

# **INNOGEN SCOPING PAPER:**

## **Intellectual property protection of biotechnological inventions and related materials**

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### **Abstract**

This paper offers an overview of patenting practices in Europe, the US and elsewhere in respect of biotechnological inventions. It considers pertinent legal instruments and rulings over the last few decades as these have been influenced by, and have influenced in turn, policy matters surrounding, on the one hand, the encouragement of biotech patents for economic reasons, and on the other hand, moral concerns about such practices. The paper assumes no specialised knowledge about patenting or the patent systems of the world and accordingly begins with an introduction to the global patent regime. The paper ends with a brief account of other intellectual property rights that might also be claimed in respect of biotechnological advances. A series of detailed cases studies forms the Appendices to the paper and there is a selected bibliography and webography of additional relevant materials.

### **Introduction**

Several questions lie at the heart of the debate about the propriety of granting patents over genetic and biological materials. First, how can property rights be granted over genes which, after all, seem to be no more than mere discoveries? Second, how appropriate is it to grant a monopoly over the building blocks of life or, indeed, life itself in the guise of genetically engineered organisms? Finally, if this is to happen, what is the optimal policy to ensure that research aims are fulfilled and individual interests respected?

### **The patent regime**

It is now well established that patents can be granted over inventions that have been created using genetic material, including human material. Before considering the specifics of this area it is important to understand the institutional framework of patent law and the general criteria for patentability.

A patent is the award of a private right in return for public disclosure of an *invention*. The philosophy of the patent system is simple: a limited, yet strong, property right is granted to the inventor in return for full disclosure of his invention and on the understanding that once his patent expires anyone can exploit the invention in question. With few exceptions, a patent cannot subsist beyond 20 years.<sup>1</sup> In the meantime, society can benefit from the additional technical knowledge that has been added to the public domain and other inventors are given an

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<sup>1</sup> Supplementary Protection Certificates are available in Europe for pharmaceuticals and agrochemicals to extend the protection period by up to five years. The rationale is that such inventions are delayed in reaching the market because of stringent safety regulations and so the actual time afforded to patentees to exploit their inventions is reduced.

incentive to create, seek and, in turn, receive their own patent protection. The pattern is cyclical and, in theory, mutually beneficial.

### *Patent Offices*

Patents are granted by patent offices around the globe. A prospective patentee must currently apply in each country where protection is sought, and protection only extends to the national boundaries of the country which has granted protection. There is no such thing as a world or European patent, although application procedures have been streamlined for many countries thanks to an international agreement (Patent Cooperation Treaty (PCT), Washington 1970). The PCT is administered by the World Intellectual Property Organisation (WIPO), and is, in fact, the Organisation's biggest revenue earner. Around half of the applications dealt with through the PCT come from the United States.

The law in Europe on the grant of patents was harmonised by the European Patent Convention (1973), which now has 26 signatory states, including the 15 member states of the EU.<sup>2</sup> This Convention also established the European Patent Office, based in Munich, which has the power to grant patents under the Convention.<sup>3</sup> Note, however, these patents only have effect in the individual countries for which they are designated and, importantly, the Office has no enforcement mechanism. Disputes and challenges to patents take place in national courts.<sup>4</sup>

A proposal for a single European patent right currently lies before the institutions of the European Union.<sup>5</sup> This has been a much debated measure, and current concerns revolve around the need for a pan-European jurisdictional basis for a single patent right. This is because there is serious concern, which is well justified, that if individual member states can interpret the law in their own courts, it will water down the effectiveness of the single right. Indeed, there is already plenty of evidence of this happening since the adoption of the EPC: although the letter of the law is now the same throughout signatory countries, each country's courts have considerable margin to interpret that law as they see fit. Thus, the substantive patent rights across countries may be at variance.

The Patent Office in Newport in Gwent is responsible for the grant of patents in the United Kingdom.<sup>6</sup>

### *International influences on patent law*

Although it has been the tradition of intellectual property law first and foremost to protect rights at the national level, the international possibilities for the exploitation of intellectual property have long been appreciated. Markets do not recognise territorial boundaries, and intellectual property producers will always gravitate towards a potential market. Thus, as international trade became a more realistic possibility with the advent of the industrial revolution in the 19<sup>th</sup> century, so too industrialised nations realised that disparities between markets in terms of intellectual property protection could have an adverse impact on the rights of their intellectual property

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<sup>2</sup> The full list of countries as of February 2003 is: Austria, Bulgaria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Germany, Hungary, Finland, France, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, The Netherlands, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

<sup>3</sup> <http://www.european-patent-office.org/>

<sup>4</sup> Opposition Proceedings before the EPO do, however, exist. These can be invoked within nine months of the grant of a patent by the EPO and relate to a challenge that the patent should not have been granted for failure to meet the requirements of the law.

<sup>5</sup> [http://europa.eu.int/comm/internal\\_market/en/indprop/patent/412en.pdf](http://europa.eu.int/comm/internal_market/en/indprop/patent/412en.pdf)

<sup>6</sup> <http://www.patent.gov.uk/>

producers and, in turn, on their own economic interests. In a spirit of economic reciprocity, then, a number of countries sought to establish multilateral treaties to minimise these adverse effects. Of particular note is the *Paris Convention for the Protection of Industrial Property* (1883, as amended). Signatory countries to this Convention undertook to provide two key elements of protection. The first is *national treatment* of foreigners, which, as the name suggests, means that any individual seeking protection in a signatory country furth of his own shores must be dealt with on the same terms as if he were a national of that country. Second, this instrument sought to establish certain baselines of protection to ensure that the same kinds of ‘property’ were protected in the various Party states. Thus, the Paris Convention has as its objects: patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition. The obligation to provide this level of protection is, however, very broadly drafted. For example, the United Kingdom does not have a specific law to guard against unfair competition, yet the argument is made that the UK none the less complies with its international obligations under the Paris Convention in a piecemeal fashion, inter alia, because of the existence of common law protection measures such as the actions of passing off and breach of confidence.

The Paris Convention, and indeed many other instruments, are administered by the World Intellectual Property Organisation (WIPO) in Geneva.<sup>7</sup> Disputes and compliance measures may be dealt with through the International Court of Justice.

#### *TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994)*

This Agreement was included in the Accord which finalised the Uruguay Round of the General Agreement on Tariffs and Trade (GATT, 1994). The Agreement touches all the major forms of intellectual property right and is administered by the World Trade Organisation (WTO), also based in Geneva.<sup>8</sup> Importantly, states which do not comply with the provisions of TRIPS may face proceedings before the GATT dispute settlement procedure and this in turn may lead to the withdrawal of GATT privileges. A variable time scale for implementing TRIPS operates to ensure that developing and least developed countries have a transitional period in which to bring their laws into compliance with the Agreement.

TRIPS is similar to the Paris Convention in that it provides for national treatment and seeks to harmonise basic intellectual property provisions. However, in other respects it goes far beyond its 19<sup>th</sup> century counterpart. For example, TRIPS puts more flesh on the bones of the elements of protection required of signatory countries. Moreover, TRIPS ties these countries into many of the essential terms of the Paris Convention, even if they are not signatory to them, thereby considerably extending the reach of this instrument.<sup>9</sup> In particular, Article 27 of TRIPS obliges signatory countries to provide patent protection ‘in all fields of technology’. Although exemptions do exist,<sup>10</sup> often individual states, and especially the United States, enter bi-lateral

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<sup>7</sup> For more information on international Treaties and Agreements, see the WIPO website:

<<http://www.wipo.org/>>

<sup>8</sup> < <http://www.wto.org/>>

<sup>9</sup> Articles 2 and 9, TRIPS (1994).

<sup>10</sup> Article 27(2) and (3) provide: (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: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) 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.

agreements with other countries - and most often developing countries - to ensure that the exceptions are not invoked.

The motivation for the implementation of TRIPS is almost entirely economic. It was driven by the concerns of Western industrialised countries, and most notably the United States, who could not countenance the multi-billion dollar trade in unauthorised intellectual property that had develop over the years, despite the existence of Paris and similar international instruments in other fields of intellectual property law. One of the problems was that these Conventions had not attracted universal support, and in particular many of the countries where illicit trading was taking place were not signatories to them, and so were not subject to their terms. How then to implement a regime that could bring offending states under its influence? The answer was trade. By linking TRIPS to GATT, and so thereby bringing all signatory states under the auspices of the WTO, the relevant politicians and governments in control have been able to establish a system which is almost impossible to resist. No state in the modern world can develop without international trade, and so tight is the hold on that regime through GATT, that no state can fail to sign up, and thereby become obliged, in turn, to comply with TRIPS. The real stroke of economic genius has been to link non-compliance with TRIPS to the withdrawal of GATT privileges - in the event of an adverse ruling by the WTO - thereby potentially crippling a state's entire economy for the sake of intellectual property rights. The potential adverse impact of TRIPS compliance on developing countries has most recently been examined by the Commission on Intellectual Property Rights (Commission on Intellectual Property Rights, *Integrating IPRS and Development Policy* (2002)).<sup>11</sup>

### **Patentability Criteria**

The result of these multiple international harmonising measures now means that the substance, if not the effect, of patent law is extremely uniform around the world. Indeed, patent law is the most harmonised area of law throughout the globe. Thus, what is said in this report about criteria for patentability represents the legal position in the vast majority of states. The same is not true of the exclusion provisions. These continue to vary considerably between jurisdictions.

Patent protection will be granted provided that the inventor can show that he has produced an invention that is *new*, i.e. not part of the state of the art (in the sense of never having previously been made available to the public), *inventive* (that is, that it would not be an obvious advance to an expert in the field), and that the invention has *utility* or is capable of *industrial application* (that is, that it has a known function, or can be made or used in any kind of industry). A number of exclusion criteria also apply in many countries. Most notably, a patent will not be granted for a discovery *as such*. On one view an attempt to patent a human or animal cell line or a sequence of DNA is merely an attempt to patent that which already exists in the natural world, that is, it is an attempt to patent a discovery and not an invention. It should be borne in mind, however, that these are legal criteria which do not necessarily accord with scientific or lay conceptions of the terms. In law 'discovery' and 'invention' have particular technical meanings which reflect fundamental policy objectives of patent law, such as encouraging innovation and rewarding endeavour. In particular, while both discoveries and inventions contribute new knowledge to the sum total of human understanding, an invention does so through the application of human endeavour to produce a technical solution to an unresolved technical problem. Locating a previously unknown gene and making it accessible for further exploitation is an example of such a technical solution.

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<sup>11</sup> Report available at: <http://www.iprcommission.org/graphic/home.htm>

This is illustrated most clearly in the Guidelines issued by the European Patent Office in respect of the criterion of ‘novelty’ and the exclusion of ‘discoveries’.

### ***EPO Guidelines on discoveries:***

...the examiner should disregard the form or kind of claim and concentrate on its content in order to identify the real contribution which the subject-matter claimed, considered as a whole, adds to the known art. If this contribution is not of a technical character, there is no invention...[however]...

