These exclusions include inventions the commercial exploitation of which would be contrary to morality and methods of human treatment (which include diagnosis as well as therapy practised on the body). One common view in patent law

circles is that exclusions and limitations by their nature must be given a restrictive application. (But, as we have seen, that is not an approach which has prevailed across Europe in relation to the research exemption).

(b) Morality

The morality and public policy provisions in UK patent law are based on Article 6 of the EC Directive on the Legal Protection of Biotechnological Inventions. Article 6 in turn is based on Article 53(a) of the European Patent Convention. Patent practice to date is to apply a utilitarian (benefit/detriment) approach to determining whether the commercial exploitation of an invention would be contrary to morality or not. Provided some benefit can be shown to result, or be likely to result, from the exploitation of the invention, then the exclusion is unlikely to be invoked.

Perhaps surprisingly the Nuffield Discussion Paper does not provide any detailed analysis of the specific provisions *within* patent law which relate to morality. The Paper states that there might not be the sufficient expertise within patent granting offices to make appropriate decisions relating to morality of a particular invention and they recommend that the EPO provide further guidance on Article 53(a) and in particular that the EPO should seek guidance from the European Committee on Ethics. It is perhaps surprising that the Nuffield Council did not provide its own thoughts on what that guidance should contain.

The Commission's Report outlines the function of the morality provisions within the EC Directive. It states that any argument that the text is insufficiently precise can be rebutted by the need to allow member states a degree of flexibility in deciding what is an invention contrary to morality within its own "ethical, sociological or philosophical context" that "the national legislative, administrative and court authorities are best placed to understand the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State." The Report is at pains to reiterate that the Directive does not undermine respect for human dignity.

The Guidelines also mention the morality provisions, but simply by way of describing their content. No analysis is provided.

Recommended DH Position

Priority - Low

For the present we recommend that the Department of Health keeps an eye on the granting practice of the EPO and the UK Patent Office to ensure that the morality provisions are properly applied following the decisions of the EPO on the subject. In making this assessment we recommend that the Department takes into account any views which may be expressed by the Human Genetics Commission which has a standing item to monitor how the morality provision is put into practice. It is worth bearing in mind that the concept of morality set down in EC Directive is deliberately formulated to give flexibility to member states. This indicates that the concept of morality in UK patent law could differ from that utilised by the EPO or other EU member states.

(c) Exclusion of methods of treatment and diagnosis

European patent law excludes of methods of human treatment and diagnosis from patent law.[131] A method of treatment or diagnosis is traditionally taken to mean anything performed upon the human body. Any treatment or diagnosis which takes place away from the body is generally held not to fall within the scope of the exclusion. The issue which requires further consideration is whether it is either a) desirable or feasible to press for an exclusion to be given a broader remit or b) whether, in light of other developments in patent law, it is more appropriate to seek a removal of the exclusion. The status of any gene therapy conducted within the body also needs to be further considered.

A difficulty arises here, which follows from that devious development of patent law in the realm of medicinal chemistry, which has involved undermining the exclusion of methods of medical treatment by permitting patents over an increasing array of "novel" substances. The cleanest way forward might well be to abandon the method of medical treatment exception, since it is now such a shadowy encumbrance; it could then be required, in relation to genetic patents, that claims be limited to the uses revealed, whether or not the use involves diagnosis or treatment "practised on the human body". That, however, is probably unrealistic. Change can only be expected by adapting that strange intermediate compromise, the claim for a thing, which is stated to be limited to that use and would therefore only be infringed when, say, a diagnostic test or a gene therapy procedure is carried out for the identified purpose. Constraints of this type would in many cases limit the possibilities of royalties from the patent, not least because the proof of infringement could be more difficult. This disadvantage could however be assuaged in some degree by presumptions that use of genetic material was for the patented purpose unless the alleged infringer showed otherwise.

Recommended DH Position

Priority - High

High because of the current UK Patent Office consultation, although it is likely that once a decision has been taken at the UK level that this will become a medium to low priority
None of the three publications discusses this exclusion in any detail or attempts to address the issue of whether it should be retained, expanded or removed. However, the recent Consultation paper published by the UK Patent Office on the proposed Patents Act (Amendments) Bill does raise the question whether the exclusion should be removed[132].

We recommend that the Department should consider whether the exclusion should be lifted only upon the condition that the activities of clinicians should not constitute infringement of any patent claim. This would put the EPO member countries in broadly the same position as now prevails in the US.

[131] The exclusion is also permitted under the TRIPs Agreement in Article 27(3)(a). In the US, effectively the same result has been achieved by granting medical practitioners an exclusion from liability for acting within the patent in the course of treatment of a patient.

[132] It is interesting to note that the consultation just begun on amendments to the Patent Act does discuss the exclusion of methods of human treatment on the grounds that these cannot be shown to have industrial application and suggests the removal of the exclusion leaving the patentability of such methods subject to the general granting criteria.

(d) Other forms of intellectual property rights

The focus of attention has been on the central issues (those issues classified in Section One as high priority). Whilst there is still much to discuss on the issue of other forms of intellectual property protection, it is not thought that these have any directly practical, as opposed to theoretical, application for the purposes of this Report[133].

Recommended DH Position

Priority - Low

In our view at present the impact of the current IPRs identified in Section One is not great. However, the relevance of, for instance, database rights to 'BioBank' are likely to increase and therefore developments need to be kept under review.

(e) Human rights

It is still unclear as to the exact extent to which the Human Rights Act affects intellectual property rights in general and the protection of genetic information in particular. The project team has not been found any direct link between the patenting of genetic material and the provisions of the Human Rights Act 1998. Equally the Nuffield Paper does not connect the two.

Recommended DH Position

Priority - Low

That the impact of the Human Rights Act 1998 on the protection of and access to genomic inventions should be monitored, particularly if any connections are drawn by the Human Genetics Commission which is also monitoring this issue.

4 Conclusion

We recommend the following policy responses for consideration by the Department of Health:

[133] On the basis of the information set out in the section on Other Forms of Intellectual Property Protection, Section One-D, the team has addressed the appropriateness of Copyright, Confidence and Utility Models for protecting genetic information. In addition, in respect of data protection, the European Commission has adopted a decision setting out standard clauses in order to ensure adequate safe guards for the transfer of personal data from the EU to non-EU countries. these standard clauses are not necessary for the transfer of data to the US where the company already adheres to the 'safe harbour' privacy principle. The option remains for United Kingdom holders of personal data to require more stringent privacy provisions than those contained the 'safe harbour' privacy provisions.

Recommendations

1. **It should recognise its unique position with regard to healthcare related intellectual property and take an active role in monitoring developments in relevant areas of intellectual property law (most notably patent law).**

2. **It should, as provider and recipient of intellectual property, support the appropriate use of intellectual property law, and in particular patent law, in protecting inventions involving genetic material.**

3. **In light of the ongoing advancements in bioscience, and difficulties in establishing and maintaining concrete distinctions between types of genetic innovation, it should focus its attention not on the *type* of material being patented but on the way in which the UK Patent Office applies the new guidelines on applications involving biological material, and on equivalent decisions in the EPO; and endorse the position taken by the Nuffield Council regarding the application of the granting criteria.**

4. **It should have in place a mechanism for assessing:**

(i) **whether to send information to the EPO or UKPO during the examination of a patent application which would restrict the scope of any patent on the disclosed genetic invention**

(ii) **whether to challenge the validity of a genetic patent once granted, either in the UK before the Comptroller of Patents or in court; or (for a European patent) by opposition proceedings in the EPO (commenced within 9 months of grant)**

(iii) **whether to challenge any abuse of monopoly in the manner in which a patentee exploits his rights by referring the matter to the *UK Office of Fair Trading* or the EC Competition Directorate.**

5. **It should seek clarification of the research use exception to patent infringement at the UK, EU, EPO and International levels, particularly with regard to use in clinical trials; and offer advice on good practice concerning the use of patented material and procedures in the course of research conducted by or in relation to its services.**

6. **It should establish a framework for partnership between the Department of Health and commercial providers of intellectual property (e.g. pharmaceutical companies and universities).**

7. **It should instigate a robust central policy for "licensing in" designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use.**

8. **It should adopt a balanced approach for "licensing out", particularly over the question of exclusivity, and where appropriate the Department should provide model agreements for use by hubs and Trusts.**

9. **It should seek greater interaction with the Department of Trade and Industry, with which it should consider the establishment of a single UK policy on IPRs and healthcare provision (encompassing both internally generated and externally sourced innovation).**

10. **It should make full use of existing monitoring and horizon scanning work being undertaken by groups such as the Human Genetics Commission, the Nuffield Council on Bioethics, and the Intellectual Property Advisory Committee and make representations to these groups where necessary.**

It is not proposed that the Department should necessarily undertake each of the recommendations made above in-house, but that it should, where appropriate, avail itself of the various professionals available such as specialist law firms and patent monitoring companies.

In making these recommendations it is recognised that the Department of Health will need to introduce an intellectual property management strategy and our thoughts on the possible form this strategy could take forms the basis for Section Three.

SECTION THREE:
PROPOSALS FOR AN INTELLECTUAL PROPERTY MANAGEMENT STRATEGY

A INTRODUCTION

The remit of this Project is to undertake "A study into the impact and management of intellectual property rights within the healthcare sector." This section is intended to fulfil the second objective by looking at possible ways which the Department of Health could utilise in order to further direct the management of IPRs. In making these recommendations the Project Team recognises that considerable work has already been undertaken by the Department of Health to oversee intellectual property management within the NHS via the publication and promulgation of the *"Framework and Guidance on the Management of Intellectual Property within the NHS"*. This document is, however, directed towards the day to day management of intellectual property generated within the NHS (broadly defined) and it does not seek to establish any points of policy nor does it discuss the more controversial aspects of intellectual property protection, namely the protectability and patentability of genetic material.

As stated in the Introduction to Section Two, there is a central question which the Project Team has not been required to address. This is whether, in light of on-going general developments in intellectual property law, and the increased emphasis within the Department of Health and NHS on income generation through intellectual property acquisition and enforcement, the Department of Health should develop an overarching intellectual property strategy which encompasses, but is not confined to, genetic innovation.

B APPROACHES TO INTELLECTUAL PROPERTY MANAGEMENT STRATEGY

It is the view of the Project Team that taking a pro-active approach to all aspects of intellectual property strategy and management would place the Department on Health in a strong position with regard to commenting on, and influencing the results of, the continuing discussions over the future developments in intellectual property law. The objective of such an approach would be to involve the Department of Health in meetings of, amongst others, the UK Patent Office and DTI, such involvement ensuring that the views of the Department of Health are represented within UK patent law strategic thinking at the wider EU and international levels. It has become increasingly the view of the Project Team that, in light of the developments towards increased income generation via the hubs (as set down in the framework and guidance document published by the Department of Health) that it would not be realistic for the Department of Health now to adopt an overly directive policy which might have the effect of hamstringing the hubs. Equally it is recognised that there may be certain intellectual property policy issues which the Department might wish to retain control over with a view to either providing guidance to the hubs or indeed requiring action from the hubs. Again there is an issue whether the Department of Health would wish to develop either policy in respect of genetics *per se* or to broaden the ambit of any such policy to include all material produced, or bought in, by the hubs.

In terms of developing a strategic management policy the Project Team would suggest that the Department could look to adopting either a light or a heavy hand approach (or combination of the two approaches) to IP management. In summary the heavy hand approach would involve developing both policy and practice to be followed by the NHS and hubs. This policy and practice would sit alongside the framework and guidance already provided. It would be developed and amended as the Department reaches its own strategic thinking. The light hand approach, in contrast, would focus much more on developing policy initiatives primarily for external discussion and would leave the hubs very largely to control their own intellectual property acquisition and exploitation.

Of central importance to either approach is the need to establish coherent lines of communication between DH, the NHS and the hubs. In order to ensure that there is a maximisation of information relevant to all parties, the Department of Health should seek to establish an IP Unit to a) monitor and advise on developments in IPRs and genetic information and b) ensure that the relevant bodies within the NHS and hubs are kept informed about these developments via briefing papers etc.

It is clear that there is a need for explicit Department of Health involvement in various ongoing and proposed external intellectual property initiatives. Examples of where there should be such involvement but none at present exists includes the Patent Office's Intellectual Property Advisory Committee, ad hoc groups such as the Royal Society's group on Intellectual Property and those automatically consulted by the Department of Trade and

Industry in respect of proposed changes to UK intellectual property law provision[134]. As stated earlier in this Report, a further consideration is the extent to which the Department of Health can, or should, be able to influence developments at the European Patent Office via the UK representative on the EPO Administrative Council.

In contrast to the Department of Health's lack of profile in this area the DTI is very visible. The DTI has the twin interests of industry and the Patent Office within its remit but the Department of Health should have a formal mechanism for involvement in particular intellectual property initiatives related to its concerns. Examples of this include the Pharmaceutical Industry's Report[135] and the current consultation on amendments to UK patent law. There is a clear need for the Department of Health to provide information to government and organisational policy makers as to the likely impact of any given intellectual property policy on healthcare provision in the UK.

The Project Team considers that there is a need for a higher Department of Health profile *vis-à-vis* those bodies and organisations traditionally involved in overseeing and developing UK intellectual property policy such as the Chartered Institute of Patent Agents.

As already stated the Department of Health needs to decide who should bear the responsibility for directing internal Department of Health policy and also what its internal policy should be for overseeing intellectual property rights in general and IPR issues affecting the hubs in particular. The latter point links directly to the Department's decision whether to adopt either a light or more heavy hand regime. The role of either regime would depend on whether the Department of Health chose to adopt a general intellectual property policy or one specific to genetic information.

Whilst we separate the two approaches in the discussion below it is recognised that it would be possible for the Department of Health to adopt one approach to licensing in (the heavy hand approach) and the other to licensing out (the light hand approach).

I Light hand regime

This would involve a two-tier approach, the first tier relating to the activities to be undertaken by the Department of Health and the second to the effect of those activities on the NHS and hubs. The effect of the light hand approach would be the keep Department of Health responsibility for intellectual property policy and management to the minimum, unless an exceptional circumstance arises.

Under a light hand regime it would be envisaged that the Department of Health would primarily concern itself with monitoring intellectual property developments. It would be responsible for and would circulate information via briefing papers, possibly also setting up a

[134] In respect of the latter it is noteworthy that amongst those automatically consulted for the purposes of the current consultation on amendments to the UK Patent Act are the Association of British Pharmaceutical Industry, British Pharma Group and the British Generics Manufacturers Association. There is no representative from a specific end user sector such as patient groups or the Department of Health.

[135] March 2001 report of the UK Pharmaceutical Industry Competitiveness Task Force (PICTF) www.doh.gov.uk/pictf/pictf.pdf

central policy, but responsibility for implementing the policy and overseeing IPRs in practice would be delegated to the hubs.

The second tier relates to the NHS and in particular to the hubs. The responsibility for the day-to-day management of intellectual property rights would be delegated to the hubs this would mean that each hub would have responsibility for deciding the following;

- decision on their own local policy;
- choices patent agents to acquire rights;
- draft and negotiating licensing agreements in and out;
- take responsibility for enforcing the rights.

Whilst this would give considerable autonomy to the hubs, and as a consequence reduce the demands on the Department of Health, such an approach could raise questions about the coherence of policy and practice between hubs. There is also the question of the extent to which, under a light hand approach, the Department of Health would be able to direct the form of the agreements being made particularly with regard to the licensing in and out of key genetic innovations, not to mention any role it might wish to have in taking decisions on the acquisition and enforcement of rights.

An example of the type of problem which could arise under a light hand approach is where Company X has both a market, and a legal, monopoly on a type of gene test. Hub A takes out a licence on the gene test, the terms of which bind Hub A to use the test for 10 years. Company Y then develops a non-infringing alternative test which is more effective. Hub B is able to utilise the new test - Hub A is not, either because of the terms of the agreement with Company X or because it cannot afford to license in two separate tests. There is an argument for the Department to oversee the licensing in of test kits.

It is possible to envisage a light hand approach with rather more involvement of the Department of Health. This would focus primarily on the role of the Department in respect of licensing in decisions. If a general Department of Health directed role is thought desirable then the Project Team suggests that the Department could look at the possibility of establishing a Department of Health licensing unit to oversee the whole of the licensing in process. There will remain the issue as to whether the whole of licensing in *and* out should be done centrally and, if licensing out is done locally, whether, hubs will be obliged to deal with each other on a preferential basis[136].

The second option would require more involvement from the Department of Health. and a greater assumption of responsibility.

[136] the issue here would be whether it would be possible (or indeed legally permissible) for the hubs to have different licensing out policies depending on whether the recipient of the licence is another Hub (the terms of the licence possibly being more favourable) or a non Hub recipients such as a foreign company or the private healthcare sector.

2 Heavy hand approach

This would build on the policy role identified above and give the Department greater control over all aspects of intellectual property strategy and management. This approach would require the Department of Health to take responsibility for overseeing the acquisition, licensing and enforcement of rights. The Project Team suggests that this could be achieved by the use of:

- a firm of patent agents who deal with all patent applications to be made by hubs;
- a centralised licensing unit which oversees both licensing in and out of protected material for the hubs and
- a law firm employed by the Department for its experience in intellectual property management, which would be used to enforce the patents (and other intellectual property rights) held by *all* the hubs.

Irrespective of which approach is used, there is a need for clear lines of communication between the Department, the hubs/Trusts and the IPR generators. It is vital, if the strategy is to work, for the Department to know what impact its IPR strategy is having on activities within the NHS in order for that strategy to evolve based on the needs of those using or producing IP as well as to encompass any overarching Departmental IP policy. There needs to be parallel lines of communication ensuring knowledge about IP policy, internal IP generation activity and use/impact of externally source IP.

3 Risks attached to the Department of Health doing nothing

Notwithstanding the concerns identified in Section One and the recommendations outlined above, it remains feasible for the Department of Health to opt to do nothing with regard to directing policy (and where apposite practice) relating to the patent law and genetic inventions. However, the Project Team would strongly resist such inertia.

The nature of the current UK healthcare system is such that the Department of Health could assume a strong position *vis-à-vis* patenting practices which could undermine the commitment to an effective, and efficient, healthcare programme. It must be remembered that any pharmaceutical company wishing to maximise the value of a patented invention on a UK-wide market basis will need to have that invention approved and used by the Department of Health. Any indication that suspect patent grants will be challenged and unjustified licence terms vigorously resisted is likely to result in a fall in applications for the former and greater acquiescence to amendment in the latter.

If the Department opts to do nothing then it is likely that the fall in suspect grants will not be as swift as many would desire. It is also likely that companies will continue to 'try their arm' at imposing unreasonable terms safe in the knowledge that threats of either invoking

compulsory licences or Crown use are unlikely to be made making them slower to come to the negotiating table.

It is possible that the concerns identified in Sections One and Two will prove to be only fleeting and that all will be resolved in time via actions brought by others through the courts and oppositions heard at granting offices. However, there are two things which the Department needs to bear in mind if this is what they propose to do.

The first is that it is unlikely that the type of concerns raised now will dissolve as the current form of genetic science gives way to newer technologies. Access to patented inventions, irrespective of the subject-matter of that invention, will continue to be an issue for the Department and there is a need to be seen to be in control of that access.

Secondly, the introduction of the hubs and the increased emphasis on income generation through the licensing out activities of Trusts allied to the hubs means that there is a need to maximise the Department's own IPR potential. In this there is a strong public interest argument for saying that the practice adopted by the hubs forms part of an overarching Department of Health strategy and is not unilateral or counter to the public service ethos generally seen to underpin UK healthcare provision. It would be logical, if a Department of Health strategy were to be adopted in respect of the hubs, to extend this to the policy of licensing in.

For these reasons the Project Team would urge careful consideration of the proposed IPR Management Strategy outlined above. We would also recommend that there should be greater interaction between the Department of Health and the Department of Trade and Industry and consideration should be given to the establishment of a single UK policy on IPRs and Healthcare Provision (encompassing both internally generated and externally sourced innovation).

APPENDICES

Appendix One

Glossary and Abbreviations

Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)

This is part of the World Trade Organisation and sets down minimum standards of intellectual property which must be implemented by each member state (currently 144).

Bioinformatics

Research, development or application of computational tools and approaches for expanding the use of biological, medical, behavioural or health data, including those to acquire, store, organise, archive, analyse or visualise such data.

Claims

These identify the contribution made by the inventor and determine the scope of the protection conveyed by a patent. Infringement is assessed by reference to the claims.

Compulsory Licence

This permits national Patent Offices to grant a licence over patented material in certain, limited circumstances. Such circumstances usually relate to the failure of the patent holder to make his invention widely available. Compulsory licences are rarely used other than to encourage a reluctant patent holder to conduct negotiations with a potential licensee. Article 31 of the TRIPs Agreement sets down the conditions under which a member state may grant a compulsory licence.

Confidence

Covers any material which can be kept confidential. Once information is made publicly available, for example via disclosure in a published patent application, it is no longer treated as being of a confidential nature. Article 39 of the TRIPs Agreement recognises that persons who hold secret information lawfully might not wish to disclose that information through other forms of intellectual property rights and states that they should be able to control its disclosure and prevent any use which is contrary to honest commercial practices. The Human Rights Act 1998 gives rise to a right of privacy in personal information which has to be respected.

Consent

The law is that a person may not be medically treated without previously giving free and informed consent to such treatment. In UK patent law there is no requirement that a person must provide consent to the use of any tissue taken during a medical procedure which is subsequently used for the purposes of developing a patentable invention nor to the filing for a patent over that invention.

Community Patent Convention

In 1975 the then Member States signed a Community Patent Convention under which a unitary Community patent could be granted by a central European patent authority. But the 1975 Convention, which was incorporated within the Agreement relating to Community patents concluded in 1989 (together "the Luxembourg Convention"), has not yet been ratified by all Member States, and therefore has not entered into force.

Copyright

The right to prevent others from copying literary, artistic and musical works as well as the interests held in such works by publishers and recording companies. In order for a work to be protected it must be original (not copied) and demonstrate skill, labour and effort on the part of the author. The relevant UK legislation is the Copyright Act 1988.

Crown Use

This enables the UK government to use a patented invention, without the authorisation of the patent holder, in return for compensation settled, if necessary, by a court. This is a rarely invoked provision which only applies when for the services of the Crown, in respect of certain types of patented material (the 1977 Act specifically states it can be used to ensure the supply of medicines through the NHS). It is not clear to what extent Article 31 of TRIPs permits this practice.

Data Protection

Personal information is protected by the Data Protection Act 1998 (at common law it is protected under the law of confidence, see above). The Act provides for the secure handling of personal information whether stored electronically or in other filing systems. Information which falls into the category of 'sensitive personal data' (such as genetic information) is subject to stricter controls under the Act. Information may only be kept for as long as the purpose for which it has been processed remains. This does not apply to data kept for research purposes, although this is subject to limitations (section 33(1) of the Act).

Database Protection

Sui generis protection for compilations of independent works, data or other materials which are a) arranged in a systematic or methodical way and b) are individually accessible by

electronic or other means. Database Regulations SI 1997 No 3037. Use of information held on a database will be subject to controls via the Data Protection Act.

Discovery

Information about natural conditions which has no direct practical utility is not patentable. If a use for that information is found which is novel and involves an inventive step then the material may be patentable.

European Directive on the Legal Protection of Biotechnological Inventions (the EU Biotechnological Directive 98/44/EC)

This was adopted in July 1998 and requires all member states of the EU to recognise the patentability of biotechnological inventions. The purpose of the Directive is to foster innovation in the bioscience industry and ensure entry into all EU markets through the removal of any obstacles to trade which could result from a divergence of patent practice between countries.

European Patent Convention (EPC)

This is the governing convention for most European patent law. It enables, upon a single application, an applicant to acquire patent rights in as many member states as the applicant designates. If successful the patent holder will acquire a bundle of national rights which are enforceable at the national level.

European Patent Office (EPO)

The Office responsible for overseeing the EPC. This is a granting office. Any matter to do with infringement or with the validity of the patent once granted (without EPO opposition) is dealt with by the relevant national court.

Human Rights

In the UK the relevant legislation is the Human Rights Act 1998. Introducing into UK law the European Convention on Human Rights, the Act provides protection for amongst others, the right to life and private life.

Industrial Application

The patent law requirement that the invention has a demonstrable practical application, (see method of human treatment below).

In Silico

Computational representation of compounds such as proteins, epitomes and genes used for structural analysis, sequencing and structure activity relationships.

Intellectual Property Rights (IPRs)

This term is now commonly used as a collective for copyright & design right, patents, trade marks & passing off. In some texts a distinction is drawn between 'intellectual' and 'industrial' property. The former relating to copyright, the latter to patents and trade marks. The term, IPR, is also often used to include confidentiality/trade secrecy. Not all material is protectable by an intellectual property right.