If a man finds out a new property of a known material or article, that is mere discovery and unpatentable. If however a man puts that property to practical use he has made an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable.

To find a substance freely occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters, and it is "new" in the absolute sense of having no previously recognised existence, then the substance per se may be patentable. An example of such a case is that of a new substance which is discovered as being produced by a micro-organism...

Thus, an invention that happens to relate to biological or genetic material can be patentable even although the material also exists in nature provided that the ‘invention’ adds something new to the state of the art - i.e. - the sum total of human knowledge. This can be achieved by removing it from its natural environment and by either describing the essential features of the invention and/or by otherwise characterising the contribution that is made by the isolation of the substance and its new-found availability.<sup>12</sup>

### *When is a naturally occurring substance ‘new’?*

The EPO Guidelines state that: ‘...it should be noted that a chemical compound, the name or formula of which was mentioned in a document, is not considered as known unless the information in the document, together, where appropriate, with knowledge generally available on the effective date of the document, enable it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.’ That is, a *known* substance can still be ‘novel’ for the purposes of patent law provided that the applicant for the patent is the first not only to describe it but also provide a means to separate it from its natural state and or make it artificially.

In the main, then, biotechnological inventions are treated in the same way as other industrial inventions.

### *Inventive Step (Non-Obviousness)*

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<sup>12</sup> See, for example, *Icos Decision* OJ EPO 6/2002 293 in which it was held that the production of a purified and isolated nucleic acid having a sequence that does not exist in nature is not a discovery (although note this patent failed on other grounds including lack of inventive step and lack of industrial applicability). Available at: [http://www.european-patent-office.org/epo/pubs/oj002/06\\_02/06\\_2932.pdf](http://www.european-patent-office.org/epo/pubs/oj002/06_02/06_2932.pdf)

It is arguable that the biggest threat to the patentability of genetic and biological material does not come from the above criteria, but rather from the requirement that the invention demonstrate ‘inventive step’, i.e that it represents a non-obviousness advance in the particular field of technology compared to what was known prior to the filing of the patent. This criterion is tested by reference to the knowledge of persons skilled in the particular area. This requires the patent office or court to identify the ‘inventive concept’ involved, to impute to the notionally skilled person the current state of the art, to identify the differences between what was invented and what was known, and to ask whether there was an obvious step taken from what was known to what was invented. The British courts have used this criterion to defeat biotechnology patents.

In *Genentech Inc.’s Patent*<sup>13</sup> the Court of Appeal considered the validity of a patent held by Genentech for human tissue plasminogen activator (t-PA) - a protein occurring naturally in the human body that assists in the dissolution of blood clots. Using recombinant DNA technology Genentech was able to produce sufficient quantities of t-PA in a sufficiently pure form to market as a therapeutic agent. At least five other teams embarked on similar work at considerable expense and with a degree of uncertainty of success. Genentech, however, won the race and sought a patent, inter alia, for t-PA produced by genetic engineering techniques and processes used in its production. Revocation<sup>14</sup> of the patent was sought, inter alia, for lack of inventive step. It was held that:

- The patent was invalid for lack of inventive step. Genentech’s goal was known, and sufficient of the theory and practice was known for them to know what they were doing. It was obvious to a person skilled in the art to set out to produce human t-PA by recombinant DNA technology. All steps taken by Genentech in finding out the composition of the relevant sequences and applying that knowledge to produce t-PA were applications of known technology without any original step.
- The fact that at least five other teams embarked towards the same goal using the same techniques was a sign of obviousness. Being the first to succeed was not enough; but if no one else had set out to produce the invention this might be evidence that it was not obvious.
- Laborious and costly effort did not necessarily involve an inventive step even if it amounted to more than the exercise of proficiency.

It has been observed that this decision seems to set a higher standard of test of obviousness for ‘hi-tech’ industries such as the biotechnology industry. Obviousness is tested by reference to the notional person skilled in the art - what would be obvious to such a person at the relevant date (priority date, normally the filing date of the application) considering the state of the art as it stood and the problem to be solved. In this case the Court of Appeal held that it was obvious to such a skilled person that t-PA could be produced using costly genetic engineering techniques even although success was by no means guaranteed. The skilled person in such a hi-tech industry, however, must possess a degree of ingenuity and inventiveness for otherwise they would not be part of the industry at all. This means that problems which are encountered on the route to the end goal are more likely to be seen as everyday run-of-the-mill hiccups for the hi-tech skilled person and therefore less likely to exhibit inventiveness in their resolution.

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<sup>13</sup> [1989] RPC 147 (CA).

<sup>14</sup> Revocation is the technical term for declaring a patent invalid. It is common in infringement actions for the alleged infringer to counterclaim that the patent is invalid and should be revoked. The most common grounds for revocation are that the invention did not in fact meet the criteria for patentability, for example that it was not new, did not involved an inventive step etc.

Invention is the norm in an industry such as biotechnology and as the law stands it seems to make sense that the concept of the skilled person, used to test obviousness, should assume the traits of those working in the field in question. Unfortunately, the application of this in practice leads to a paradox: those who make significant advances in the name of benefiting humanity, and who spend considerable sums in the process, are less likely to be rewarded by the grant of a patent in recognition of their endeavour and as a means of recouping outlays.

More recently, the Nuffield Council on Bioethics has endorsed the European (UK) interpretation on inventive step and has called for more stringent assessments of this criterion of patentability.<sup>15</sup> The Council suspects that many patents have been granted over 'inventions' that do not meet these rigorous requirements. It goes on to note, however, that the US and European interpretations of this criterion differ slightly, but to a sufficient degree to make a real difference to a prospective patentee's chances of gaining protection. Thus, while in Europe we consider the need for 'inventive step' - i.e. that there must be evidence of non-obvious inventiveness of the part of the inventor, the US interpretation focuses on 'non-obviousness' - i.e. that so long as the particularities of the result were not obvious to an expert then the criterion is satisfied. For example, that the precise sequence of bases that would appear in a recombinant DNA molecule would not be obvious to an expert. This latter is a lower threshold and consequently means that genetically engineered products remains, potentially at least, more easily patentable in the US than in Europe.

#### *Other differences between the US and Europe*

The requirement that an invention be new (or display 'novelty') is tested by reference to the state of the art. Before any invention can receive patent protection it must be shown that it has not previously been made available to the public.<sup>16</sup> Once again, however, this is a technical legal expression which has different meaning in Europe compared to other jurisdictions. In Europe, the state of the art means the sum total of human knowledge available by any means anywhere in the world. In the United States, the state of the art refers primarily to the sum total of knowledge available in the United States. Foreign knowledge becomes relevant only if it has been patented or appeared in a printed publication prior to the priority date (35 USC s.102(a)). This is a further advantage to prospective patentees in the U.S. as there is less likelihood that an invention will be anticipated.

The requirement of industrial applicability in Europe means that it must be shown that the invention can be made or used in any kind of industry, including agriculture. There is therefore no necessary requirement that the invention be of any benefit or use to society. In the United States, the equivalent criterion requires *utility*, an issue which has caused some controversy in the context of biotech patents over the years. Various attempts were made in the early 1990s to patent ESTs (Expressed Sequence Tags), being partial gene fragments with no known utility. The rationale, however, was that these might point the way to complete gene sequences and so may help to stake a claim to the full sequences once it was found. The US Patent and Trademark Office (USPTO) rejected such claims, and most notably those of the National Institutes of Health, for lack of utility: the function of the invention could not be sufficiently described. Since

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<sup>15</sup> Nuffield Council on Bioethics, *The Ethics of Patenting DNA*, July 2002.

<sup>16</sup> If the invention has been previously available then it is said that the patent application (or the invention itself) has been *anticipated*. Anticipation can occur either because another party has already invented the product or process that is the subject of the current patent application or because the prospective patentee has made his invention public before filing his patent and being given a priority date. Novelty is only tested prior to the priority date - after this an invention can enter the public domain without fear of anticipation. It is for these reasons that secrecy surrounding patenting is of paramount importance.

then the USPTO has revised its guidelines on utility (January 2001).<sup>17</sup> An invention now must show a ‘specific and substantial and credible utility’, but it should be noted that ‘credible’ here includes a theoretical credible use - i.e. it is not necessary to show that the invention actually works in order to obtain a patent. There is therefore no specific prohibition on the patenting of ESTs, or indeed, other gene variations or gene fragments such as SNPs (Single Nucleotide Polymorphisms), so long as the criteria for patentability are met. In contrast, the EC Directive on the patentability of biotechnological inventions from 1998 specifically addresses issues relating to patenting such inventions, and provides specific exclusions from patentability for certain biotechnological inventions. These are detailed below. As regards function, the Directive states that full or partial gene sequences with no known function will not be patentable. This has been endorsed most recently by the European Patent Office which has confirmed that mere speculative function for a genetically engineered gene sequence cannot lead to a conclusion that it is capable of industrial application.<sup>18</sup> Indeed, the EPO indicated that uses must be ‘specific, substantial and credible’ to meet this criterion, thereby reflecting the wording of the US model and, potentially, approximating the legal standards on both sides of the Atlantic.

Exemptions for using patented inventions exist on both sides of the Atlantic. In the US the so-called ‘Bolar’ exemption provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Note, however, there is no specific ‘research exemption’ in the United States, although some very limited common law authority has allowed it in a few cases. This, however, received its strictest interpretation yet in a Federal Circuit ruling in 2002 when the court restricted the scope of the exemption ‘strictly to philosophical enquiry only’, and made it clear that the exemption does not apply where the use ‘furthers the researcher’s legitimate business’, which the court interpreted widely.<sup>19</sup> An application to have the decision appealed currently lies before the Supreme Court of the United States. It is unlikely, however, that leave to appeal will be granted.

In Europe research protection exists in many countries on a statutory basis. Thus, for example, s.60(5)(a) of the UK Patents Act 1977 provides:

An act which...would constitute an infringement of a patent for an invention shall not do so if...it is done or experimental purposes relating to the subject-matter of the invention.

Note, however, that this is construed narrowly and does not allow the use of a patented invention to research other products, processes or phenomena unrelated to the invention itself. The research must be in relation to the protected invention and it must not be done with a view to commercial ends. The position regarding research exemptions in Europe is confused and requires clarification. As the Nuffield Council has observed: ‘...it is not clear whether the research exemption extends to clinical trials. Case law in some countries suggests that it does, in other

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<sup>17</sup> <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>

<sup>18</sup> *Ibos Decision* OJ EPO 6/2002 293, available at: [http://www.european-patent-office.org/epo/pubs/oj002/06\\_02/06\\_2932.pdf](http://www.european-patent-office.org/epo/pubs/oj002/06_02/06_2932.pdf)

<sup>19</sup> *Madey v. Duke*, 307 F 3d. 1351 (Fed. Cir. 2002).

countries, the contrary is suggested'.<sup>20</sup> Whatever the position in Europe, however, the exemption, where it exists, is invariably interpreted more generously than any counterpart in the U.S.