Inventive Step

The patent law requirement that it was not obvious to produce the invention. It is determined by asking whether, in light of the state of the art, the invention would have been obvious to a person skilled in the art.

Licence

The agreement between a patentee or other IPR holder and a licensee granting the latter the right to use a patented invention usually in return for payment of a royalty. A licence can be exclusive, (the patent holder agrees not to license the invention to any other party nor to produce or sell the invention himself - this usually gives the licensee the right to sue in cases of infringement), or non-exclusive, (where the patent holder retains the right to enter into as many licence agreements as he wishes).

Methods of Human Treatment

These are usually excluded from patent protection, *inter alia* as lacking industrial application. However, "method of treatment" has a limited technical meaning in patent law. A distinction is drawn between *in vivo* methods of treatment, which are excluded, and *in vitro* methods of treatment which may be protected by a patent.

Novelty

The patent law requirement that the inventive concept contained in an invention must not have been available to the public, in that form, prior to the priority date of the patent. This assessed by reference to the prior art.

Obviousness

See inventive step.

Patents Act 1977

The Act which governs UK patent law.

Patent

A right to prevent others from using the protected product or process for a period of up to 20 years from the date of application.

Patentable subject-matter

Patent law does not contain a definition of an invention. Any type of invention may be patentable provided it meets the granting criteria of novelty, inventive step, industrial application, is sufficiently disclosed and it is not specifically excluded. The exclusions, which are given a restrictive interpretation, include discoveries, schemes for performing mental acts, presentation of information, aesthetic creations, scientific theories and mathematical models, computer programs, inventions the commercial exploitation of which would be contrary to morality or *ordre public,* plant and animal varieties and essentially biological processes. Micro-organisms are patentable as are the products of microbiological processes.

Research Exemption

In patent law it is permitted to use the protected invention for private and non-commercial use or experimental use.

SME

Small-to-medium sized enterprise.

Sui generis

Meaning of its own kind or class.

Trade Marks

The protection of the goodwill and reputation in a business brand. At common law the goodwill and reputation is protected by the tort of passing-off. Under the Trade Marks Act 1994 trade marks gain enhanced protection through registration (for which there are UK and Community registers).

United States Patent and Trade Mark Office (USPTO)

The US equivalent of the UK Patent Office.

Utility

The US patent law equivalent to industrial application.

Utility Model

A short-term right of the patent type granted over incremental innovations. In order to make the right cheaper and quicker to acquire than a patent the application is usually not examined prior to grant. The form of the right varies around the world. At present the UK does not have a utility model system but a Community utility model is in contemplation).

World Trade Organisation (WTO)

Oversees the international agreement on trade and tariffs (GATT) and the TRIPs Agreement.

Appendix Two

Selected bibliography (in English only)

Academy of Clinical Laboratory Physicians and Scientists Resolution: *Exclusive Licenses for Diagnostic Tests* 1999: http://depts.washington.edu/lmaclps/license.htm

Alberts & Klug *The Human Genome Must be Freely Available to All Humankind* 404 Nature, 326 (2000)

Andrews *Genes and Patent Policy: Rethinking Intellectual Property Rights* Nature October 2002 Vol 3, 803

Baker Report *Creating Knowledge Creating Wealth - Realising the Economic Potential of Public Sector Research Establishments* HM Treasury August 1999

Barton. *Reforming the patent system*, 287 Science (2000) 1938

Bobrow & Thomas *Patents in a Genetic Age* 409 Nature 763, 2001

Bostyn *The Patentability of Genetic Information Carriers* [1999] 3 IPQ, 1

Bostyn *A Test Too Far? A Critical Analysis of the (non) Patentability of Diagnostic Methods and Consequences for BRCA1 Gene Type Patents in Europe* [2001/2002] 4 BSLR 111

British Medical Association *Gene Patenting: A Discussion Paper* July 2001 (also available at http://www.bma.org.uk/ap.nsf/Content/Gene+patenting+paper?OpenDocument&Highlight=2,gene,patenting

Bovenberg *Should Genomics Companies set up Database in Europe -? The EU Database Directive Revisited* [2001] 8 EIPR 361

Canadian Biotechnology Advisory Committee Steering Group *Patenting of Higher Life Forms and Related Issues - Interim Report*
(www.cbac.gc.ca/documents/ip_biotech_en.pdf)

Cole *Pioneering Pays - or Does It?* [2000] 11 EIPR 534

Collard, Conn & Marsman *Biotechnology and Chemical Patent Practice in Canada* 2002 Borden Ladner Gervais LLP

Cornish *Experimental Use of Patented Inventions in European Community States* IIC Vol 29, 1998, 735

Crespi, *Patents on Genes. Can the issues be clarified?* [1999-2000] 8 BSLR at 199

Crespi *Gene and Compound Claims: Another View* The CIPA Journal May 2002, 255

Crespi *Patenting and Ethics: A Dubious Connection* [2001/2002 BSLR 71

John Doll *The Patenting of DNA* 280 Science 689 (1998)

Domeij *Pharmaceutical Patents in Europe* Kluwer Law International 2000

Drahos *Biotechnology Patents, Markets and Morality* [1999] European Intellectual Property Review 441

DTI *Biotechnology Clusters* Report of a team headed by Lord Sainsbury August 1999

DTI *Excellence and Opportunity - A Science and Innovation Policy for the 21st Century* DTI July 2001

DTI *"Framework and Guidance on the Management of Intellectual Property within the NHS".* http://www.innovations.nhs.uk/nhs_ip_guidance.htm

Eisenberg *Patent Swords and Shields* Science Vol 299 14 February 2003, 1018

GeneWatch *Patenting Genes – Stifling Research and Jeopardising Healthcare.* http://www.genewatch.org/Patenting/Reports/Patents.pdf

Gitter *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exemption* New York University Law Review December 2001 [Vol 76, 1623]

Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology* OUP 1999

Guardian Supplement *Who Owns the Genome* The Guardian November 2000

Hass *The Wellcome Trust's Disclosures of Gene Sequence Data into the Public Domain and the Potential for Proprietary Rights in the Human Genome* 16 Berkeley Technology Law Journal 145

Heller & Eisenberg *Can Patents Deter Innovation? The Anti-commons in Biomedical Research* 280 Science 698 (2000)

Report of the House of Lords Select Committee on Science and Technology www.parliament_the_stationary-office.co.uk/pa/ld200001/ldselect/ldsctech/67/5701.htm

Human Genetics Commission *Whose Hands on Your Genes?* HGC November 2000 (also available at www.hgc.gov.uk)

Jacob *Law and the Human Genome Project* Paper given at Washington University, April 2002

Laddie, Prescott, Vitoria, Speck and Lane, *The Modern Law of Copyright and Designs*, 3rd ed. Vol. 2, 2000, Chapter 38

Knoppers, Hirtle & Glass *Commercialisation of Genetic Research and Public Policy* 286 Science 2277 (1999)

Laurie, *Intellectual Property and the human genome*. Science and Public Affairs June 2001, 10

Lonati *Patentability of Receptors and Screening Methods: Does In Sillico Screening Pose New Legal Problems?* [2000/2001] 4 BSLR 144

Merz, Kriss, Leonard & Cho *Diagnostic Testing Fails the Test: The Pitfalls of Patents are illustrated by the Case of Haemochromatosis* Nature Vol 415, 7th February 2002, 577

Moore & Gilbert *Amgen v TKT: Bye Bye Biogen?* [2001/2002] 4 BSLR 122

MRC publication on Patents and Licensing: http://www.ich.ucl.ac.uk/cmgs/part2/patent.htm

OECD Papers from the Expert Workshop on Genetic Inventions, IPRs and licensing Practices, Berlin 24-25 January 2002 at www.oecd.org

Rimmer *Myriad Genetics: Patent Law and Gene Testing* [2003] 1 EIPR 20

Sampson *Rewriting the Genetic Code: The Impact of Novel Nucleotides on Biotechnology Patents* [2002] 8 EIPR 409

Schatz *Patentability of Genetic Engineering Inventions in the European Patent Office* IIC Vol 29, 1998, 2

Schertenleib *The Patentability of DNA-based Inventions in the EPO and the European Union* [2003] 3 EIPR 125

Sheraton & Sharples *The Court of Appeal Puts Biogen Insufficiency Back Where it Belongs* [2002] 12 EIPR 596

Sterckx *Biotechnology, Patents and Morality* Ashgate 1997

Straus *Patenting Human Genes in Europe* IIC Vol 26, 1995, 920

Sulston & Ferry *The Common Thread: A Story of Science, Politics, Ethics and the Human Genome* Bantam Press 2002

Thomas, Hopkins and Brady *Shares in the Human Genome - the Future of Patenting DNA* Nature Biotechnology December 2002, Volume 20, 1185

Thompson & Kempton *Construction Issues in Pharmaceutical and Biotech Cases* [2002] 12 EIPR 591

Walsh *Working Through the Patent Problem* Science Vol 299 14 February 2003, 1021

White *Gene and Compound per se Claims - An Appropriate Reward? Part I.* The CIPA Journal February 2002, 89

White *Gene and Compound per se Claims - An Appropriate Reward? Part II.* The CIPA Journal March 2002, 134

Appendix Three

Relevant Sections of the UK Patents Act 1977

Section 1: Patentable inventions

(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

The invention is new;
it involves an inventive step;
it is capable of industrial application;
the grant of a patent for it is not excluded by subsections (2) and (3) below;

and references in this Act to a patentable invention shall be construed accordingly.

(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -

a discovery, scientific theory or mathematical method;
a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

(3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

(4) For the purposes of subsection (3) above behaviour shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

(5) The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.

Section 2: Novelty

(1) An invention shall be taken to be new if it does not form part of the state of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say -

that matter was contained in the application for that other patent both as filed and as published; and
the priority date of that matter is earlier than that of the invention.

(4) For the purposes of this section the disclosure of matter constituting an invention shall be disregarded in the case of a patent or an application for a patent if occurring later than the beginning of the period of six months immediately preceding the date of filing the application for the patent and either -

(a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person -

(i) from the inventor or from any other person to whom the matter was made available in confidence by the inventor or who obtained it from the inventor because he or the inventor believed that he was entitled to obtain it; or
(ii) from any other person to whom the matter was made available in confidence by any person mentioned in sub-paragraph (i) above or in this sub-paragraph or who obtained it from any person so mentioned because he or the person from whom he obtained it believed that he was entitled to obtain it;
(b) the disclosure was made in breach of confidence by any person who obtained the matter in confidence from the inventor or from any other person to whom it was made available, or who obtained it, from the inventor ; or
(c) the disclosure was due to, or made in consequence of the inventor displaying the invention at an international exhibition and the applicant states, on filing the application, that the invention has been so displayed and also, within the prescribed period, files written evidence in support of the statement complying with any prescribed conditions.

(5) In this section references to the inventor include references to any proprietor of the invention for the time being.

(6) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

Section 3: Inventive step

An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

Section 4: Industrial application

(1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

Section 14: Making of application

(1) Every application for a patent -

shall be made in the prescribed form and shall be filed at the Patent Office in the prescribed manner; and
shall be accompanied by the fee prescribed for the purposes of this subsection

(hereafter in this Act referred to as the filing fee).

(2) Every application for a patent shall contain -

a request for the grant of a patent;
a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and
an abstract; but the foregoing provision shall not prevent an application being initiated by documents complying with section 15(1) below.

(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

(4) Repealed -see Section 125A

(5) The claim or claims shall -

define the matter for which the applicant seeks protection;
be clear and concise;
be supported by the description; and
relate to one invention or to a group of inventions which are so linked as to form a single inventive concept.

(6) Without prejudice to the generality of subsection (5)(d) above, rules may provide for treating two or more inventions as being so linked as to form a single inventive concept for the purposes of this Act.

(7) The purpose of the abstract is to give technical information and on publication it shall not form part of the state of the art by virtue of section 2(3) above, and the Comptroller may determine whether the abstract adequately fulfils its purpose and, if it does not, may reframe it so that it does.

(8) Repealed -see Section 125A

(9) An application for a patent may be withdrawn at any time before the patent is granted and any withdrawal of such an application may not be revoked.

Section 48: Compulsory licences

(1) At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the Comptroller on one or more of the relevant grounds-

for a licence under the patent;
for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or
where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent.

(2) Subject to sections 48A and 48B below, if he is satisfied that any of the relevant grounds are established, the Comptroller may-

(a)where the application is under subsection (1)(a) above, order the grant of a licence to the applicant on such terms as the Comptroller thinks fit;
where the application is under subsection (1)(b) above, make such an entry as is there mentioned;
where the application is under subsection (1)(c) above, order the grant of a licence to the person specified in the application on such terms as the Comptroller thinks fit.

(3) An application may be made under this section in respect of a patent even though the applicant is already the holder of a licence under the patent; and no person shall be estopped or barred from alleging any of the matters specified in the relevant grounds by reason of any admission made by him, whether in such a licence or otherwise, or by reason of his having accepted a licence.

(4) In this section "the relevant grounds" means-
in the case of an application made in respect of a patent whose proprietor is a WTO proprietor, the grounds set out in section 48A(1) below;
in any other case, the grounds set out in section 48B(1) below.

(5) A proprietor is a WTO proprietor for the purposes of this section and sections 48A, 48B, 50 and 52 below if-
he is a national of, or is domiciled in, a country which is a member of the World Trade Organisation; or
he has a real and effective industrial or commercial establishment in such a country.

(6) A rule prescribing any such other period under subsection (1) above shall not be made unless a draft of the rule has been laid before, and approved by resolution of, each House of Parliament.

Section 48A: Compulsory licences: WTO proprietors

(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are-
where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;
that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms-
(i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or
(ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

(2) No order or entry shall be made under section 48 above in respect of a patent whose proprietor is a WTO proprietor unless-

the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions; and
his efforts have not been successful within a reasonable period.

(3) No order or entry shall be so made if the patented invention is in the field of semi-conductor technology.

(4) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(b)(i) above unless the Comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

(5) A licence granted in pursuance of an order or entry so made shall not be assigned except to a person to whom the patent for the other invention is also assigned.

(6) A licence granted in pursuance of an order or entry made under section 48 above in respect of a patent whose proprietor is a WTO proprietor-

shall not be exclusive;
shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part;
shall be predominantly for the supply of the market in the United Kingdom;
shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence; and
shall be limited in scope and in duration to the purpose for which the licence was granted.

Section 48B: Compulsory licences: other cases.

(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are-

where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;
where the patented invention is a product, that a demand for the product in the United Kingdom-
(i) is not being met on reasonable terms, or
(ii) is being met to a substantial extent by importation from a country which is not a member State;
where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked-
(i) where the invention is a product, by the importation of the product from a country which is not a member State,
(ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;
that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms-
(i) a market for the export of any patented product made in the United Kingdom is not being supplied, or
(ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or
(iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent,

or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

(2) Where an application is made on the ground that the patented invention is not being commercially worked in the United Kingdom or is not being so worked to the fullest extent that is reasonably practicable; and
it appears to the Comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, he may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.

(3) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(a) above if-

(a) the patented invention is being commercially worked in a country which is a member State; and
(b) demand in the United Kingdom is being met by importation from that country.

(4) No entry shall be made in the register under section 48 above on the ground mentioned in subsection (1)(d)(i) above, and any licence granted under section 48 above on that ground shall contain such provisions as appear to the Comptroller to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee

(5) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(d)(ii) above unless the Comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

Section 51: Powers exercisable in consequence of report of Competition Commission

Where a report of the Competition Commission has been laid before Parliament containing conclusions to the effect -

on a monopoly reference, that a monopoly situation exists and facts found by the Commission operate or may be expected to operate against the public interest,
on a merger reference, that a merger situation qualifying for investigation has been created and the creation of the situation, or particular elements in or consequences of it specified in the report, operate or may be expected to operate against the public interest,
on a competition reference, that a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest, or
on a reference under section 11 of the Competition Act 1980 (reference of public bodies and certain other persons), that a person is pursuing a course of conduct which operates against the public interest, the appropriate Minister or Ministers may apply to the Comptroller to take action under this section.

(2) Before making an application the appropriate Minister or Ministers shall publish, in such manner as he or they think appropriate, a notice describing the nature of the proposed application and shall consider any representations which may be made within 30 days of such publication by persons whose interests appear to him or them to be affected.

(3) If on an application under this section it appears to the Comptroller that the matters specified in the Commission's Report as being those which in the Commission's opinion operate, or operated or may be expected to operate, against the public interest include -

conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences, or
a refusal by the proprietor of a patent to grant licences on reasonable terms he may by order cancel or modify any such condition or may, instead or in addition, make an entry in the register to the effect that licences under the patent are to be available as of right.

(4) In this section "the appropriate Minister or Ministers" means the Minister or Ministers to whom the report of the Commission was made.

Section 55: Use of patented inventions for services of the Crown

(1) Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say -

where the invention is a product, may -
(i) make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or
(ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;
where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above;
without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;
may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;
may dispose or offer to dispose of anything which was made, used, imported or kept in the exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported or kept (as the case may be), and anything done by virtue of this subsection hall not amount to an infringement of the patent concerned.

(2) Any act done in relation to an invention by virtue of this section is in the following provisions of this section referred to as use of the invention; and "use", in relation to an invention, in sections 56 to 58 below shall be construed accordingly.

(3) So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a government department or the United Kingdom Atomic Energy Authority otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

(4) So far as the invention has not been so recorded or tried, any use of it made by virtue of this section at any time either -

after the publication of the application for the patent for the invention; or
without prejudice to paragraph (a) above, in consequence of a relevant communication made after the priority date of the invention otherwise than in confidence; shall be made on such terms as may be agreed either before or after the use by the government department and the proprietor of the patent with the approval of the Treasury or as may in default of agreement be determined by the Court on a reference under section 58 below.

(5) Where an invention is used by virtue of this section at any time after publication of an application for a patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) above include terms as to payment for the use, then (notwithstanding anything in those terms) any such payment shall be recoverable only -

after such a patent is granted; and
if (apart from this section) the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.

(6) The authority of a government department in respect of an invention may be given under this section either before or after the patent is granted and either before or after the use in respect of which the authority is given is made, and may be given to any person whether or not he is authorised directly or indirectly by the proprietor of the patent to do anything in relation to the invention.

(7) Where any use of an invention is made by or with the authority of a government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, the department shall notify the proprietor of the patent as soon as practicable after the second of the following events, that is to say, the use is begun and the patent is granted, and furnish him with such information as to the extent of the use as he may from time to time require.

(8) A person acquiring anything disposed of in the exercise of powers conferred by this section, and any person claiming through him, may deal with it in the same manner as if the patent were held on behalf of the Crown.

(9) In this section "relevant communication", in relation to an invention, means a communication of the invention directly or indirectly by the proprietor of the patent or any person from whom he derives title.

(10) Subsection (4) above is without prejudice to any rule of law relating to the confidentiality of information.

(11) In the application of this section to Northern Ireland, the reference in subsection (4) above to the Treasury shall, where the government department referred to in that subsection is a department of the Government of Northern Ireland, be construed as a reference to the Department of Finance for Northern Ireland.

Section 60: Meaning of infringement

(1) Subject to the provision of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say-

where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;
where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

(3) subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above.

(4) Without prejudice to section 86 below, subsections (1) and (2) above shall not apply to any act which, under any provision of the Community Patent Convention relating to the

exhaustion of the rights of the proprietor of a patent, as that provision applies by virtue of that section, cannot be prevented by the proprietor of the patent.

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -

it is done privately and for purposes which are not commercial;
it is done for experimental purposes relating to the subject-matter of the invention;
it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;
it consists of the use, exclusively for the needs of a relevant ship, of a product or process in the body of such a ship or in its machinery, tackle, apparatus or other accessories, in a case where the ship has temporarily or accidentally entered the internal or territorial waters of the United Kingdom;
it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing the United Kingdom (including the air space above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle;
it consists of the use of an exempted aircraft which has lawfully entered or is lawfully crossing the United Kingdom as aforesaid or of the importation into the United Kingdom, or the use or storage there, of any part or accessory for such an aircraft;
it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;
it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention.

(6) For the purposes of subsection (2) above a person who does an act in relation to an invention which is prevented only by virtue of paragraph (a), (b) or (c) of subsection (5) above from constituting an infringement of a patent for the invention shall not be treated as a person entitled to work the invention, but -

the reference in that subsection to a person entitled to work an invention includes a reference to a person so entitled by virtue of section 55 above, and
a person who by virtue of section 28A(4) or (5) above or section 64 below is entitled to do an act in relation to the invention without it constituting such an infringement shall, so far as concerns that act, be treated as a person entitled to work the invention.

(6A) Schedule A1 contains -

provisions restricting the circumstances in which subsection (5)(g) applies; and
provisions which apply where an act would constitute an infringement of a patent but for subsection (5)(g).

(6B) For the purposes of subsection (5)(h), use for an agricultural purpose -

includes making an animal or animal reproductive material available for the purposes of pursuing the farmer's agricultural activity; but
does not include sale within the framework, or for the purposes, of a commercial reproduction activity.

(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

(7) In this section -" relevant ship" and "relevant aircraft, hovercraft or vehicle" mean respectively a ship and an aircraft, hovercraft or vehicle registered in, or belonging to, any country, other than the United Kingdom, which is a party to the Convention for the Protection of Industrial Property signed at Paris on 20 March 1883 or which is a member of the World Trade Organisation; and "exempted aircraft" means an aircraft to which section 89 of the Civil Aviation Act 1982 (aircraft exempted from seizure in respect of patent claims) applies.

Appendix Four

Relevant Sections of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)

Article 27

Patentable Subject-Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

where the subject-matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (6) for these purposes that product;

where the subject-matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for

sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (7) of the subject-matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

authorization of such use shall be considered on its individual merits;

such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search,

knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

such use shall be non-exclusive;

such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date (8)

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

if the product obtained by the patented process is new;

if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Article 39

Protection of undisclosed information

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (10) so long as such information:

is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

has commercial value because it is secret; and

has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Declaration on the TRIPS agreement and public health (the 'Doha Statement')

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

    - in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

    - each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

    - each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

    - the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an

expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Appendix Five

Summary of Frascati Manual definition

The OECD has for many years provided the most reliable and consistent international analyses of R&D expenditures, under the guidance of the Frascati Manual which sets out how to describe and measure R&D activities. The Frascati Manual subdivides R&D into three related activities:

Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.

Applied research is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.

Experimental development is systematic work drawing on existing knowledge gained from research and practical experience that is directed to producing new materials, products or devices; to installing new processes, systems or services; or to improving substantially those already produced or installed.

Identifying the boundary between basic and applied aspects of R&D is often difficult and subjective. Many commentators combine the overlapping parts of these two categories into a wider grouping called 'strategic research'. This is achieved by taking advantage of the definitions contained in the OECD Frascati Manual. This allows for the optional further breakdown of basic research into 'pure-basic' and 'orientated-basic' and the long-standing UK practice of subdividing applied research into 'strategic-applied' and 'specific-applied'.

Strategic research is the sum of orientated-basic and strategic-applied. The definitions are:

Pure-basic research is carried out for the advancement of knowledge, without working for long-term economic or social benefits, and with no positive efforts being made to apply the results to practical problems or to transfer the results to sectors responsible for its application.

Orientated-basic research is carried out with the expectation that it will produce a broad base of knowledge likely to form the background to the solution of recognised or expected current or future problems or possibilities.

Strategic-applied research is directed toward practical aims, but has not yet advanced to the stage where eventual applications can be clearly specified.

Specific-applied research will have quite specific and detailed products, processes, systems, etc. as its aims.

The wider term 'strategic research' describes work that has evolved from pure-basic research and where practical applications are likely and feasible but cannot yet be specified, or where the accumulation of underlying technological knowledge will serve many diverse purposes.

(From Office of Science and Technology website http://www.ost.gov.uk/index_v4.htm)

Appendix Six

Tripartite Framework

1 Introduction

The following sections outline specific issues surrounding the patenting of genetic material. The object is to characterise the types of objection to undue patenting which are being voiced today with growing insistence and to suggest the types of solution which need to be investigated by the Department of Health and other healthcare providers in Europe.

2 The Tripartite Framework

As is clear from the previous passages the thinking of the Project Team has been greatly assisted by the Nuffield Discussion Paper. In addition the publication of the European Commission's Report on the implications of patent law in biotechnology and genetic engineering and the UK Patent Office guidelines for the examination of patent applications relating to biotechnological inventions provide further clarification as to the thinking of those currently charged with directing patent policy and practice in this area.

It is the view of the Project Team that together these three publications provide a tripartite framework within which it is possible to establish a Department of Health responses and management strategy as outlined in Section Two.