### **Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions<sup>21</sup>**

It was precisely because of disparities between protection mechanisms for biotechnological inventions in Europe and the US that the Institutions of the European Community decided to harmonise patent law in the field. Matters were all the more acute because certain member states, such as the Netherlands, refused to protect such invention at all within their domestic systems. The aim of the Directive is to harmonise the law throughout all 15 member states, making it clear that biotechnological inventions are patentable, subject to certain narrowly defined exceptions and limitations.

The Directive had one of the most difficult passage through the European institutions of any piece of European legislation. Although it was initiated in 1988, it was not adopted until 1998, and the European Parliament used its power of veto for the first time ever in respect of an earlier version of the law in 1995. Even now only 6 member states have implemented the provisions into their domestic laws,<sup>22</sup> provoking a very worried response from the Commission. In December 2002 the Commission formally requested the remaining nine states to implement the law or face the prospect of being taken to the European Court of Justice.

A Group of Experts has been established to monitor and advise on biotech and patenting in Europe, as was required by the Directive itself, and this Group reported for the first time in October 2002.<sup>23</sup> In essence, the Group reiterated the need, as it saw it, to maintain competitiveness through full and proper implementation of the Directive, lest Europe lose out on the enormous potential of the biotechnology market. The report reflects the contents of a January 2002 communication from the Commission which lays out a strategy for biotechnological development and protection within the European context and its regulatory frameworks.<sup>24</sup> It was followed by a public consultation,<sup>25</sup> that makes for very interesting reading and includes sections on (a) points of agreement [e.g. - need for better access to information, better education, application of the precautionary principle, support for developing countries etc.], (b) points of debate [e.g. - the benefits of biotechnology, biotechnology and food, agriculture, the environment, medicine, the role of ethics, experts and risk evaluation], and (c) points of conflict [e.g. - experiments on embryos, "patenting life", GMOs, ethical issues, and European trade policy]. The uses to which the consultation outcomes will be put include: informing the biotechnology strategy, facilitating better dialogue with society, and creating a stakeholder forum in certain areas where the Commission itself has not yet adopted a final position. In addition, there will be a review of how ethical questions are addressed at the European level, including an evaluation of the European Group on Ethics (see below).

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<sup>20</sup> Nuffield Council (2002), para 5.44, note 26.

<sup>21</sup> A full copy of the text of the Directive is available at:

[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31998L0044&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31998L0044&model=guichett)

<sup>22</sup> These are Denmark, Finland, Greece, Ireland, the United Kingdom, and Spain (as at February 2003).

<sup>23</sup> [http://europa.eu.int/comm/internal\\_market/en/indprop/invent/com02-2en.pdf](http://europa.eu.int/comm/internal_market/en/indprop/invent/com02-2en.pdf)

<sup>24</sup> For a summary of the strategy paper, see:

[http://europa.eu.int/rapid/start/cgi/guesten.ksh?p\\_action.getfile=gf&doc=IP/02/122|0|AGED&lg=EN&type=PDF](http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.getfile=gf&doc=IP/02/122|0|AGED&lg=EN&type=PDF).

<sup>25</sup> For the results of the public consultation: [http://europa.eu.int/comm/biotechnology/pdf/results\\_en.pdf](http://europa.eu.int/comm/biotechnology/pdf/results_en.pdf)

It should be noted too that the European Parliament issued a resolution on the Commission's communication in November 2002 in which it stressed its support for greater public engagement with the issues surrounding biotechnology, including its protection by legal means.<sup>26</sup> The Parliament also voiced its opposition to the apparently predominant view that in certain areas such as medicine and genetic technology the promise of biotechnology is seen as bringing benefits, while in others, such as agriculture, the emphasis is largely on the perceived risks. A more balanced view is called for across all areas of biotechnological development, and the Parliament has called upon the Commission to develop and initiate a "B-Europe" political agenda for the next few years to address the following areas: (a) Knowledge, education and the workforce, (b) public information and debate, (c) international cooperation, (d) legislation and enforcement of existing legislation, (e) consumer protection, (f) research and development, industry, employment and SMEs, (g) environment, agriculture and food, and (h) health and reproductive medicine. As regards patenting, the Parliament specifically calls upon member states to introduce a single European patent right and to implement the biotechnology Directive in a way that promotes necessary research activities in Europe, while at the same time preserving citizens' interests. In this last respect the Parliament urges the Commission to revisit the text of the Directive, and in particular Article 5 (2) to exclude the total or partial sequence of a gene isolated from the body from patentability. It is interesting to consider how this will promote research activity on a level playing field given that other competitive jurisdictions such as the US and Japan do not have these exclusions in their patent law. On ethical matters, the Parliament points to the decision of the European Patent Office in respect of the so-called "Edinburgh Patent" (discussed below) and asks member states to recognise that this demonstrates that the EPO shows due concern and respect for the ethical dimensions of patenting. Ethical policy issues related to biotechnological patenting and social shaping are the remit of the European Group on Ethics in Science and New Technologies,<sup>27</sup> which has, inter alia, already reported on ethical aspects of patenting inventions involving human stem cells.<sup>28</sup>

The remit of the formerly mentioned Expert Group is legal and technical aspects of biotechnological inventions. For 2003 this latter Group will consider, inter alia, 'the level of protection to be given to patents of sequences or partial-sequences of genes isolate from the human body (March 2003), and 'the patentability of human stem cells and cell lines derived from them' (May 2003). These are the two areas of most doubt and controversy to emerge from the public consultation and the Commission's negotiations with the member states.

*The terms of the Directive on the legal protection of biotechnological inventions*

It is important to note that the effect of the Biotechnology Directive can only be directly felt in the 15 member states of the Union. The European Patent Convention (EPC) is *not* an EC instrument, although all 15 member states are also signatories. Initially, therefore, there was concern that those countries that were signatories to the EPC but not member states of the EU would apply potentially different patent law. Indeed, given that the effect of the Directive is only to harmonise national patent laws, and the effect of the EPC is to allow the European Patent Office (EPO) to grant 'European' patents based on the terms of the Convention, there was also scope for continuing disharmony between patents granted under the different systems. However, the relevant provisions of the European Patent Convention were brought into line with the key

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<sup>26</sup> For the provisional edition of the text see:

<http://www3.europarl.eu.int/omk/omnsapir.so/calendar?APP=PDF&TYPE=PV2&FILE=p0021121EN.pdf&LANGUE=EN>

<sup>27</sup> [http://europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://europa.eu.int/comm/european_group_ethics/index_en.htm)

<sup>28</sup> [http://europa.eu.int/comm/european\\_group\\_ethics/docs/avis16\\_en.pdf](http://europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf)

Articles of the Biotechnology Directive by a Decision of the Administrative Council of the European Patent Organisation of 16 June 1999.<sup>29</sup>

The 1998 Directive is divided into five chapters, two of which, (I and IV), deal with matters of patentability, two of which, (II and III), deal with matters of scope and infringement, and one of which, (V), concerns formal issues relating to the Directive's implementation and review of its terms. It is also important to note that the Articles of the Directive are preceded by 56 recitals which explain the reasoning behind the terms of the Directive and which will be used in its interpretation.

Some comment on certain terms of the Directive is apposite.

**Article 1** confirms that biotechnological inventions shall be protected by the laws of all member states.

**Article 3** makes it clear that an invention which satisfies the criteria for patentability shall be patentable *even if* it concerns a product which consists of or contains biological material or a process by which such material is processed or produced. Moreover, biological material which is isolated from its natural environment may be patentable even if it was already to be found in nature. Once again, this makes it clear that biological material is not excluded from patentability merely because it is naturally occurring.

**Article 4** excludes certain entities from patentability, including plant and animal *varieties*. However, it should be noted that Article 4.2 states that “[i]nventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety”. This is a more generous interpretation of ‘plant and animal varieties’ than the EPO had given in previous rulings (see below).

**Article 5** establishes the principle that the human body, at various stages in its formation and development is **not** a patentable invention. Nor is the mere discovery of one of its elements, such as a gene or a partial gene sequence. However, Article 5(2) goes on to say that an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention, *even if* the structure of that element is identical to that found in its natural state. In such cases the claims in the patent application would be drafted to ensure that no monopoly was sought over the entity in its natural form, but only in its isolated form (which may be purified or reproduced artificially). Moreover, the technical application of a sequence or partial sequence of DNA must be disclosed in order to be patentable. In other words, sequences of no known function are not patentable.

**Article 6** retains a form of morality test for the Directive.

Inventions shall be considered to be unpatentable where their commercial exploitation would be contrary to ordre public or morality...the following in particular shall be considered to be unpatentable:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;

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<sup>29</sup> [http://www.european-patent-office.org/epo/ca/e/16\\_06\\_99\\_impl\\_e.htm](http://www.european-patent-office.org/epo/ca/e/16_06_99_impl_e.htm)

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

More will be said about the morality provisions relating to European patent law below.

**Article 7** gives a role to the Commission's European Group on Ethics in Science and New Technologies to evaluate all aspects of biotechnology. **Article 16** imposes obligations on the Commission to report to the Council and the Parliament on a number of matters arising from the Directive operation: (a) to report on relationship between Directive and international human rights agreements, (b) to report on the implications for genetic engineering research of failure to publish or late publishing of papers on material which is patentable and (c) to report on the implications of patenting on the biotech industry and its work. As detailed above, the first such report was issued in October 2002.

**Article 11** allows for a so-called 'farmer's privilege' in that farmers have a right to use the product of a harvest - e.g. seeds) for use on his own farm and a right to use protected live-stock for an agricultural purpose (including the right to sell provided that the sale is not related to a commercial reproduction activity).

**Article 12** provides for compulsory cross-licences for plant breeders in respect of patented plant inventions where s/he cannot exploit a plant variety for which they have, or could receive, plant variety protection without a risk of infringing the plant patent. The same scheme will apply for plant patent holders in respect of plant variety rights.

**Article 14** concerns deposit requirements and details the technical nature of access provisions.

### **The UK domestic situation**

The Patents Regulations 2000<sup>30</sup> came into force on 28 July 2000 and implement most of the terms of the EC Directive into UK law. A number of points of difference can, however, be noted between the Regulations and the Directive. In particular:

- The Directive Recitals require donor consent to the filing of a product derived directly from material taken from the donor (though not on information derived from that sample). This provision has been left out of the UK law. As a matter of strict law the Recitals of a Directive do not form part of the law requiring implementation. None the less, they represent the drafters intention and the spirit of the law, and these particular provisions were hotly contested at an earlier stage in the passage of the Directive when, originally, they were intended to be encompassed in an Article of the Directive itself.
- The British regulations talk of 'public policy or morality', rather than 'ordre public'. This is a possible route for divergence of application. 'Ordre public' is a term of art in the EPO acquiring a specific meaning, and 'public policy' similarly has a specific meaning in English law, but not one that necessarily accords with 'ordre public'. There is no evidence as yet that this will prove to be a problem.