3 The Nuffield Bioethics Discussion Paper

As the first phase of the project was being completed, the Nuffield Council on Bioethics produced its Discussion Paper, *The Ethics of Patenting DNA* (July 2002). That document is bound to become a primary reference in the general debate about patents in the realm of human genetics. This is for two reasons. First, thanks to the Council's contacts with leading patent professionals and academics, it approaches the patent system upon its own terms and with real knowledge of its evolution and capacity for adaptation. Second, the Council has the benefit of scientific members who are highly informed about recent developments in genetic research and can offer front-line judgments upon its scientific and industrial importance. We have referred to its conclusions at various points, particularly as they relate to patents which have already been granted or are about to be, since the Department of Health's concerns are in the first instance with these rights.

We were considerably helped by the analysis in the Nuffield Discussion Paper, which divides the problems under the broad heads of:

(i) *diagnostic testing* (taking the Myriad Genetics' patents on the BRCA-1 gene and Chiron's on its test for hepatitis C as case studies);

(ii) *research tools* (taking the HGS patents on the CCR5 receptor and the various patents relating to the MSP-1 malarial antigen as case studies);

(iii) *gene therapy* by replacing faulty genes with normal versions;

(iv) *therapeutic proteins* (taking Biogen's hepatitis B virus antigens as case study).

This division of the subject allows for pertinent reflections on the application of basic patent law criteria to the current research situation in relation to each.

Much emphasis, particularly in relation to categories (i) and (ii), is placed on the rapidly shifting prospects for genetic research which accompanied the completion of the drafts of the human genome and the increasingly routine nature of gene identification and correlation, notably by *in silico* methodology. The Nuffield Discussion Paper emphasises that much of what is now being disclosed is novel only in its informational content, particularly where what is involved is the identification of potentially significant structures within the published genome. In consequence there is a strong case for treating the results as non-patentable discoveries rather than patentable as inventions. In any case, much of the research which provides information about ESTs, SNPs, the structure of proteins (etc) is today the result of straightforward routine work. Arguably it would not meet the required standard of inventive step in European patent law – a standard with which the laxer US ought also to apply.

In many cases, equally, the identification is only of potential for investigation and it has therefore to be questioned whether the requirement of industrial application (roughly equivalent to utility in US law) has been satisfied. In some cases there ought to be serious questioning, whether there has been an adequate disclosure of the invention in relation to the scope of the claim sought. When, as is frequently the case, the claim is for DNA or its expression without limitation as to use, there must be serious doubts about both these factors.

The Nuffield Discussion Paper strongly supports the case for limiting the grant of patents, even in cases where there is strong evidence of inventiveness, to claims for the genetic material in respect of the use which has been shown for it and not for all potential uses which it may prove to have in future. That limited approach is strongly resisted in some industry quarters, but the case for it has been fostered by such instances as the patents for the CCR5 receptor, subsequently found by others than the patentee to effect entry of the HIV/AIDS virus into cells.

In perhaps the most powerful paragraph in the Paper, the authors, referring to patents upon DNA sequences which are nothing more than tools for further research, write:

> "we take the view that the exercise of a monopoly over what are now essentially discoveries of genetic information accessible by routine methods is, in principle, highly undesirable. We consider that the development of a culture among those who carry out scientific research, whereby claims are made to naturally-occurring material which can be isolated by routine procedures and to which a weakly demonstrated or hypothetical utility may

be ascribed to secure some possible future value, if endorsed by the patent offices, amounts to a misapplication of the patent system" (para. 5.40)

Many of the recommendations of the Paper target the policies of Patent Offices in handling applications for patents on genetic material and procedures. It is vitally important that its discussion is taken into account in those offices. They stand as the front rank of arbiters over the public policy issues of adapting the patent system to a new and astonishing technology which is still only beginning on a journey to the production of significant medical results. The patent application process is expensive and cumbersome, but it is there because the system would be a serious danger without it. It is vital therefore that examiners in these offices go about their tasks with an awareness that this is their role and that they are something other than a minor security check to weed out flagrant abusers.

Ultimately, of course, it is for judges to decide how the law should apply to particular cases, but litigation is a very lengthy process which is reserved for those few instances where the value of the subject-matter is highly important to the contestants. All the more reason then for taking notice of the Nuffield Discussion Paper for the up-to-date and highly informative view of the range of current issues before they become the concerns of yesteryear.

The rationale for the views propounded by the Nuffield Council is given added validity through the publication, in *Nature Biotechnology* in December 2002[137], of the research results of a long-term study undertaken under the leadership of the Nuffield Council's Director, Dr Sandy Thomas. These results, which focus on data about the number and type of gene patents being granted and evaluate the statistical evidence relating to their use and impact, clearly indicate cause for concern unless action is taken to curb any overly enthusiastic approach to granting patents. The paper concludes that the problems encountered in gene patenting could be resolved by a more stringent application of the granting criteria and a limitation of the scope of protection of product patents to only the specific uses identified in the patent.

4 The European Commission's Report on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering.

Article 16(c) of the EU directive on the Legal Protection of Biotechnological Inventions requires the Commission to undertake an evaluation of the provision of patent law over biotechnological inventions every five years. The Report published by the Commission in October 2002 is the first such report and its focus is primarily in the Directive itself.

The Report provides an extensive overview of the Directive. In addition to discussing the substantive legal issues arising from the text of the Directive the Report provides detail of the action brought by the Dutch government to annul the Directive and the responses of both the Advocate General and the European Court of Justice to that action. It also explains how the Directive sits alongside the European Patent Convention and outlines its relationship with

[137] Thomas, Hopkins and Brady *Shares in the Human Genome - the Future of Patenting DNA* Nature Biotechnology December 2002, Volume 20, 1185

the international agreements such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)[138].

As with the Nuffield Discussion Paper it is not proposed to discuss the contents of the Commission's Report in great detail. The relevance of this Report for the present purposes is the reiteration of the presumption of patentability which applies to inventions involving genetic material and also the identification of two issues which the Commission intends to investigate via further research. These two issues are:

- The scope to be conferred to patents on sequences or partial sequences of genes isolated from the human body

- The patentability of human stem cells and cell lines obtained from them

(a) Integrity of the Human Body

The Report considers the issue of the patentability of inventions relating to elements isolated from the human body[139]. It stresses that "neither the human genome in its natural state, nor the crude fundamental data relating to the human genome constitute patentable inventions" and therefore that the Directive does not contravene the UNESCO Declaration on the Human Genome which bans financial gain resulting from the use of the human genome in its natural state[140]. In line with such concerns, the Report also stresses that the Directive is not intended to jeopardise the integrity of the human body and that patent protection can not be obtained from any invention "aimed at isolating from its natural state an organ of the human body".[141] In stating when elements isolated from the human might be regarded as patentable the Report emphasises the need for the isolation to be the result of a technical process and for the result of that process to meet the ordinary granting criteria of novelty, inventive step and industrial application.

(b) Cloning Genes

The Report states that given the routine nature of cloning genes it is likely that such clones will not be patentable as they will not meet the inventive step requirement.

(c) Deduction of Function via Computer

Where a computer is used to deduce the function of a gene, the Report states that this will not comprise an inventive step and the resulting 'invention' will not be patentable.

---

[138] The Report states that it is "incontestable that the [biotech patenting] Directive is fully compatible with the existing treaties" including the TRIPs Agreement.
[139] note 6 at 16
[140] www.unesco.org/ibc/en/genome/projet/index.htm
[141] *Ibid*

(d) The Granting Criteria

In respect of both novelty and inventive step, the Report makes it clear that there is no need to refine the ordinary meaning and application of these criteria within patent law. It does, however, make specific reference to the industrial application which must be shown and states that it is essential to the success of an application for an actual as opposed to speculative, function to be shown[142]. The Report appears to lend full support for a narrow interpretation of sufficiency. Article 83 of the European Patent Convention lays down that the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Furthermore, Article 84 adds that the claims must be clear and concise and be supported by the description[143]. This allows the granting office to reject applications whose claims are too broad, or more likely in discussions with the applicant, limit the claims to what is actually described in the patent. Patents should only then be granted on the gene sequences essential for the function described, and exclude those that are not indispensable for that function. The Report does make a general comment relating to the granting criteria in that it is not sufficient for only one or two of the criteria to be met, but that all three have to be appropriately demonstrated within the patent application.

(e) Ethical Issues and Patenting Inventions involving Elements of Human Origin

The Report refers to the 1996 Report of the European Group on Ethics[144] which states that the issue does carry an ethical dimension, that it is not possible to obtain a patent over simple knowledge of a gene or partial gene and that a patent will only be acceptable if the function of the gene or partial gene allows new possibilities (they cite the example of the production of new drugs) *and* that this use, which realises the new possibilities, is "sufficiently specific and identified".

(f) The Myriad Patents

The Report acknowledges the concerns raised over the Myriad patents and specifically identifies those concerns relating to freedom to undertake research and patient access to the technology contained within the patent. In respect of the former the Report states that the Directive is not intended to fetter the freedom to research and emphasises the role the research exemption plays in underlining this freedom. In respect of the latter, very importantly the Report clearly states that where a licence is refused by the patent holder then a compulsory licence should be sought although, by way of a footnote, the Report concedes that the availability of the compulsory licence will depend on the national implementation of Article 31 of TRIPs.

---

[142] In so doing the report approvingly cites the decision of the EPO in *ICOS/SmithKline Beecham* in June 2001, OJEPO 6/02 at 293 which stated that, in respect of a gene sequence, the potential utilisation must not be speculative but specific, substantial and credible.

[143] It should be pointed out that national law on the granting of patents contains numerous provisions identical to those contained in the European Patent Convention.

[144] www.europa.eu.int/comm/european_group_ethics

(g) The Scope of Protection Conferred

The Report provides an exhaustive statement referring to various recitals within the Directive which can serve to limit the scope of the patent granted. It recognises that there are legitimate concerns over the scope of some patents and, in light of technological advances, that there is a need for further review of the scope of protection granted. The Report singles out patents granted on inventions involving DNA sequences, proteins derived from those sequences and those based on ESTs and on SNPs for specific consideration.

(h) Morality

The Report simply states that the existing provisions within Article 6 provide "a clear source of legal certainty" and that the fact that the list of inventions to be regarded as contrary to morality, and therefore excluded, was non-exhaustive indicates an ability to revise the notion of what is unacceptable within the confines of the existing text.

(i) Processes for Cloning Human beings.

The Report merely states that this exclusion relates to the human body from the embryonic stage and that the fact that such a patent claim was revoked in the Edinburgh patent case[145], indicates that the exclusion is operating appropriately.

(ii) Patentability of Human Stem Cells and Cell Lines Obtained from them

The view is taken that work on human stem calls and the resulting cell lines maybe of great importance in the development of cures, especially in respect of degenerative diseases. Patent protection could play a vital role in realising this potential. The Report recognises the sensitivity of the issue and states that further discussions should take place on the question of patenting stem cells and cell lines with a particular emphasis on encouraging research in this area. Referring to the European Group on Ethics, the Report indicates that a central issue is to ensure a proper balance between the interests of the inventor and society, particularly with regard to the need to avoid overly broad patent claims.

(iii) Processes for modifying the germ line genetic identity of human beings

The Report states that this does not avoid processes for modifying somatic cells and that this is an appropriate distinction to draw in light of the value in treating genetic disorders.

(iv) Use of human embryos for industrial and commercial purposes

These are clearly excluded and the Report makes it clear that where the use is for a therapeutic or diagnostic purpose then this exclusion should not apply.

---

[145] Patent EP 0695351

In general terms the Report reinforces the views stated in the Recitals to the Directive that the Articles of the Directive both provide appropriate support for European bioscience[146] and also "takes account of society's concerns". In so doing the Articles of the Directive "comply strictly with the ethical rules recognised in the European Community".

In summary the two issues which the Commission will further review are the patentability of human stem cells and the scope of patents granted over inventions involving human genetic material. These are going to the subject of further review by the Commission. It is also important to note the statement made in the Report that "Regular assessment [of intellectual property rights] will be needed to determine whether the patent system is meeting the needs of researchers and companies"[147]. In light of this, any queries about either those issues discussed in the Report which the Commission does not view as problematic but which the Department of Health does or any new issues which the Department of Health might wish to raise, could form the basis of the next review to be undertaken in 2007/8.