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<sup>30</sup> Available at: <http://www.hmso.gov.uk/si/si2000/20002037.htm>

- The exclusions from patentability in the UK regulations state: “the following are not patentable”, while the Directive makes it clear that the exclusions are mere examples of exclusions, i.e. - the European list is not exhaustive of the possible examples of ‘immoral inventions’, yet the implication is that the UK list is indeed exhaustive.

### *UK practicalities*

The policy concerns surrounding biotechnological inventions were first aired by the British courts in the *Genentech* case, discussed above. Many matters were laid to rest, however, by the House of Lords ruling in *Biogen v. Medeva* which clarified the law in this area and admitted as a matter of policy the patentability of biotechnological inventions in the UK. A full analysis of this decision is offered in Appendix 1 of this paper; a brief account is sufficient for current purposes. In essence, the patent - which related to the Hepatitis B virus - was deemed to be excessively broad compared to the actual contribution which the inventors had made to the state of the art. That is, patent protection will only be given for the additional knowledge that inventors add to the sum total of human knowledge and no more. Few could argue that this is rightly so. It can be posited that this is an example of a common phenomenon that occurs whenever any emerging technology seeks patent protection, namely, that there is a period when the patent offices and the courts grapple with the implications of the new technology and usually err on the side of granting broad monopolies which are then slowly removed or whittled down once the true extent of the contribution becomes clear. In all other respects the House of Lords confirmed that biotechnological patents are subject to precisely the same criteria for patentability as any other field of technology, no more and no less. It had been argued, for example, that in addition to meeting the existing criteria it was also necessary in this area to show there was an ‘invention’ because the subject matter of biotechnological inventions was taken from naturally occurring material. This was resolutely rejected by their Lordships. Other grounds for the failure of the Biogen patent were standard grounds of objection, adding nothing new to the way in which biotech inventions will be treated. These are examined in Appendix 1.

One major issue that has beleaguered the biotechnology industry in Europe, and which was not in issue in the *Biogen* case is that concerning the morality of granting patents in this field under any circumstances. It is to a consideration of this issue that we now turn.

### **Morality and Biotechnological Patents**

There is no prohibition on the patentability of biotechnological inventions in the United States if the standard criteria such as novelty, inventive step and utility are satisfied.<sup>31</sup> Elsewhere, biotechnological patents have raised considerable moral concerns, usually vilified under the misleading banner of ‘patenting life’. Objections to biotechnological patents on moral grounds have therefore sought legal support, which can be found in a variety of instruments. For example, Article 53 of the European Patent Convention provides that:

European patents shall not be granted in respect of:

- (a) inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall

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<sup>31</sup> See Supreme Court ruling in *Diamond v Chakrabarty*, discussed above.

not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

This terminology is reflected, in part, in Article 27 of the TRIPS Agreement which allows, but does not require, signatory countries to exclude from inventions from patentability on the following grounds:

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:

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

(b) 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 European Directive imposes certain limitations on patenting, including a general prohibition on patents that are contrary to ‘morality’, but this is left undefined (Article 6, see above). Specific exclusions are also applied to the patenting of processes for cloning human beings or modifying the human germ-line, and to any processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal. As has been stated, this list is not exhaustive and represents the few, most contentious, issues that all concerned could agree upon at the time of the adoption of the Directive. It is possible to speculate that this list was effectively a political fudge to get the Directive through. By identifying and prohibiting clearly controversial areas there was a hope that this would placate the moral objectors, while at the same time the legislation would be passed permitting patenting in all but a few narrowly defined realms.

Indeed, the inherently subjective nature of morality and the increasing presumption in favour of patentability has led the patent granting institutions of Europe to interpret the morality provisions of patent law very narrowly. Thus, for example, in the *Oncomouse* case (*HARVARD/ONCO-mouse* [1991] EPOR 525) the European Patent Office (EPO) allowed a patent on a transgenic animal that had been bred as a research tool for cancer studies despite objections that it was immoral to patent life, especially when that life was created simply to suffer. The Office held - on a strictly utilitarian analysis - that the potential benefit to mankind outweighed the suffering of these animals, and as such was no bar to patent protection. Opposition proceedings were immediately instituted against the decision and these remained unresolved for a decade, during which time the patent remained in force. Eventually a resolution was found in 2001 and the scope of the patent was restricted to ‘transgenic rodents containing an

additional cancer gene' rather than 'any non-human transgenic mammal'.<sup>32</sup> A full account of the initial Onco-mouse decision is contained in Appendix 2 to this paper.

In *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* ([1995] EPOR 357) the EPO held that it was only prepared to entertain challenges on grounds of morality if actual evidence of harm to society could be demonstrated. The case concerned the patentability of crops that had been genetically modified to be resistant to herbicides, and the concern was a threat to the environment if such hybrids were released into the plant world. Applying its ruling, however, the EPO sought verifiable data that the environment was at risk from the invention. This could not be produced and the patent was granted, despite other findings that a high degree of moral opprobrium towards such inventions existed among sectors of the European population. This is not only a very limited view of morality - reducing it to an empirically-driven balancing exercise - but it also potentially signals the end of any successful challenge on such grounds. The very essence of patent law is the prohibition on releasing details of an invention into the public domain prior to applying for a patent. To do so means that the invention will not be new when it is considered for a patent because novelty is determined by examining what is already available to the public. How, then, are those who would challenge patents on the grounds of morality to acquire the necessary data about the effects of an invention in order to lodge a valid objection timeously? The permissibility of patenting genetically engineered plants was later considered by the Enlarged Board of the Appeal of the EPO which held that only claims to 'plant varieties' *as such* are excluded from patent protection. While this extends to genetically engineered plant varieties it does not rule out the possibility that 'plant-related products', including plants themselves, can receive patent protection. A full account of the ruling is given in Appendix 4. For present purposes, it is suffice to note that the practical outcome of these plant cases is that so long as you do not specifically claim *varieties* in your patent application, then a genetically engineered or otherwise 'invented' plant will be patentable.

This does not, of course, put an end to challenges on inventions based on naturally-occurring materials. The challengers simply change strategy faced with a dead-end such as is represented by these morality clause cases. Thus, for example, at the time of writing (February 2003) a challenge is before the EPO relating to corn plants with improved oil composition. The opposition proceedings have been initiated, inter alia, by the Mexican government on the grounds that the patent lacked *novelty*, i.e. that maize having the characteristics described in the patent was already known in Mexico.<sup>33</sup> This strategy has worked successfully before; for example in 2000 the Neem Tree Oil patent was revoked because of lack of novelty based on evidence from India.<sup>34</sup>

Returning to morality provisions, the EPO has also ruled that it is not immoral to use genetic material taken from consenting human beings to create genetically engineered products. In *HOWARD FLOREY/Relaxin* ([1995] EPOR 541) the Office upheld a patent for a genetically engineered form of the human H<sub>2</sub>-Relaxin protein despite challenges that it was tantamount to slavery and an attempt to patent life. The protein eases childbirth and had been derived from samples voluntarily donated by pregnant women. The Office dismissed out-of-turn the claim

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<sup>32</sup> By way of contrast the Supreme Court of Canada revoked the Harvard patent over Onco-mouse itself (but not the process to manufacture it) in December 2002, claiming that, "A higher life form is not patentable because it is not a 'manufacture' or 'composition of matter': see, *Harvard College v Canada (Commissioner of Patents)*, 5 December 2002. This ruling cannot now be changed except by express legislation. It is thought, however, that this will not be too much of a blow to the biotechnology industry for the simple reason that the Canadian market does not represent a large portion of the global biotech market. None the less, this decision is out of keeping with trends elsewhere and for that reason alone is of interest.

<sup>33</sup> For the press release on the on-going proceedings, see:  
[http://www.european-patent-office.org/news/pressrel/2003\\_02\\_07\\_e.htm](http://www.european-patent-office.org/news/pressrel/2003_02_07_e.htm)

<sup>34</sup> [http://www.european-patent-office.org/news/pressrel/2000\\_05\\_11\\_e.htm](http://www.european-patent-office.org/news/pressrel/2000_05_11_e.htm)

that this was in any way a form of slavery and was categoric in its assertion that whatever life is, it is not a string of DNA. A fuller account of this case is available at Appendix 5.

Most recently, in 2002, two cases confirmed the narrow interpretative approach of the EPO to morality questions. In *LELAND STANFORD/Modified Animal* [2002] EPOR 2 the patent for an immuno-compromised chimera mouse was upheld and the EPO ruled that the controversial nature of the technology did not, in and of itself, act as a bar to patenting. Similarly, the controversial so-called “Edinburgh patent” was initially granted over ‘animal transgenic stem cells’ but this raised controversy when it was suggested that this might lead to human cloning. In opposition proceedings before the EPO in July 2002, however, the patent was amended to exclude human or animal embryonic cells, although it still covers modified human and animal stem cells, and on this basis the patent was upheld.<sup>35</sup>

Despite these cautious rulings, the presence of a morality clause in European patent law has remained problematic in the biotechnology industry’s search for protection of its work. Objections to the European Biotechnology Directive based on moral grounds were primarily responsible for the delay in adopting the legislation. Even after its eventual adoption in July 1998, the Directive was challenged by the Netherlands, Italy and Norway before the European Court of Justice. The court took until October 2001 to uphold the validity of the law,<sup>36</sup> but nine member states have still not implemented the Directive, some on the basis that moral objections remain. For example, the French Government is in negotiations with the European Commission over the meaning of Article 5, alleging that there is inconsistency between the meaning of paras 1 and 2. Article 5 states:

‘1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. 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.’

The debacle in Europe stands in very stark contrast to the position in the United States where the Supreme Court has held that: “Congress intended statutory subject matter to include anything under the sun that is made by man” (*Diamond v. Chakrabarty* 447 US 303 (1980), 309). The main controversy in the US has been the need to demonstrate the ‘utility’ of an invention, i.e - the applicant must show a credible and substantial use for his invention that represents an advantage over the existing state of the art. It is for this reason, and not on the grounds of immorality, that partial gene sequences with no known function have been refused protection.

This divergence of approach has been criticised as being contrary to the economic interests of European states. However, on the other hand, it could be said that European law at least recognises that patenting is not a morally neutral exercise, although the objection to patenting on moral grounds is frequently founded on a misconception of the function of the patent system and the value of a patent.

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<sup>35</sup> For the press release on the ruling, see:

[http://www.european-patent-office.org/news/pressrel/2002\\_07\\_24\\_e.htm](http://www.european-patent-office.org/news/pressrel/2002_07_24_e.htm).

<sup>36</sup> C-377/98 *Kingdom of the Netherlands v Council of the European Union and the European Parliament* [2002] All ER (EC) 97. Available via the ECJ website at: <http://europa.eu.int/cj/en/index.htm>

A patent is merely a right to control new information that has been contributed to the state of the art. In particular, it is only a right to prevent others from using this information in direct public competition. It is not a property right over life as is so often claimed, nor is it a means to regulate the science and technology industries.<sup>37</sup>

But these fallacies are nevertheless perpetuated by European objections to patenting on morality grounds. At their core is a desire to prevent the creative process itself. But the patent system cannot do this. The refusal to grant a patent does not preclude the act of creation. Indeed, paradoxically it might encourage creation because a patent is merely a right to stop others exploiting an invention. If, then, such a right is denied, there is no check on the use of the science that lies at the heart of the invention.

The proper role for morality objections lies with the question of whether a monopoly right should be granted over a particular invention. The power to exclude all competitors from unauthorised use of an invention for 20 years - even those who have produced the same invention independently and innocently - is a considerable force to reckoned with, and compulsory licences are rarely granted. Added to this is the private nature of the right, which gives the distinct impression that patents are the preserve of the entrepreneurial few at the expense of the consumer public. The tension is felt most acutely in the health care sector, where pharmaceutical and biotechnological companies are often denigrated for the aggressive way in which they exploit patents to control drug and therapeutics markets, as seen most recently in the case of South Africa and access the combination therapies for the treatment of HIV infection.<sup>38</sup> The European Parliament issued a Resolution in October 2001 calling on the EPO to reconsider the grant of patents to Myriad Genetics over the genes for breast cancer, BRCA1 and BRCA2,<sup>39</sup> and opposition proceedings instigated by the Institut Curie, the Assistance Publique-Hôpitaux de Paris and the Institut Gustave-Roussy are currently before the EPO in respect of these patents. The concern is summed up by the Nuffield Council on Bioethics in its discussion paper on the ethics of patenting DNA:

The opposition is aimed at curtailing any possible deleterious consequences which might stem from sanctioning the monopoly conferred on Myriad Genetics, including the possible threat to the development of research and the identification of new tests and diagnostic methods. It has also been argued that the patent will have a serious impact on equitable access to testing. It is suggested that the monopoly is antithetical to an approach to public health that is based on a commitment to the comprehensive care of patients at high-risk.<sup>40</sup>

Moreover, and as the Council goes on to point out, because of the way in which Myriad Genetics has used its patent monopolies world-wide, 'there are currently no other methods of diagnosing the presence of the breast cancer susceptibility gene BRCA1 that can be used without infringing the patents'.<sup>41</sup>

The DOHA Declaration of November 2001, issued by the Council of Ministers of the World Trade Organisation, is designed to address some of the issues arising from the existence and

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<sup>37</sup> See further, Laurie, G.T.; 'Biotechnology and Intellectual Property: A Marriage of Inconvenience?' in McLean, S.A.M.; 'Contemporary Issues in Law, Medicine and Ethics', Aldershot, Dartmouth, 1996, chapter 12 (pp.237-267).

<sup>38</sup> For recent commentary of the pros and cons of pharmaceutical patenting and access to drugs, particularly in the context of HIV/AIDS, see Guardian Unlimited, *Special Report: AIDS*, 18 February 2003. Available at: <http://www.guardian.co.uk/aids/0,7368,405525,00.html>

<sup>39</sup> European Parliament *Resolution on the Patenting of BRCA1 and BRCA2 ('Breast Cancer') Genes* (4 October 2001, B5-0633, 0641, 0651, and 0663/2001). Available at: <http://www.cptech.org/ip/health/biotech/eu-brca.html>

<sup>40</sup> Nuffield Council, *The Ethics of Patenting DNA*, 2002, para. 4.6.

<sup>41</sup> *ibid*, para 5.4.

exercise of IPRs as these relate to public health.<sup>42</sup> The Declaration stresses the importance of interpreting and implementing the TRIPS Agreement in ways that both promote access to existing medicines and encourage the creation of new medicines.<sup>43</sup> The primary effects of the Declaration, and a separate Declaration on the issue,<sup>44</sup> is to make it incumbent on the TRIPS Council to address the use of compulsory licences by developing countries in the pharmaceutical realm, and to extend the deadline for least-developed countries to provide pharmaceutical patent protection under the TRIPS Agreement until 1 January 2016. This, of course, does not deal with the problem of individual (western) countries finding other means to ensure that developing countries provide the sort of protection they would wish, for example, by forcing the issue of bilateral treaties, linked perhaps to aid or other trade incentives, in return for ‘adequate’ patent protection.

Other innovative recommendations include the Human Genome Organisation’s Ethics Committee statement in April 2000 that: “profit-making entities dedicate a percentage (i.e. 1-3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts”. There would have to be considerable political will to make this *quid pro quo* a part of patent law, although there is no theoretical or practical reason why it should not happen. On the plus side, this form of benefit-sharing could go a long way to restoring the delicate balance between public and private interests in encouraging and protecting innovation, and it might give a more acceptable face to the prospect of patenting the human genome.

Yet further innovative proposals include the Matching Funds project supported by the U.S. Consumer Project on Technology.<sup>45</sup>

## **Other intellectual property rights relating to biotechnological developments**

### *Plant Breeders Rights*

The UPOV Convention (1961, 1991) provides for a separate form of protection for plants and related products, which, under the initial version of the Convention at least, was mutually exclusive with the patent system - i.e. - it was not possible to seek both PB rights and patent rights over the same entity. This is no longer a problem, however, and the generous interpretations in relation to plant patents, as discussed below in Appendices 3 and 4, demonstrate how overlap is possible. To obtain a PB right the new plant must be (a) new, (b) distinct, (c) uniform and (d) stable. As well as domestic PB rights in the UK, a Community Plant Variety Right is also available, although it should be noted that a Community right precludes protection by an independent national right if the former is sought. For a guide to PB Rights and the relevant law see the website of the Department for Environment, Food and Rural Affairs (DEFRA).<sup>46</sup>

### *Copyright*

Other forms of intellectual property protection might be available in respect of information derived from genetic material. For example, the generation of genetic data from tissue samples

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<sup>42</sup> For the text of the DOHA Declaration, see: [http://www.wto.org/english/res\\_e/booksp\\_e/ddec\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/ddec_e.pdf)

<sup>43</sup> For an account of the history of DOHA and its future direction, see, World Trade Organisation, *The Road to DOHA and Beyond*, 2002, available at: [http://www.wto.org/english/res\\_e/booksp\\_e/roadtodoha\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/roadtodoha_e.pdf)

<sup>44</sup> Declaration on the TRIPS Agreement and Public Health, November 2001: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

<sup>45</sup> <http://www.cptech.org/>

<sup>46</sup> <http://www.defra.gov.uk/planth/pvs/pbrguide.htm>

gives rise to information not previously available and, as such, could be subject to copyright protection. This arises whenever the information in question is stored in an accessible form such as manual or computer files. There is no need to register for protection, and copyright prevents unauthorised copying of the material by others. Copyright subsists for the life of the author of the protected material plus a prescribed number of years after his death (normally 70 years in Europe and the US). It extends to all original written or artistic works, which in a laboratory setting would include notes and journals, diagrammatic representations, and possibly even multi-dimensional models of molecules, whether virtual or real. Limitations on copyright include the need to show originality (which varies between countries), and the fact that a monopoly only exists over one's own creation. That is, only the form in which data derived from a sample are expressed is protected from unauthorised copying by another. Were that party to generate the same data independently by direct analysis of the sample, those data would attract their own copyright protection. Occasionally, academic argument has been made the copyright might protect genetic sequences per se, but this has never been accepted by any legislative or state body.<sup>47</sup>

### *Databases*

In Europe, a database of genetic data would attract automatic protection under the database right. A database is defined as: '...a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means' (Directive 96/9/EC, Article 1).<sup>48</sup> The right goes to the creator of the database when there has been substantial investment of time, money and/or effort, in either the obtaining, verification or presentation of the contents of the database. Protection includes the prohibition of unauthorised temporary or permanent reproduction of the contents of the database by any means, and in any form, in whole or in substantial part. Licences can be granted to permit uses of the database on terms to be agreed between the parties, and in payment of mutually acceptable royalties.

### *Confidentiality and restrictive covenants*

Protection of confidential information arises in many countries from the common law, i.e. judge-made law. The action of breach of confidence can serve an extremely useful purpose in protecting innovative ideas at their inception and throughout the development process, particularly when they are at too early a stage of development to apply for statutory IPRs such as patents. It is vitally important for researchers and innovators to take an integrated approach to protecting their intellectual property using common law and statutory rights together and at different stages in the innovation trajectory.

It is helpful to use the UK position as a good illustration of the utility of the law of breach of confidence. A duty of confidence arises either through contract or in circumstances which, objectively assessed, would tend to indicate that the information was confidential and that a reasonable person would realise that it was being disclosed in confidence. This is a question of fact and circumstance in every case. There is no requirement that the obligation be put in writing, although this is vastly preferable from an evidential point of view. The party claiming the duty should be able to specify which information s/he considers to be confidential and the disclosure should be put on notice of this. An actionable case arises when the information in question is

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<sup>47</sup> For argument to this effect, see Laddie, H. Prescott, P. and Vitoria, M.; 'The Modern Law of Copyright and Designs' (2000), Vol. 2, pp.1749-1753, where there is also argument that genetic molecules could be protected as an aspect of design right.

<sup>48</sup> The text of the Database Directive is available here: <http://europa.eu.int/ISPO/infosoc/legreg/docs/969ec.html>

used, or is likely to be used, without the authority of the discloser. A public interest defence is possible, but this only operates when (a) a valid public interest is identified, e.g. public safety, (b) the public interest cannot be furthered without disclosing the information, and (c) the disclosure is only made to parties who have it in their power to act to further the particular public interest.

Obligations of confidence should ideally be imposed through contract. In the UK and in the context of the employer/employee setting, the obligation of confidence does *not* come to an end with the end of the relationship. Two possible scenarios can apply. First, it is possible to include terms in the employment contract that restrict uses of confidential information after the end of the relationship. These are called restrictive covenants. These are only enforceable to the extent that they are a *reasonable* restraint on the trade of the ex-employee. Once again, this is a matter of fact and circumstance in every case, but limits can be imposed both as to the location where an ex-employee can work as well as to the time period before which s/he can work for a rival company.

Alternatively, it is even possible to constrain a former employee even if no contractual restriction on trade has been included in the employment contract. This is because the law will continue to protect the ex-employer's *trade secrets*. This is a narrower category than 'confidential information' and only covers those data which are easily and clearly separable from the ex-employee's general stock of knowledge and experience and which is vital to the ex-employer's trade interests. Examples of trade secrets can include traditional notions such as secret formulae, processes and products as well as less obvious examples such as customer lists, working practices and management models. The law allows the employer a high degree of latitude in defining what s/he considers to be a trade secret. However, where it is not possible to differentiate between the ex-employee's stock of knowledge and the claimed trade secrets of the ex-employer, the law will generally favour the ex-employee and allow him/her to use the knowledge in question.