5 UK Patent Office Guidelines

In September 2002 the UK Patent Office published its examination guidelines for patent applications relating to biotechnological inventions. The Guidelines recognise that developments in biotechnology mean it is difficult to set precise benchmarks as to what can be protected under a patent and also to state in absolute terms the precise nature of the granting criteria to be applied. In light of this, the Guidelines seeks to establish basic parameters recognising that these are likely to be subject to change in light of new scientific developments. The objective of the Guidelines is to train attention onto the technical criteria within patent law rather than on the more controversial issues such as whether or not patents should be available for inventions involving genetic material.

The Guidelines provide a comprehensive appraisal of the approach to be taken when evaluating the patentability of inventions involving biological material. It is not proposed to detail the Guidelines here, but rather to outline some general principles demonstrated within them and to draw out appropriate issues for further discussion. As the UK has implemented the EU Directive via the Patents Regulations 2000, the Guidelines take as their starting point the fact that this implementation establishes "beyond doubt the legitimacy of biotechnology patents in the UK". The Guidelines do not therefore address any issues relating to the question of *whether* such patents should be available but rather focus on *how* the law will be applied.

The following is a summary of those sections in the Guidelines regarded as relevant to the study. It is important to note that the Guidelines seek only to define broad perimeters within

[146] And in this the Commission directly links the function and effect of the Directive with the needs of the 'Life Science' industry as set down in an earlier Commission document *Life Sciences and Biotechnology: A Strategy for Europe* COM (2002) 27 Final.
[147] Note 6 at 6

which examiners might operate. They do not provide hard and fast rules. It is relevant to note that as these Guidelines are intended to simply outline the *practice* of the Patent Office they are not intended to act as a forum for discussion over the appropriateness of the principles being applied. However, the Guidelines do make a number of key statements on policy and these are to be applauded as they indicate a clear desire to ensure that patent law is applied in an appropriate and effective manner which is consistent with the public interest objectives which underpin the system.

(a) Novelty

(i) General

The Guidelines state that where genetic information has been isolated from a natural source for the first time then it will not lack novelty simply because it previously existed in nature. The key factor is that it must be a *first* isolation. Where it is contended that the gene claimed is not novel then the issue for consideration by the Patent Office is whether the information previously existing was sufficient to be considered *an enabling disclosure*. This means that the information about the gene must have been such that someone having access to that information would enable a person skilled in the art to reproduce the gene as claimed in the subsequent patent application. It is possible also to destroy novelty by a document or use which provides instructions leading to the supposedly novel gene or product.

The Guidelines also provide specific comment on biotechnological inventions

(ii) Product by Process claims

The Guidelines affirm that a patent over a process will extend to the product produced by that process or method and they cite the recent *Kirin-Amgen* case as authority for this.

(iii) Sequence Claims

In determining whether a gene sequence can be claimed the Guidelines state that relevance must be given to the *context* within which the sequence has been published, in order to assess whether an earlier publication will destroy novelty of the sequence now being claimed. Where the prior publication did not cover the sequence in the context which is the subject-matter of the patent, (for example if a new application has been identified), then it is unlikely that novelty will have been broken.

(b) Inventive Step

The Guidelines identify a number of concepts which relate to the determination of inventive step. These involve circumstances where the goal is known, where the invention fulfils a need, and where the invention is an obvious replacement. In addition it provides information about the person skilled in the art against whose notional skill and knowledge the question whether the invention is obvious or not is tested.

The Guidelines note that the inventiveness of claimed subject-matter will be determined by the context within which the decision to pursue a line of inquiry was taken. This could involve many different considerations including the situation where a goal is known but the route to that goal is not known. A key issue is whether the result would have been arrived at if others working in that area had merely carried on with their routine research and development. If this would have happened then, in the absence of a remarkable leap forward leading to the development, it is likely that this would not meet the inventive step requirement. Equally where all the steps leading up to achieving a particular goal are known then following these steps will equally not be regarded as non-obvious. In addition, where there is a reasonable expectation of success then the fact of attempting may not be sufficient to demonstrate that it was inventive to try – the main exception to this arises where the field of study is so new that the extent of certainty over the likelihood of success is necessarily curbed. In this instance it may be possible to show that deciding to carry out the research despite the uncertainty of outcome can involve an inventive step. The Guidelines are keen to emphasise that where the invention is alleged to rest in the production of a replacement for part of a known element the claim may fail the inventive step test if the replacement is an obvious one to try. The same argument applies where a replacement process or technique is used.

In demonstrating these approaches to determining inventive step the Patent Office sets out a number of case studies including examples from litigation such as the *Genentech, Biogen v Medeva and Kirin-Amgen* cases.

The most important statement made in the Guidelines is that, as developments in bioscience continue, it will become increasingly difficult to demonstrate an inventive step[148].

(c) Industrial Application

The requirement is that all inventions must be capable of industrial application. The Guidelines focus primarily on the identification of genetic sequences. They draw a distinction between inventions which reside within a sequence in a *gene* and inventions which reside within the sequence of a *protein.* In respect of the former where a sequence to a gene is claimed, then the sequence must be sufficiently disclosed with respect to that application or function. In the absence of this sufficient disclosure the application would fail on this ground. Where the claim is to an invention within a sequence or partial sequence for a protein, then the application will need to comply with the industrial application requirement.

The Guidelines discuss methods of medical treatment, but only to the extent that these are not regarded as being capable of industrial application.

The primary focus of the section of industrial application is on the requirement that the patent application must disclose a function or industrial application which is *specific, substantial and credible.* In using this terminology the Guidelines reflect the USPTO Guidelines for examination adopted in January 2001. Whilst the US Guidelines do not have any official

[148] This mirrors the views of many patent practitioners, see footnote 105.

status under the EPC, the language used mirrors the practice of the UK Patent Office. This approach has also been followed by the EPO in recent decisions. The Guidelines do not discuss what would constitute a specific, substantial and credible use and indeed they specifically recognise that this approach is one which has yet to be tested in the courts. They do refer to an EPO decision[149] where the failure to disclose a function for a claimed protein meant that the claimed uses of that protein were found to be purely speculative. This rendered the claims invalid for lacking credibility. It is also worth noting the approach taken by the USPTO as this could influence the UK application of this concept.

The Guidelines do not discuss the issue of whether the patent application must only refer to one function or application, which must be specific, substantive and credible, of the claimed genetic material or if it is possible to claim any number of functions only one of which must be shown to be specific, substantive and credible. An example of the possible implications of the latter rather than the former approach being the CCR5 patent. Human Genome Sciences (HGS) isolated a gene belonging to a family of cell receptors, believed to be that of chemokines, which play a role in inflammatory diseases. This gene (CCR5) was subsequently found to encode for the cell receptor which governs the entry of the HIV virus into human cells. HGS were able to show their invention had one function or application, which was specific, substantive and credible, but by the use of a broad patent claims, were able to exert their rights over a function that had not been realised at the time of the patent application. The US takes the latter view. It would have been interesting to have an indication of what the UK Patent Office would permit.

(d) Sufficiency of Disclosure

The Guidelines then go on to discuss the related concepts of sufficiency of disclosure and the requirement that the description of the invention must support the claims made. These issues are important as it is they which will determine the scope of the grant made. The Patent Office recognises that, for granting purposes (and the Guidelines are intended to operate only at the application stage) the relevant issue would be whether there is sufficiency of disclosure. The question of support for the claims will rarely be appropriate for consideration before the patent is actually granted.

In a key paragraph, the Guidelines state that *care is needed not to stifle further research and healthy competition by allowing the first person who had found a way of achieving an obviously desirable goal to monopolise every other way of doing so.*

This constitutes a welcome acknowledgement of a matter first emphasised for biotechnology by the Court of Appeal in *Genentech v. Wellcome*: there is always a need to maintain a proper public interest balance between rewarding dramatically new initiatives in new fields of technology and preventing over extensive monopolies.

[149] *ICOS Corporation/Seven Transmembrane receptor* (EP-B-0630405)

(e) Enabling Disclosure

As with any other type of patented invention, the requirement that the application provides an enabling disclosure (that is a disclosure which enables another skilled in the relevant field to perform the invention without further research and development) simply applies to providing an enabling disclosure for one embodiment of the invention. If any further investigation is required then the disclosure is insufficient and the application will fail.

(f) Scope of the Claims

This is one of the most contentious of all issues relating to gene patenting and strictly speaking this is something for determination at the point of infringement. The relevant issues for the granting stage relate to whether the information concerning the invention is sufficient to enable a person skilled in the art to perform the whole invention. If so then the scope has been properly defined.

The Guidelines do discuss the primary point of contention, namely the claiming of uses of the protected material where such use has not been identified at the point of either application or grant. The Guidelines do not engage in an extensive discussion of this point, but merely state that such a claim does not necessarily fall simply because it lacks apparent support within the claims. What the Guidelines do say is that any variant on the invention, which would include a non-identified use, could be covered if the achievement of this variant could not have been envisaged without the invention. The key to securing protection is that the variant must share a common specific activity with the already identified material. *In essence what is required is the specific disclosure of a principle of general application*. If a third parties then seeks to provide new variants or substitutes then this arguably would be obvious developments in light of the work already undertaken by the patent holder. Where a third party is required to engage on experimentation with the patented material in order to achieve a particular result not identified in the patent then this is likely to involve an new inventive step and fall outside the scope of the first patent.

(g) Reach Through Claims

Another type of claim which is cause for concern is the reach through claim. Generally speaking this is understood to refer to situations where the patent holder seeks to acquire rights in any developments made to the patented material by a third party. However, the Guidelines treat the concept slightly differently and refer to reach through claims in the context of acquiring rights over broad swathes of material. The Guidelines refer to a genus of compounds, where the research work undertaken has only applied to one specific area. The Guidelines state that unless a function can be provided which extends the specific function to the specific area to the area in general then the claim to the whole area will not be supported.

Following the discussion of the substantive issues which determine grant, the Guidelines turn to the categories of excluded material. It is not proposed to discuss the statements made relating to plants and animals as these have little resonance for the study. It is worth noting the comments made relating to discoveries, morality and claims to micro-organisms.

(h) Discoveries

The statement made in the Guidelines does not provide any additional assistance as to the distinction between a discovery and an invention. Instead the Guidelines merely reiterate the statement made in the EU Directive on the Legal Protection of Biotechnological Inventions, as introduced into UK patent law via the Patents Regulations 2000, that biological material isolated from its natural environment may be patentable notwithstanding that it previously existed in nature. They also note that the human body and the simple discovery of one of its elements are not patentable. There is some further explanation given to the status of sequences in that the Guidelines state that a sequence where it is only known as a sequence but not as a sequence with a specific function would be classified as a discovery as *nothing more is known about it other than that it exists as a piece of information.*

(i) Morality

The Guidelines merely note that the EU Directive, and the 2000 Regulations, contain a non-exhaustive list of inventions which would automatically be excluded as contrary to public policy and morality. The Guidelines do not discuss this list but simply states that there may be other inventions which might be added to this list in the future.

(j) Micro-organisms

It has long been recognised that patent protection is available over micro-organisms even where the organism itself has simply been produced via the use of a microbiological process. Claims to micro-organisms *per se* are also permitted, but it is unlikely that claims would be permitted over generalisations up to a novel species consisting of this micro-organism. It is possible to claim, in general term, genetically modified micro-organisms where these have been derived from known micro-organisms. The issue here is purely one of the inventiveness and novelty of the genetic modification. The Guidelines then provide examples of the types of micro-organism over which protection would extend. It is not proposed to discuss these in detail.

The Guidelines are very welcome as they provide the first fully clear information about the approach to be taken by the UK Patent Office in applying the general patent law concepts to biotechnological innovation. However, as they are Guidelines for practical implementation by examiners they are not intended to raise any fundamental questions about the nature of patent protection, nor are they intended to discuss alternative approaches not currently consistent with general Patent Office policy.

It is the view of the Project Team that the Nuffield Discussion Paper together with the European Commission's Report provide the theoretical context within which it is possible to identify possible routes forward in order to mitigate any inappropriate monopolisation of genetic material. The European Commission's Report together with the Patent Office Guidelines defines the current government policy thinking and practical approaches taken. Together it is submitted these provide an appropriate contextual framework for the discussion of key issues in patenting genetic material in Section Two.