## APPENDIX 1

### ***Biogen Inc. v Medeva plc* [1997] RPC 1, HL**

#### *Facts :*

This was an appeal to the House of Lords for infringement of a European patent with a counterclaim for revocation on four different grounds (see below). The patent in question related to the hepatitis B virus (HBV) and products were claimed which were recombinant DNA molecules displaying HBV antigen specificity. The molecules had been produced using genetic engineering techniques. Biogen had been the only company to proceed along this path for others considered that the chances of success were very remote indeed. The work was carried out by Professor Sir Kenneth Murray of the University of Edinburgh. Priority for the European patent was claimed from a earlier UK patent (Biogen 1 - 22 December 1978). The following grounds for revocation were argued by the defendants:

- ⇒ The claimed invention was obvious both at the date of application and at the priority date (Biogen 1);
- ⇒ The patent in suit was not entitled to the priority date of Biogen 1 because the latter did not contain sufficient material to support the claimed invention;
- ⇒ The claimed invention was not an invention at all; and
- ⇒ The description in the application for the patent in suit was insufficient.

The plaintiff conceded that the claimed invention was obvious at the date of application for the patent in suit but not at the date of Biogen 1.

#### *Held:*

The patent was invalid and the appeal was dismissed. The unanimous decision of the House was given by Lord Hoffman.

- The plaintiff had already conceded that the invention in suit was obvious at its application date, but was it obvious at the claimed priority date (Biogen 1)? The Court of Appeal had taken the unusual step of calling into question the interpretation of the judge at first instance (Aldous J.) of the expert evidence as to obviousness, and had come to the opposite conclusion, namely; that it had been ‘obvious to try’ to apply genetic engineering techniques to isolate the sequences in question. The view of the Court of Appeal was that once the commercial decision had been taken to apply genetic engineering techniques to the hepatitis B virus, everything that flowed thereafter was obvious. Lord Hoffman took issue with the Court of Appeal’s decision on three grounds. First, he considered that the reference to commerciality was irrelevant: ‘[t]he fact that a given experimental strategy was adopted for commercial reasons, because the anticipated rewards seemed to justify the necessary expenditure, is no reason why that strategy should not involve an inventive step’ (at 44). Second, he considered that the Court of Appeal was wrong to adopt without question the view of Aldous J. on the ‘inventive concept’ involved. To do so led to the conclusion drawn. Aldous J. had held that the inventive concept was “the idea or decision to express a polypeptide displaying HBV antigen specificity in a suitable host”. The Court of Appeal agreed with this and held that this as simply a choice to pursue an identified goal by known means. Lord Hoffman also agreed that, so stated, the concept was obvious. However, his

view of the inventive concept was different. He saw it as, ‘the idea of trying to express unsequenced eukaryotic DNA in a prokaryotic host’ (at 45). Finally, on the basis of this alternative view of the inventive concept of the invention, Lord Hoffman disagreed with the Court of Appeal which had held that the invention was obvious. Or rather, he said that he was ‘content to assume, without deciding, that what Professor Murray did [in 1978] was not obvious’ (at 46).

- As to the question of whether the European patent could claim priority from Biogen 1, Lord Hoffman held that an earlier application can only ‘support’ a later patent application if the former contained an ‘enabling disclosure’ in respect of the latter invention. That is, the earlier patent application must contain sufficient detail and description of the later invention to allow a person skilled in the particular field to ‘work’ (reproduce) the later invention. If it does not, it cannot be used to claim priority for the later invention. Did, therefore, Biogen 1 contain an enabling disclosure in respect of the later European patent? Lord Hoffman held that it did not. The European patent application of 21 December 1979 contained very wide claims for (effectively) *all* proteins made by *any* recombinant DNA techniques which display HBV antigen specificity. Thus, the monopoly, if granted, would cover *any* protein produced from HBV, by *any* genetic engineering technique (existing or yet to be discovered) and irrespective of the host cells used to express the protein (bacterial, mammalian or otherwise). What Biogen 1 disclosed (at best) was a means of crudely cutting up the DNA of hepatitis B and expressing certain kinds of proteins with certain kinds of antigen specificity in very simple host cells (prokaryotic cells). On this basis Lord Hoffman held that the claimed invention was excessively broad. This, he said, was due, ‘not to the inability of the teaching to produce all the promised results, but to the fact that the same results could be produced by different means...[t]he metaphor used by one of the witnesses was that before the genome had been sequenced everyone was working in the dark. Professor Murray invented a way of working with the genome in the dark. But he did not switch on the light and once the light was on his method was no longer needed.’ (at 51- 52).
- Was the claimed invention an ‘invention’ at all? This was an issue which had troubled the Court of Appeal in the present case, as it had done in *Genentech* to some extent. In the latter case Mustill LJ seemed to indicate (albeit vaguely at 263, *supra*) that in addition to satisfying the four criteria for patentability contained in section 1(1) of the **Patents Act 1977**, one must *also* show that one has produced ‘an invention’. Lord Hoffman was unconvinced by this argument. He noted that the drafters of the European Patent Convention, implemented into UK law by the 1977 Act “as nearly as practicable” in its entirety, considered there to be no need to define ‘invention’ since in practice to satisfy the four criteria of patentability *is* to produce an ‘invention’. He accepted that in the future it might be possible for a novel creation to satisfy all four criteria and yet not be properly describable as an ‘invention’, but he noted that neither the draftsmen of the EPC, nor those who drew up the 1977 Act, nor indeed counsel for the defendants could offer a single example of such a creation. Given this, Lord Hoffman was content to cross the bridge should he ever come to it, and determined that for the time being it was sufficient for prospective patentees simply to meet the criteria for patentability contained in section 1(1). In the only passage of substance to be uttered by any of their Lordships other than Lord Hoffman in this case, Lord Mustill (at 31 - 32) felt bound to state that he did not want to be seen to accept the view that the need for an ‘invention’ would always be an academic matter, nor that s.1(1) did not require an ‘invention’ to be demonstrated. Looking to the future he stated: ‘I believe that in some instances a close conceptual analysis of the nature of patentability will not be a waste of time.’ (at 31).

- Finally, Lord Hoffman was able to deal briefly with the question of whether the description of the invention contained in the patent application was sufficient. For, once the House had decided that no priority could be claimed from Biogen 1, it became unnecessary to rule on the question of sufficiency (the case having already been lost). Nevertheless, his Lordship stated that ‘...the reasoning by which I have come to the conclusion that the patent was not entitled to the earlier priority also, in my view, leads to the conclusion that it was insufficient’ (at 53). In other words, because the claims were too broad to be supported by Biogen 1, the description of the invention was insufficient because it could not fairly be said to describe an invention which could do everything which the patentees had claimed.

*Commentary:*

Much has been clarified by the House of Lords in this ruling. On the question of obviousness, three issues in particular merit comment. First, the problem of identifying the ‘inventive concept’. As we have seen, Lord Hoffman’s view of the essence of the invention produced by the plaintiffs differed from that of both the judge at first instance and the Court of Appeal. The consequence of this was that the House of Lords was prepared to accept that what had been done by Professor Murray in 1978 was not obvious. It was also accepted, however, that on the view of ‘inventive concept’ adopted by the lower courts, what had been done had been obvious! Thus, although the nature of what had been done is clearly a constant, the way in which it was described and interpreted led different courts to different conclusions. So often, the question of obviousness is determinative in a patent dispute, and the decision in *Biogen* demonstrates very well the need to describe as favourably as possible the ‘inventive concept’. This is, however, problematic for patentees because the question of what constitutes the ‘inventive concept’ in their invention is not for them to describe or decide. It is always a matter for the court.

The second important obviousness point to arise concerns the role of the judge at first instance. Lord Hoffman was extremely reluctant to reconsider the evidence presented to the judge by experts on matters such as obviousness. As he stated: ‘[t]he question of whether an invention was obvious has been called “a kind of jury question” (see Jenkins LJ in *Allmanna Svenska Elektriska A/B v The Burntisland Shipping Co. Ltd.* (1952) 69 RPC 63, 70) and should be treated with appropriate respect by an appellate court.’ (at 45). He went on to conclude, ‘[w]here the application of a legal standard such as negligence or obviousness involves no principle but is simply a matter of degree, an appellate court should be very cautious in differing from the judge’s evaluation.’ (at 45). It is interesting to note that after this he does not actually *rule* or *decide* that the invention in question was non-obvious. He simply states that he is prepared to assume that it is, following the trial judge. Presumably, he is following his own view that one must have good reason to overrule a ‘quasi-finding of fact’. Lord Hoffman relied on the same grounds to criticise the Court of Appeal for re-examining the evidence on whether Biogen 1 disclosed a method for making Hepatitis B surface antigen (HBsAg) and concluding that it did not (in opposition to the trial judge).

A final point can be made concerning obviousness. Although the House of Lords was prepared to assume that what Professor Murray did in 1978 was non-obvious, it should not be forgotten that by 1979 this view had changed. By 1979 the genes in HBV had been sequenced and it then became obvious to apply genetic engineering techniques to try to isolate the genes more accurately. We see too that in *Genentech* the application of such techniques was also held to be obvious. Thus, the decision in *Biogen v Medeva* does nothing to alleviate the more general problem which has beleaguered the biotechnology industry, namely, that much of its work is now obvious. In practice, this is likely to affect the patentability of products rather than processes. The development of genetically engineered molecules or other compounds by now ‘traditional’

techniques is likely to be an obvious thing to do, although the development of new processes to overcome particular hurdles in any one field might still be patentable. An exception to this however is likely to be the case where the product which is claimed had no previously known existence. If this is so, and through biotechnological techniques the product is isolated, then it will deserve to be called non-obvious, since there is no prior art against which to test its inventiveness, see *HOWARD FLOREY/Relaxin* [1995] EPOR 541.

The ruling of the House on the question of what is an ‘invention’ is to be welcomed. For all (current) practical purposes it is perfectly sensible to assume that a creation which satisfies the criteria laid down in s.1(1) of the 1977 Act is an ‘invention’. To rule otherwise would be to introduce a wide degree of discretion to the courts to exclude matter from patentability on potentially arbitrary grounds. Whereas one can accept Lord Mustill’s point that in the future we may choose or require to review this, Lord Hoffman’s response to this is correct: section 1(5) of the 1977 Act allows the Secretary of State to exclude from patentability new creations by laying an order before both Houses of Parliament. This is surely preferable to the haphazard introduction of an indistinct and undefined requirement for ‘invention’.

If one theme pervades this judgement it is that of ‘enabling disclosure’. This concept has many varied applications in the law of patents. It is used to test the criterion of ‘novelty’ (see, *Asahi Kasei Kogyo KK’s Application* [1991] RPC 485); it is used to establish priority from earlier applications (see, *Biogen v Medeva* [1997] RPC 1); it is a requirement for sufficiency of description of the invention in the patent application (s.14(3) and s.14(5)(c)), and it is a ground for revocation if the specification does not disclose the invention clearly enough or completely enough (s.72(1)(c)). What this judgement does is to confirm that the concept has the *same* meaning in each of these various contexts: there must be enough information about the invention made available to allow a person skilled in the particular art to perform the invention. Moreover, Lord Hoffman elaborated further on this meaning. In sum, what is disclosed must enable the invention to be worked *to the full extent* of the monopoly claimed. That is, if your invention embodies a principle which is capable of general application across a wide range of products, then it is permissible to claim all such products. Furthermore, Lord Hoffman confirmed that in such cases it is not necessary for the patentee to prove that his/her principle applies in all cases - one example is sufficient to amount to an enabling disclosure. However, if the patentee claims different products or processes in the same application, each must be described by a separate enabling disclosure. Moreover, if no unifying principle links the claimed inventions together, then all that can be claimed is that which can be described. In the circumstances of the present case, all that could be described (at best) was an invention for a molecule produced by crude genetic engineering techniques which exhibited antigen specificity for core and surface Hepatitis B antigens in host cells. Yet, what was claimed was an invention which covered *all* molecules displaying HBV antigen specificity produced by *any* technique using *any* host. In holding that the monopoly claimed was too broad, Lord Hoffman focused on the extent to which the invention made a technical contribution to the state of the art. The technical contribution made was a way of working with HBV to produce recombinant molecules which had antigen specificity *in the absence* of knowledge about the make-up of the base sequences. It was confirmed that monopolies will be awarded for inventions *only* to the extent that the inventions contribute to the state of the art. In particular, if there are available ways of achieving the same result without relying on the invention (and therefore without relying on its contribution to the state of the art) then those ways fall outside the monopoly which can legitimately be claimed by the patentee of the invention in question. Here, once the sequences of the HBV genes were known, it was easily possible to produce HBV antigens without using Professor Murray’s technique at all. Indeed, it was preferable to do so.

Despite the brevity with which Lord Hoffman was able to dismiss the argument surrounding sufficiency of disclosure, he nevertheless took the opportunity to settle a long-disputed matter concerning the date at which a patent specification must sufficiently enable a claimed invention. Under s.72(1)(c) revocation can be sought if the specification of a patent application does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art. However, in the past, two schools of thought have vied for supremacy on the issue of *when* the specification must so enable the invention. Either a specification had to enable the invention at the date of filing the patent application, or it had to enable the invention at the date of publication of the application. In the present case these two dates were, respectively, 21 December 1979 and 28 May 1986. Although the outcome of *Biogen* was not affected by a preference of one date over the other, it is generally the case that if the later date is preferred, it means that a patent application might not enable the claimed invention at the date of filing but can be amended to do so in light of advances in the state of the art up to the date of publication of the application. As a matter of general principle, Lord Hoffman held that the correct view is that a specification must enable the invention at the date of filing. To hold otherwise, he said, would be illogical because it would mean that a patent application which should have been rejected under s.14(3) [for not containing an enabling disclosure at the date of filing] might be rendered immune from revocation under s.72(1)(c) if it could subsequently be amended prior to publication. This is an entirely sensible view and should now hopefully put the matter beyond question.

It is important to bear in mind that the European Patent Office also had occasion to examine the patentability of Biogen's invention, given that the patent in suit was a European patent (UK) (*BIOGEN/Hepatitis B* (Decision T296/93) [1995] EPOR 1). In the EPO the patent was granted for 11 Contracting States (Austria with less claims). Opposition proceedings were commenced by four parties and initially the Opposition Division of the EPO revoked the patent. However, on appeal to the Technical Board of Appeal the validity of the patent was upheld and priority from Biogen 1 was allowed. The patent was held to be valid primarily because it was non-obvious. The test applied by the EPO was whether what was done was 'obvious to try with a reasonable expectation of success'. As we have seen, the House of Lords was merely prepared to *assume* that the invention was non-obvious on the basis of the trial judge's decision. In that decision the test for obviousness which was applied was whether the route employed by the patentee was 'obvious to try'. Arguably, the EPO test is more stringent and therefore less likely to defeat patent claims. If the House of Lords has indeed endorsed the latter test (which is unfortunately not entirely clear) then its decision in *Biogen v Medeva* perpetuates the disparity of approach to obviousness which has beleaguered many biotechnology cases.

Finally, the EPO allowed priority to be claimed from Biogen 1 on the grounds that the prior document must as a matter of substance disclose the claimed invention. By this is meant that all of the essential features of the claimed invention must be disclosed in the prior document. EPO jurisprudence has held that disclosure of the essential elements 'must be either express, or be directly and unambiguously implied by the text. Missing elements which are to be recognised as essential only later on are thus not part of the disclosure.' (*COLLABORATIVE/Preprorennin* (Decision T81/87) [1990] EPOR 361). On the facts of *Biogen* the Technical Board of Appeal held that Biogen 1 *did* disclose the essential elements of the invention, and the fact that some elements of the invention worked less successfully (the expression of HBsAg), did not affect the validity of the claim. This point is endorsed by the House of Lords - it was *not*, however, concerned with efficacy. Rather, it was concerned with the breadth of the claim over means of production. Unfortunately, this point was not addressed by the EPO. The conclusion which Lord Hoffman draws from this is that his decision is therefore not at odds with the EPO decision, because on other EPO jurisprudence his 'breadth' conclusion is supported. He is at

pains to stress that EPO decisions are highly persuasive in the UK as a matter of law (*Merrell Dow Pharmaceuticals Inc. v H.N. Norton & Co. Ltd.* [1996] RPC 76, 82). Nevertheless, one cannot help but note that not only is there an apparent duality of approach concerning ‘obviousness’, but also there is no indication of a harmonised approach to the question of priority: the requirement of an enabling disclosure and the requirement that all essential features be disclosed, do not necessarily amount to the same thing.

## APPENDIX 2

### ***HARVARD/ONCO-mouse* [1991] EPOR 525**

#### *Facts:*

Harvard University produced a mouse into the genome of which had been inserted a human cancer gene (an 'oncogene'). As a matter of course the mouse would develop strains of cancer and was by this fact allegedly useful in experimentation and clinical trials. In the US a patent was successfully awarded by the Patent and Trademark Office in 1988. However, the Examining Division of the EPO, initially at least, refused the application under the provisions of Article 53 (a) and (b). This decision is reported at [1990] EPOR 4. On appeal to the Technical Board of Appeal a different interpretation of the above sections was taken and the case remitted back to the Examining Division for reconsideration (TBA decision - [1990] EPOR 501).

#### *Held:*

- The specific wording of the claim in question related to 'non-human mammals'. This was held to be much wider than mere 'animal varieties' and therefore was not expressly excluded by Article 53(b). It was stated that, 'An 'animal variety' or 'race animal' is a sub-unit of a species and therefore of even lower ranking than a species. Accordingly, the subject-matter of the claims to animals *per se* is considered not to be covered by...Article 53(b).'
- The question of the immorality of the invention was to be tested by balancing, on the one hand the potential risks to the environment and the suffering of the animals and on the other, the potential benefits to humanity from the exploitation of such inventions. The Division accepted without question that the invention at issue was of usefulness to humanity and stated as a matter of course that the suffering to the animals was acceptable in relative terms.

#### *Commentary:*

This decision was immediately the subject of opposition proceedings brought by 16 different groups, and was not eventually resolved until an EPO ruling of November 2001 which upheld the validity of the patent but reduced its scope to transgenic rodents. The case generated much discussion about the appropriateness of morality provisions featuring in patent law at all, as well as the acceptability of the tests laid down in the decision. Certainly, morality is a highly subjective matter, and there is undeniable strength in the argument that patent examiners alone are not in a position to rule on such issues. Nonetheless, very important policy considerations underlie this decision and those considered in the other Appendices, and there is considerable pressure to conform to the American practice of effectively ignoring morality issues in the grant of a patent. This has not happened as yet, and a revised form of the morality test laid down in this case has been retained by the EC Directive which is discussed above. While the European Group on Ethics in Science and New Technologies is designated the role of advising on ethical/moral decisions, the ultimate responsibility for deciding the appropriateness of a particular patent grant will remain on the shoulders of patent examiners in individual granting countries.

## APPENDIX 3

### *PGS/Glutamine Synthetase Inhibitors [1995] EPOR 357*

#### *Facts:*

This was a decision of the Technical Board of Appeal concerning a patented invention to develop plants and seeds which were resistant to a particular class of herbicides (glutamine synthetase inhibitors). DNA had been inserted into the genome of the plants which encoded for a protein capable of neutralising or inactivating the effect of the herbicides. Opposition was raised on the basis of Article 53, primarily on the grounds that it was immoral to patent 'life' and that it was contrary to 'ordre public' to sanction the production of organisms which, if released into the environment in an uncontrolled way, could cause untold damage to the ecology of the planet.

#### *Held:*

- The concept of 'ordre public' also encompasses protection of the environment, and inventions which were contrary to public morality should rightly be denied patent protection. However, survey and opinion poll evidence on such matters was not determinative.
- Seeds and plants *per se* were not inherently unpatentable. What had been done was not 'wrong' in the light of conventionally accepted standards of conduct of European culture. The morality provision had to be interpreted narrowly as had been decided in previous cases.
- Revocation under Article 53(a) on the basis that serious prejudice to the environment might result from exploitation of such a patent, must be sufficiently sustained by appropriate evidence at the time of the EPO decision. No such evidence was forthcoming.
- However, the claims in the invention to plants themselves were not allowed because they were produced by essentially biological processes (even although initially they were subject to the microbiological processes of DNA implanting).

#### *Commentary:*

This decision is very interesting on a number of grounds (in particular the question of patentability of plants), and certainly from the perspective of the meaning of Article 53(a) it is very illuminating. It confirms once again that morality is very difficult to define and that irrespective of how we choose to do so, it should be within narrowly defined parameters. The onus is clearly on those seeking to object to the grant of the patent, for once the essential criteria of patentability (novelty, inventive step and industrial applicability) are met - it is presumed that an invention is present and good reason must be offered for not proceeding to grant.

The Technical Board of Appeal rejected survey and opinion poll evidence on the 'immorality' of patenting as inconclusive and pointed out that genetic manipulation of plant life (and indeed animal life) has always been a part of European culture. Inventions which have this as their end cannot, therefore, be unpatentable *in se*. Furthermore, because no direct evidence could be produced that the invention in question would prejudice the environment the objections under 53(a) were disallowed. The Board refused even to consider a 'balance' of interests, as had

happened in ONCOMouse, because “no sufficient evidence of actual disadvantages had been adduced” (at 373).

This is to interpret the morality provision very narrowly indeed. Evidence was led that potential risks from herbicide-resistant plants generally could be high, but no actual evidence regarding the claimed invention could be brought. Fortunately, this was so, but the attitude of the Board was that only if faced with hard evidence of actual risk having occurred to the environment from the invention would a patent be denied. Surely, however, if an invention has been allowed to pose a risk to the environment, it must have been placed in that environment. If this is so, the invention would be in the public domain; for the prospective patentee this is a problem because ultimately a patent would be refused for lack of novelty and/or obviousness. No prospective patentee will do such a thing, and therefore arguably prior to grant there will never be any evidence of an actual risk to the environment. Those who are likely to oppose such patents will not be aware of the invention prior to publication of the patent and even once they become aware they will be unlikely to be able to adduce sufficient evidence of actual risk in the time between publication and grant. After grant, only nine months are available in which to object, which again is insufficient time to gather evidence of this kind. Thus, it would seem that the interpretation given to the morality provision in this case effectively renders it useless as a ground for refusal or revocation. It has been interpreted out of existence.

It should be noted, however, that the claims in the patent to the plant itself were nevertheless revoked under Article 53(b). It was held that because the genetically altered plant could reproduce and pass on its resistance in a relatively stable manner, it qualified as a ‘plant variety’ and as such should be excluded from patentability. The argument that the plant was a product produced by a microbiological process was rejected because the insertion of the resistant gene was but one small part of the general process of replicating the plant. This stands in stark contrast to the ONCOMouse decision. There it was held that not only could the animals be claimed because they were not animal varieties, but also that the offspring of such animals could be claimed. In essence the animals were products-by-process, that is, they were the products of microbiological process; namely, genetic engineering techniques. This was so even although the mice would reproduce normally.

The Enlarged Board of Appeal refused to hold that these two decisions were in any way inconsistent (*Inadmissible referral* [1996] EPOR 505). It did so on the simple basis that what had been produced by PGS was a ‘plant variety’ *as defined by* UPOV 1991. This is problematic for many reasons.

First, there is no basis in patent law for ruling that the definition of ‘plant varieties’ under Article 53(b) need have anything to do with UPOV. Indeed, why should it, given that the 1991 provisions could not have been contemplated when the EPC was drafted.

Second, the definition of plant varieties in UPOV 1991 is more generous to plant breeders than UPOV 1961, which means paradoxically that it will exclude more from patent protection, and in particularly probably all forms of genetically engineered plants.

Third, there must be serious doubt as to whether one can persist in excluding plant varieties from patent protection given that the original reason for the exclusion has been removed by the 1991 Convention.

Finally, it is hard to see how one can in all conscience reconcile *Plant Genetic Systems* with ONCOMouse when at one level of abstraction that which has been done in each case is essentially

the same, yet different outcomes are reached. Moreover, neither exclusion has remained true to the original policy underlying its existence. 'Animals' but not 'animal varieties' are patentable (morally, rather difficult to justify), and 'plant varieties' are excluded from patent protection by reference to a convention which now permits their patentability.

If one takes a step back from all of these proceedings we see that at the heart of the 'morality' objections which are advanced against biotechnological inventions is a fear and concern about the work of the industry itself. This in turn calls into question the role of the law in regulating that work. Thus, arguably, at the end of the day the debate is really one of deciding if the law of patents is the best, or even a good way of regulating the biotechnology industry.

## APPENDIX 4

### Transgenic Plant/Novartis II G 1/98, [2000] EPOR 303

#### *Facts:*

Novartis invented a transgenic plant and sought to claim the plant, its seed, the gene used to create the transgenic product and the method of its preparation in an European patent. The EPO Examining Division rejected all claims and an appeal was lodged which went to the Technical Board of Appeal and then to the Enlarged Board of Appeal. Central to the decision is the question of what constitutes a ‘plant variety’ and whether claims can be protected which do not mention any such variety, even although the embodiment of those claims would necessarily be plant varieties.

Initially, the Technical Board of Appeal held (*NOVARTIS/Transgenic Plant* T1054/96 OJ EPO 1998, 509):

- The patent was denied in respect of the plant, the seeds and the method, but upheld in respect of the gene.
- It is irrelevant that no mention is made of ‘plant varieties’ in a patent claim if, the patent would, de facto, cover embodiments of the claims which are plant varieties.
- The Board did not ruled definitely on the question of what constitutes an ‘essentially biological process’. Three options were laid out: (a) that the process in doubt should contain no ‘essentially biological steps’, alternatively, (b) the essence of the invention must be established and a decision reached on an overall assessment of the facts and circumstances as to whether the process was ‘*essentially*’ biological [some authority exists for this - *LUBRIZOL/Hybrid Plants* [1990] EPOR 173], or (c) the process would not be ‘essentially biological’ provided that one clearly identifiable step involved non-biological human intervention. The Board did not adopt any one of these, but none the less concluded that what Novartis had done was unpatentable.
- The Board rejected the argument that what had been produced was the product of a microbiological process (which would be patentable) and stated that the test to be applied was to ask whether what had been produced was closer to the original concept of a plant variety (and so unpatentable) or to the product of a microbiological process (and so patentable). The former was held to apply.
- The claim to the gene was upheld, and so by default it would cover plants containing the gene. However, and inconsistently, the claim to the plant itself would cover plant varieties and so would not be upheld.
- A very narrow view was taken of the EC Directive, Article 4.2, and it was stated that 4.2. could be satisfied by only allowing for protection of processes claims and not products claims in respect of plants and animals. This fundamentally undermines the intention of the drafters of the Directive.

The decision of the Board of Appeal was referred to the Enlarged Board of Appeal.

*Ruling and commentary:*

(1) A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties. Such a claim, not being one to a variety, could not attract plant breeder protection, and as such the mutual exclusivity of the two systems is maintained, on this interpretation.

(2) When a claim to a process for the production of a plant variety is examined, a patent that is valid in respect of that process, will also be valid in respect of any products derived from that process, even if these are plant varieties. The Board saw no contradiction in holding that plant varieties as such are unpatentable, but allowing them indirect protection as products from processes, and indeed this was consistent with the above ruling that claims that encompass plant varieties may be valid so long as plant varieties are not claimed as such.

(3) The exception to allowing the patenting of plant varieties applies to all claims to patent plant varieties, and it is irrelevant how the plant varieties are produced. No special case is to be made of varieties created by genetic engineering techniques. The key question is whether or not a 'plant variety' is being claimed, not whether a genetically engineered plant variety is being claimed.

(4) The term 'plant variety' has to be ascertained by relying on definitions developed in the plant breeders' system - that which is excluded from patentability is the same subject matter as is protected by that system. A group of plants merely characterised by one or more single feature(s) falls short of qualifying as a plant variety. The exclusion of plant varieties should not be extended to cover other product inventions related to plants.

Under UPOV - "variety means a plant grouping within a single botanical taxon of the lowest rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be (i) defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, (ii) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (iii) considered as a unit with regard to its suitability for being propagated unchanged". N.B. A plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed.

The claimed plants in the patent are defined by certain characteristics allowing the plants to inhibit the growth of plant pathogens. The taxonomical category within the traditional characterisation system of the plant kingdom is not specified, nor any further characteristics necessary to assess homogeneity or stability of varieties within a given species. Hence, the claimed invention neither expressly nor implicitly defined a plant variety.

(5) A process for the production of plants is essentially biological if "it consists entirely of natural phenomena, these being understood as including the methods used by conventional plant breeders, such as crossing or selection." In contrast, a microbiological process for the production of plants is patentable. But it does not follow that genetically-modified plants are to be treated as products of microbiological processes, so as to allow patenting if the outcome is to allow claims to plant varieties. Mutual exclusivity of the patent and UPOV systems must be maintained. Article 4 of the EC Directive is intended to be interpreted in this sense.

## APPENDIX 5

### ***HOWARD FLOREY/Relaxin [1995] EPOR 541***

#### *Facts:*

Human H2-relaxin is a protein produced by pregnant women who are about to give birth. Its effect is to relax connective tissue around the pelvis to ease the passage of the child. Before the work and patent of Howard Florey, H2-relaxin had no previous known existence. The patent sought before the EPO was objected to on a number of grounds, including that it was a discovery and that it lacked novelty and inventive step. None of these objections was upheld. Of interest for present purposes is the fact that objections were also lodged on the grounds of morality. It was argued that the granting of the patent was tantamount to slavery of women because it involved the dismemberment of women and the sale of their parts, that it was offensive to human dignity (to use pregnant women for profit), and finally that because DNA was 'life' itself patenting of human DNA was intrinsically immoral.

#### *Held:*

- Citing prior EPO jurisprudence, the Opposition Division held that the morality provision must be interpreted narrowly. In particular, and as the EPO Guidelines suggest, the measure should be applied to prevent the grant of patents only for inventions which would universally be regarded as outrageous.
- On such an interpretation, the Opposition Division rejected the submissions of the opponents. Concerning the use of tissue taken from pregnant women, the Division relied exclusively on the importance of individual consent: if the women from whom the original material was taken consented, then what is done with the tissue cannot be immoral. The Division pointed to the multiple uses to which human tissue is already put. Furthermore, no other women need donate tissue for the invention to be repeated, because new material could easily be produced using genetic engineering techniques.
- The Division rejected out of turn the arguments that DNA was 'life' and that the granting of a patent over such DNA was tantamount to slavery. DNA is not life, but a chemical substance that carries information. Indeed, even if it were life, to grant a patent over such samples is not to give an exclusive property right in the persons from whom the tissue was taken: 'no woman is affected in any way by the present patent'.

#### *Commentary:*

This decision represents a clear policy decision by the EPO to favour the work of the biotechnology industry over the concerns of many that the work is somehow morally corrupt or corrupting. The individualistic approach of the Division to the question of consent masks wider concerns that the human genome is in very large part common to all of humanity, and ignores the fact that many members of the human race have an interest in objecting to the exploitation of that genome. Clearly, strong economic influences are behind the decision.

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## ***Webography***

### **Frequently Asked Questions about biotechnological inventions (UK Patent Office)**

<http://www.patent.gov.uk/about/ippd/faq/biofaq.htm>

### **Frequently Asked Questions about biotechnological inventions (European Commission)**

[http://europa.eu.int/comm/internal\\_market/en/indprop/invent/2k-39.htm](http://europa.eu.int/comm/internal_market/en/indprop/invent/2k-39.htm)

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### **Food Ethics Council, *TRIPS with Everything? Intellectual Property and the Farming World* (2002)**

<http://www.foodethicscouncil.org/trips.htm>

### **Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002)**

<http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf>

### **Centre for Law and Genetics (Australian site providing very useful daily update service)**

<http://www.lawgenecentre.org/>

### **Patenting Higher Life Forms and Related Issues: Report of Canadian Biotechnology Ministerial Coordinating Committee (June 2002)**

[http://www.cbac-cccb.ca/documents/en/E980\\_IC\\_IntelProp.pdf](http://www.cbac-cccb.ca/documents/en/E980_IC_IntelProp.pdf)

## ***Related Links***

**Human Genetics Commission**

<http://www.hgc.gov.uk/>

**Human Genome Organisation**

<http://www.gene.ucl.ac.uk/hugo>

**Human Genome Project Information:  
Ethical, Legal and Social Issues**

<http://www.ornl.gov/hgmis/elsi/elsi.html>

**Human Genome Project News**

<http://www.ornl.gov/hgmis/publicat/hgn/hgn.html>

**Human Genome Project - Genetics  
and Patenting**

<http://www.ornl.gov/hgmis/elsi/patents.html>

**National Human Genome Research  
Institute**

<http://www.nhgri.nih.gov/>

**News on Genetic Engineering**

<http://www.netlink.de/gen/Zeitung/2000/home.htm>

**Sheffield University's MA in Biotech &  
Law**

<http://www.shef.ac.uk/~sible/>