Appendix Seven

Background to further research on a patented invention

1 Experimental development

In section B8(a) we drew attention to the definitions and distinctions drawn in the OECD's Frascati Manual[150] for the purpose of analysing R&D expenditure on an international scale. The classification begins with the well-known but imprecise distinction between *basic* and *applied* research. It proceeds by distinguishing a third stage -- *experimental development*. This is defined as:

> *systematic work drawing on existing knowledge gained from research and practical experience that is directed to producing new materials, products or devices; to installing new processes, systems or services; or to improving substantially those already produced or installed.*

The definition draws attention to experimental development as a valuable stage in its own right in the process of turning scientific knowledge to commercial account, representing as it does the continuing quest to improve the performance of every type of useful product, service and process. It is at this stage of innovation that exceptions for experimental use in patent laws are most likely to be applicable in practice. But in law such exceptions are not confined to any defined stage in the developmental cycle. Rather the governing criterion is whether the testing goes to improving or modifying or providing more information concerning the patented invention.

(a) Relevant aspects of patent law

The patent laws of most countries admit some form of exception which applies in the sphere of experimental development of the last kind – improving upon technology which was itself once new. But they do so in varying degrees, so that striking differences exist, as has been pointed out in outline in Section 8. Patent law pursues strategies which are related to the policy of fostering R&D through a period of market exclusivity. Those strategies are not easy to settle when it comes to the tension between sustaining an initial pioneering technology and encouraging its further development. Much of patent law is directed towards a reasonable balance between the two, but inevitably the circumstances vary considerably. Each of the following patent law requirements may therefore have a bearing:

- The restriction of patentable subject-matter to inventions with a practical outcome ("industrial applicability", "utility") and the exclusion of scientific discoveries and theories – a distinction which corresponds roughly to that between basic and applied research and one which in genomics serves in most countries to exclude patents on genes or gene fragments which have no practical applications which can be defined

[150] See Appendix Five

with some specificity (see above). This ought to leave much scientific information open to all to use free of any patent over it at all.

- The requirement that the invention be disclosed so that it can be put to practical use, and the correlative rule that the scope of the patent, as set forth in its claims, must be proportionate to that disclosure. These legal criteria ought to restrict the scope of many genetic patents, particularly those where the invention comprises one way of reaching a desired practical result, such as the recombinant expression of a known protein. Hence the whole battle over "reach-through" claiming, which has been brought into sharp focus by over-general patents for diagnostic tests and the attacks on them which have been launched in various countries after the patent has been granted

- The fact that where an improvement is made to a first invention it may be the subject of a further patent. Depending on the technological circumstances, that second patent may stand alone as being for a different technique which does not fall within the scope of the earlier patent as defined in its claims and any extension through "purposive construction" or "equivalence" Or it may operate within the compass of the first patent, so that between the two patentees cross-licences may be necessary, and a third party will need licences under each patent so long as its term has not expired. In the genetic sphere, multiple patent blockages could build up quite rapidly, and these may require unclogging by standardisation pools, backed possibly by compulsory licensing or the application of competition law.

(b) Research exemptions: legal basis

A legal exception for experimental purposes cuts significant corners. It is built upon the assumption that there exists a valid patent which would otherwise be infringed by the competitor's activity in question. Yet with the exception, further research can be undertaken without having to challenge either the validity or scope of the patent. That is its particular value. Its limitation is that where the new research leads to an improved product or procedure, the exception gives no entitlement to go into commercial production so long as the first patent remains in effect and the activity would still be within its claims. To do so would constitute infringement, unless a licence has been obtained.

(i) Legal sources in Europe

In the countries of the European Patent Convention, as outlined in section b8(a), the introduction of two separate exceptions – one for private and non-commercial use, the other for experimental use[151] – had an important consequence. Formerly, in many of these countries, experiments which used patented inventions were permitted if they were in private in a strictly limited sense – the loner in his outhouse, the professor in his laboratory. But now this is catered for under the exception for private, non-commercial use. By implication,

[151] The two exceptions occur in the Community Patent Convention, Art. 27 (not in the EPC) . They have been carried over into the national patent legislation of European states in order to ensure common rules upon the scope of patent infringement.

experimental use goes further and embraces research by commercial operations with industrial exploitation in mind. So the courts of England, Germany, France and elsewhere concluded in case-law which began in the 1980s with the decision of the English Court of Appeal in *Monsanto v. Stauffer*.[152] It is most unsatisfactory that this should have become apparent only fitfully and to an extent which still requires expert legal advice.

(ii) Medicines regulation and generic imitators: Europe and US contrasted

The context in which most of the European cases arose was specific. The introduction of new drugs requires the licence of a medicines authority for marketing. A generic company, waiting for the moment when the patent on a long-running drug expires, will wish, if possible, to gain its licence in advance of that expiry date. To do so, they often have to conduct safety tests on their own formulations of the drug. Patentees wish to be in a position to refuse licences for precisely that activity, thus buying themselves further exclusivity for a time after the end of the patent.

On a separate tack, the pharmaceutical industry secured the ability to seek an extension of patent term -- in Europe by a Supplementary Protection Certificate running for up to five years; in the US under the Hatch-Waxman Act of 1984. This special concession is granted in order to compensate for their loss of time during the patent term which results from their own need to satisfy government agencies before first introducing the drug.

In the US, when the opportunity to extend the patent term was introduced, a special exception was also created, allowing generic imitators to do their authorisation tests before expiry of the patent – otherwise the original patentee would be protected twice over.[153] In Europe, there has been no legislation to settle this second question. Nor have most courts in European countries been willing to intervene in place of legislators.[154] Most have held that, where the generic firm was testing the safety of using an already known drug in order to satisfy a regulator, that does not constitute experimental use and so will amount to infringement (there being no chance of a licence). Thus the English decision in *Monsanto v. Stauffer*, while holding that in principle research would be exempt even though it was commercial, also established that the research must be intended to add to the technological knowledge revealed in the patent specification in issue (in the general sense of "experimental research" in the Frascati Manual). It was not enough that the patented invention was being replicated in order to satisfy a regulator or to attract customers.[155]

---

[152] *supra* note 43 and see *Auchinloss v. Agricultural & Veterinary Supplies* [1999] R.P.C. 397, CA. For the case-law elsewhere in Europe, see Cornish, "Experimental Use of Patented Inventions in European Community States" (1998) 29 Int. Rev of Industrial Property and Copyright 735. For a time it seemed that, thanks to the specific language used in its legislation, the Netherlands would not be able to follow suit; but there have been signs that this is not so.

[153] Often referred to as the "Bolar" exception, this legislative change in fact reversed the decision of the Court of Appeals for the Federal circuit in. *Roche Products v. Bolar Pharmaceuticals,* 733 F. 2d 858 (1984), which held that there was no research exemption in US law extending to commercially-funded activity.

[154] One exception was the District Court of Milan, Decision of June 12, 1995.

[155] The case arose on a motion to the court for an interim injunction. The injunction was granted in relation to the defendant's field trials of a herbicide within the claimant's patent because the court considered at that stage that, even though the defendant's product was not the same as the claimant's own product, these tests were for regulation and marketing only. No injunction was granted against the defendant's in-house testing because that was probably to further knowledge about its own product.

The argument that pharmaceutical patentees should not enjoy both an extended term and the right to stop generic testing for regulatory purposes throughout that term is in principle a strong one. It has recently been accepted by the Supreme Court of Japan.[156] The Department of Health should consider whether and when it should be raised in the European context. It has, after all, long had an interest in fostering competition in drug provision in order to procure beneficial pricing of pharmaceuticals for its patients. While the encouragement of a thriving pharmaceutical industry in Britain and more generally in Europe is clearly important to the British government, it needs to be remembered that the patent incentive is primarily concerned with the intellectual commitment and financial backing that is needed at the initiatory stages of drug development. As leading economists have pointed out often enough, the returns from patents after several years of commercial production are so substantially discounted that they add very little to the persuasive value of the patent system. Those who have to judge the operation of the patent system from a broad perspective engendered by a public national health system should not feel inhibited in arguing that "double protection" has no sufficient justification, necessary though it is to have a system regulating drug safety.

The truly striking comparison with US law is that in that country the research exemption appears still to be stuck in the former position of most European patent systems before the changes begun in legislation such as the Patents Act 1977 (UK). In the US, there is a special exemption for generic companies in conducting tests to gain the regulatory authority's licence to market a drug, as already mentioned. But otherwise there is no exception unless the research is strictly non-commercial. Even work in universities and other public and charitable research institutes is not exempt if the funding comes from a commercial source. That at least is the common understanding of the US case-law. Possibly there has been no recent challenge because patentees rarely make a practice of pursuing those who are conducting genuine research along the same line of inquiry as in the patent but going beyond it.

As already pointed out, the current European view of the experimental use exemption puts biotech SMEs and their backers in a safer position to pursue further technical developments during the research stage. It will not give any indemnity at the commercialisation stage, if the result still falls within the earlier patent, whether or not the research produces an improvement which counts as a patentable invention in its own right. If there is a second patent, of course, the developer will have its own bargaining tool, especially where it has established what is for the moment the best product or service. The European balance is one which the Department ought to defend against attack at the legislative level; assert strongly against any patentee that its trying to press its luck beyond legal bounds; and explain (for all its complications) to researchers within the Health Service or associated with it (e.g. through hubs).

[156] Clinical Trials III (1999) 28 I.I.C

(c) Standard research techniques

Two particular aspects of the European exception for experimental purposes call for further discussion. The first is its restriction to research which builds upon the knowledge provided by the patent, and aims to discover something unknown about the subject-matter of the patent or to test a hypothesis about it. [157] This does not cover any use without licence of a patented research tool or medium which is needed for the research but is not being experimented upon for its own sake. The classic example in genetics has been provided by Hoffmann-La Roche's patent on polymerase chain reaction (PCR), needed for the amplification of genetic material. Work to provide an improved PCR would count as an experimental use, but not work which simply used PCR as a standard procedural step. Of course the result may be that, because of general demand, for the patented material the patentee will earn very considerable royalties and other licence fees. Such cases arouse an unease that undue reward is passing to the lucky winners of the particular jackpot. But this lottery-like effect provides a type of incentive for future R&D which is part and parcel of the market orientation of the patent system. It is hard to see that any legal challenge to the present understanding of the law would succeed, either in legislatures or in courts.

What is vital is to recognise the obverse of this aspect of experimental use. Those who patent research techniques should have a monopoly only over the technique, whether it is a product (such as PCR) or a procedure (such as a diagnostic test). They should not be entitled to "reach through" claims to inventions by others, where those inventions are related only by the fact that the patented substance or method was the standard experimental technique for the particular research being carried on. In the complexities of genetic patents it is sometimes rather difficult to spot that this is indeed what is being claimed and so nuisance patents are actually granted and may be used as commercial detonators against those who are not prepared to fight back.

The Department needs to be ready to spot what is going on and to be prepared to take a tough line with would-be licensors. It may be particularly important to pass this awareness to genetic developers who are associated with hubs.

(d) Clinical testing

As with medical experimentation in general, practical applications of genetic knowledge will require a final stage of clinical testing on human patients before the treatment, whether diagnostic or therapeutic, is made available generally. At this stage with an ultimately successful idea, the clinicians and their associates will be gaining important additional information at the same time as patients are receiving treatment. Obviously a health authority and its staff could not administer a patented gene therapy to patients across the country without having to secure a licence under the patent, simply by saying that clinicians were in the process of gaining personal knowledge about it. For there to be experimental use, there has to be more systematic investigation of unknown characteristics of the therapy or of related indications with a view ultimately to making the results available to the research

[157] see Aldous L.J., *Auchinloss v. Agricultural & Veterinary Supplies supra note 155*.

community. It is undoubtedly difficult to know what precisely a court will treat as an experimental use, as distinct from general therapy or diagnostics. Some help can be gleaned from court decisions in Europe:

- In Holland, Boehringer Mannheim, who were marketing their version of erythropoietin under licence from Kirin-Amgen as patentees, were held entitled to conduct clinical tests of their product for further medical indications.[158] However questions are raised on what basis Boehringer Mannheim were marketing erythropoietin and how much was for clinical testing and how much was for research.

- In Germany, a drug company was marketing genetically-engineered interferon-gamma under a compulsory licence from a patentee, government authorisation having been given for its use in treating rheumatoid arthritis. It conducted clinical tests for other indications (the treatment of cancer, Aids, allergies, leukaemia, asthma and chronic hepatitis). To do so amounted to experimental use needing no patent licence.[159] The exception was not limited to experiments on the protein itself, as distinct from its medical uses. They were justified because they would gain information and so would carry out scientific research. The exception would apply whether the purpose was to check statements in the patent specification or to produce further results; and the fact that the work was by an industrial firm which would ultimately seek to commercialise it did not alter the protected legal position of the researcher.

- Again in Germany, clinical trials of patented erythropoietin were permitted which aimed to produce further knowledge of patient tolerance and side-effects when using the protein for a known indication. The patentee had argued that this testing was taking place after the basic effectiveness of the formulation in humans had already been established, and that therefore the tests were directly related to the commercial potential of the drug and to securing medical authorisation for it. This argument was rejected and the decision stands as highly persuasive authority favouring a broad scope for experimental use in the context of clinical trials.[160]

Although there has not yet been any significant view of clinical testing by UK courts, it is at the very least probable that they will take a similarly broad view of experimental use in this context. For the current NHS, the issue is likely to concern the extent to which a licence from an outside patentee is needed for clinical work within hospitals. The question will not be to distinguish experiment from the furthering of commercial prospects. The main distinction will be between genuine scientific research and ordinary treatment.

There will be practical indicators of what constitutes the former:

- regular programs of research in the institution, as for instance in a teaching hospital;

---

[158] Court of Appeal of The Hague, February 3, 1994 (Docket No. 93/960), affirmed on other grounds by the Netherlands Supreme Court.

[159] German Supreme Court, *Klinische Versuche I* [1997] Reports of Patent Cases 623.

[160] German Supreme Court, *Klinische Versuche II* [1998] Reports of Patent Cases 423. See similarly *Wellcome Foundation v Parexel International & Flamel,* Tribunal de Grande Instance de Paris, 20th February 2001: Intellectual Property News Issue 17, July 2001.

- outside funding for the project (not just by a research council or charity, but also from an industry source);

- publication of results;

- no undue repetition, etc.

No one factor can be taken as conclusive in the many different situations that arise. It would appear from the European case-law, that it is only where a non-experimental objective (such as marketing or medical authorisation) is the prime or real motivation that the tests will require a licence. In other words where the Department faces a demand relating to clinical testing, it will be for the patentee to show that genuine experimentation is not one of the significant purposes of the activity. That experimentation does not have to be, as was the rule under some of the older patent laws of Europe (notably that of Germany) was that experimentation had to be the sole or predominant aim of the work. It seems from the case-law that this is no longer the case.

Appendix Eight

Background to the Specific Issues relating to Licences, Gene Testing and Clinical Trials

(a) Background

As is well-known the American company Myriad Genetics holds the patents on the BRCA 1 and 2 genes[161]. In early 2000 Rosgen and Myriad announced that they had agreed a licence agreement for the delivery of BRCA1/2 testing in the UK[162]. As a result of the exclusive nature of this agreement Rosgen might have been placed in the position whereby they could force the NHS to stop all BRCA1/2 testing in the UK unless such testing was undertaken under a licence from Rosgen. Negotiations between the NHS and Rosgen produced an agreement over which tests NHS labs would be able to perform and set the level of royalties for the testing. The main points of this agreement were:

- No licence fee, royalties or back charges for tests
- No cap on the number of patients undergoing BRCA testing in the NHS
- The agreement would be for the remaining lifetime of the patents
- Rosgen would share mutation data with the NHS
- The NHS may purchase tests from Rosgen at a discounted rate

However, Rosgen went into liquidation and the Department of Health began negotiations with Myriad, to date the content of any final agreement is unknown. Initial indications from Myriad suggest that they would wish to restrict the licence to use the BRCA1 and BRCA2 sequences in order to concentrate, in Salt Lake City, a key part of the testing process - scanning for the causative mutation in a new family. Their rationale for this is that the Myriad system brings together the best of current automated sequencing technology with informatics to allow a highly specific and sensitive test for unknown mutations in BRCA1 and BRCA2. An analysis for unknown mutations can be completed in 10 to 21 days. Their current charge for a complete sequence of both genes is $2,400.

In light of this Myriad may grant licences for laboratories in Europe only to test for characterised mutations for confirmation of diagnosis or predictive testing and for a limited set of population-specific founder mutations. Any other use of the testing kits would have to be undertaken in conjunction with Myriad and would probably involve sending sampled tissue to the US for examination by Myriad. This carries with it concerns over privacy not to mentions worries over Myriad using the sampled tissue in its research programme which would not be controlled by UK regulation. From the information available it would seem that Myriad would allow research protocols to be exempt from licence restrictions but

[161] By way of reminder the European Patent Office granted two patents to Myriad Genetics relating to an invention permitting the screening for breast and ovarian cancer - European Patents 699 754 and 705 903. The patents give Myriad rights over the processes and materials used to isolate and screen for mutations in the BRCA 1 & 2 genes.

[162] MRC publication on Patents and Licensing: http://www.ich.ucl.ac.uk/cmgs/part2/patent.htm

that they would reserve the right to define research from patient testing activities.

(b) The Impact of the Myriad Patent on Research - the US experience

In the US scientists feared that when Myriad began enforcing its patents for BRCA1/2 the cost of having the company provide its full-sequence genetic analysis would limit their research[163]. About a dozen diagnostic laboratories have been licensed by Myriad to perform a breast cancer screening test, all others can no longer offer either type of testing commercially.

Not surprisingly this caused grave concern with the result that the US National Cancer Institute intervened and reached an agreement with Myriad that offers all NIH and NCI research institutions a reduced testing rate of around $1,200 for both genes, with individual gene analysis costing $600 for BRCA1 and $750 for BRCA2. Furthermore, the agreement prevents Myriad from accessing or asserting an interest in research findings that result from these tests. This agreement *only* relates to the NIH and NCI research institutes, but could form a model for the Department of Health.

(c) The Impact of Myriad-type Patents - UK Concerns

In the absence of any ongoing use of the Myriad invention, the full impact of the type of patent held by Myriad patent has yet to be felt in the UK[164]. However, a number of points of possible tension have been identified which might arise when would require a balancing to task place between protecting the patent holder and ensuring that the patented material is widely accessible.

(d) Patent Stacking/Multiple Royalties

It is possible that any single commercial company might not hold the patents over, and therefore have the right to licence, all the important genes in any one disease. This could lead to a situation where there will be a need to obtain multiple licences in order to complete a diagnosis. In addition where a company acquires a bundle of patent rights over different, yet related, aspects of any given invention the resulting thicket of patents could make further research work difficult as the morass of patents to work around could be perceived to be impenetrable.

(e) Limitation of testing centres

At present the NHS offer a comprehensive service profile. Allowing genetic testing into disease specific entities to be concentrated in one or a few licensed centres, could lead to gross inefficiencies as resources are duplicated for each of the major diseases.

---

[163] Academy of Clinical Laboratory Physicians and Scientists Resolution: Exclusive Licenses for Diagnostic Tests 1999: http://depts.washington.edu/lmaclps/license.htm

[164] Patenting Genes – Stifling Research and Jeopardising Healthcare. http://www.genewatch.org/Patenting/Reports/Patents.pdf

(f) Commercial Uncertainty

There are also public interest concerns in that allowing a single company a monopoly on genetic testing is potentially dangerous because of commercial uncertainties. A company may become insolvent, bought out or decide to end a particular area of testing for commercial reason. This has already happened with Rosgen and Oncormed have been bought out by Gene-Logic and have discontinued testing for certain hereditary colon cancers.

(g) Research

If each new technology is to be locked into patent protection that restricts the freedom of research and development in that area, the capacity of the UK public sector and its UK biotechnology sector partners to develop a research capability and products will be severely restricted. It appears that Myriad is only prepared to grant licenses to some laboratories to carry out part of the analytical process (testing for a limited number of founder mutations and carrying out predictive and diagnostic tests based on family specific mutations found by Myriad). However, one of the central 'research' benefits of carrying out the test is the identification of unknown mutations in index cases. This will be carried out entirely by Myriad, who will use the information before any of it is released. This approach will compromise the ability of UK centres to carry out research involving mutation searching in the BRCA genes.

The Myriad approach to genetic testing and the new technologies under development concentrate in the area of detecting previously unknown mutations in the DNA of a patient. Removing this ability from the testing centre will prevent them from experiencing, evaluating and further developing these new systems to the detriment of UK centres.

(h) Cystic Fibrosis Case Study

In 1993 "The Hospital for Sick Children" in Toronto sent royalty demands to many diagnostic laboratories in the UK that offered testing services for cystic fibrosis[165]. The DH agreed a common policy and consequently individual laboratories do not have to pay royalties for CF gene testing directly. The royalty payments to the CF gene patent holders are hidden in the cost of the Elucigene CF20m kits, similar to the situation with PCR[166]. There are no restrictions on who can carry out the test (except on the basis of cost) and what can be done with the results of the test.

(i) Experimental Use

In the US the case of (John M.J. Madey v. Duke University, No. 01-1587, Fed. Cir.) decided that the experimental use defence to alleged patent infringement still exists but only in a "very narrow and strictly limited" form. The defence, "if available at all," must be established by the alleged infringer and the accusing party need not establish as part of its initial claim that use

[165] Report by the American Chamber of Commerce Executives http://www.fbr.org/projects/acce-cdc/acce_elsi_june2002.pdf
[166] [166] MRC publication on Patents and Licensing: http://www.ich.ucl.ac.uk/cmgs/part2/patent.htm

was not experimental. As discussed elsewhere in this Report, the US concept of experimental use is more limited than that employed within Europe. Nonetheless, the policy and practice of the US, when looked at in conjunction with the uncertain scope of the European research exemption in respect of clinical trials, does raise a number of issues.

A fundamental question in the area of genetic testing is does, or can, the use of the testing kit fall under the experimental use exception? The confusion arises out of the fact that clinical tests not only provide knowledge of the patient but also further our knowledge of a particular disorder. However, although an argument may be made that clinical trials in fact fall under experimental use (research on the subject-matter of the patented invention to investigate its properties, improve upon it, or to create a new product or process) it seems very unlikely that the courts would view it in this way. Perhaps if the results were not disseminated, it may fall under experimental use, but otherwise it will be seen as for commercial purposes.

The EC Report reiterated that, if research results are commercialised and these results use a technique which has already been patented, a sub-licence should be obtained from the holder of the patent. However, it went on to say that "if the latter refuses to grant this licence on reasonable grounds, a compulsory licence could be granted against equitable remuneration in accordance with the applicable national provisions in the Member States' legislation"[167]. The problem still remains as to what is "reasonable grounds".

The EC Report also reiterated that all national legislation in the Member States of the European Community contains the principle of exempting prior use, which allows anyone who had already used the invention in the European Community, or had made effective and serious preparations for such use, before the patent was filed[168], to continue such use or to use the invention as envisaged in the preparations. If clinical laboratories can show that their "home brew" test was developed before the patented invention then continued use of that kit will not infringe a subsequent patent.

[167] In so far as the conditions laid down in the national legislation for the granting of compulsory licences (which are based on Article 31 of the TRIPS Agreement) are fulfilled.

[168] Or, where priority is claimed, before the date of priority of the application on the basis of which the patent is granted.

Appendix Nine

Inventions involving human embryonic stem cells

Advances in stem cell technology have triggered questions about the patentability of:

- stem cells which have been isolated from human embryos, and
- processes involving these cells.

Uncertainty about what can be patented in this field has arisen because the Patents Act 1977, as amended to implement Directive 98/44/EC on the legal protection of biotechnological inventions, does not directly address the patentability of human embryonic stem cells. This Notice sets out what will be the Patent Office's general practice on the patentability of inventions involving such stem cells, although each case will be treated on its own merits in the light of all the relevant circumstances. Moreover, the Office's practice is subject to any future guidance from the UK courts.

(i) Processes for obtaining stem cells from human embryos

According to Paragraph 3(d) of Schedule A2 to the Patents Act 1977 uses of human embryos for industrial or commercial purposes are not patentable inventions. On this basis, the Patent Office will not grant patents for processes of obtaining stem cells from human embryos.

(ii) Human totipotent cells

Human totipotent cells have the potential to develop into an entire human body. In view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability by Paragraph 3(a) of Schedule A2 to the Patents Act 1977. The Patent Office will therefore not grant patents for human totipotent cells.

(iii) Human embryonic pluripotent stem cells

Human embryonic pluripotent stem cells, which arise from further division of totipotent cells, do not have the potential to develop into an entire human body. Moreover, although there is some opposition in the United Kingdom to research involving embryonic stem cells, a number of reports from influential UK political, medical and scientific bodies in recent years has emphasised the enormous potential of stem cell research, including embryonic stem cell research, to deliver new treatments for a wide range of serious diseases. This indicates that on balance the commercial exploitation of inventions concerning human embryonic pluripotent stem cells would not be contrary to public policy or morality in the United Kingdom. Thus, the Patent Office is ready to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability.