How Europe has learnt how to Deal with Exclusions from Patentability

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The issue of subject matter that is excluded from patentability as not being patentable subject matter is one of lively current interest in the USA. European patent law, albeit under a different legislative framework, and one which unlike that in the USA specifically lists certain exclusions from patentability, has had to grapple with similar issues, but has over time largely resolved these so as to focus instead on the more familiar issues of novelty and inventive step. This article discusses how this resolution has taken place in Europe and what conclusions can be drawn from this experience for other jurisdictions.

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The issue of subject matter that is excluded from patentability as not being patentable subject matter is one of lively current interest in the USA. The most recent decision on the subject is that of the Supreme Court on 13 June 2013 in The Association for Molecular Pathologies v Myriad Genetics Inc, holding that claims to isolated genomic DNA sequences are patent-ineligible products of nature, although claims to cDNA sequences are patent eligible. In the area of computer implemented inventions, the recent fractured en-banc decision of the Court of Appeals for the Federal Circuit (CAFC) in CLS Bank International v Alice Corporation Pty Ltd, concerning patents for a computerised trading platform used for conducting financial transactions in which the third party settles obligations between a first and a second party so as to eliminate ‘counterparty’ or ‘settlement’ risk shows the apparently confused state into which US law as to subject matter eligibility was thrown by the earlier Supreme Court decisions in Bilski v Kappos in 2010 and Mayo v Prometheus in 2012.

The common feature of all of these decisions has been a focus on patent eligibility (under Section 101 to the Patent Act) to the exclusion of any consideration of those traditional stalwarts of the patent system, namely novelty and obviousness (under Sections 102 and 103 respectively). This focus on patent eligibility as opposed to novelty and obviousness, rather than the specifics of the reasoning that has been adopted in these cases, has a resonance with similar controversies that have taken place in the past in Europe as to exclusions from patentability but which have to a large extent now been resolved.

Exclusions from Patentability in Europe

Whereas the exclusions from patentability in US patent law as manifested in such recent case law on patent eligibility have largely been created by the courts (and notably the Supreme Court) in interpreting the broad, unspecific and apparently permissive language of Section 101 of the Patent Act, Europe has had to come to terms with several specific exclusions from patentability which were expressly listed in the European Patent Convention (EPC) when it was signed in 1973. They are now set out in Articles 52(2) EPC, which is however subject to Article 52(3) EPC:

Article 52
1 - European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
2 - The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
   (a) discoveries, scientific theories and mathematical methods;

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(b) aesthetic creations;
(c) schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers;
(d) presentations of information.

3 - Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

The expression ‘invention’ is not defined, but Article 52(2), by listing specific examples of things which are not regarded as inventions, gives a pointer towards its scope. The European Patent Office (EPO) has drawn attention to the fact that the items on this list are all either abstract (e.g. discoveries, scientific theories, etc.) and/or non-technical (e.g. aesthetic creations or presentations of information), from which it has concluded that an ‘invention’ for these purposes must be of both a concrete and a technical character.

For completeness Article 53 EPC should also be mentioned, as this sets out under the heading ‘exceptions’ three types of invention for which patents cannot be granted:

**Article 53**

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to ‘ordre public’ or morality; such exploitation shall 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 shall not apply to microbiological processes or the products thereof;
(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Although Article 53 (ref. 7), along with Article 52(2) (a) as to discoveries, finds application in the life sciences sector, the interpretation of the ‘exceptions’ listed in Article 53, each of which has a clear rationale, and which in the cases of Article 53(b) and (c) are primarily concerned with how certain inventions should be claimed, does not really touch on the issue of patentable subject matter. In contrast, Articles 52(2) (c) and (d), in addition to Article 52(2) (a), are encountered in the context of computer implemented inventions and business methods.

**Exclusions from Patentability and DNA Sequences**

In the USA, the Supreme Court has in *The Association for Molecular Pathologies v Myriad Genetics Inc* now reversed the CAFC and held that a segment of naturally occurring (i.e. genomic) DNA is a product of nature and is not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring. In contrast in Europe there has for the last 15 years been no doubt that isolated genomic DNA (and *a fortiori* cDNA) is potentially patentable subject matter by virtue of Article 5(2) of the Biotechnology Directive, which provides:

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 reasoning behind this provision is explained in Recitals 20 and 21 to the Directive:

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;
The Guidelines for Examination in the EPO\textsuperscript{9} relate this approach to DNA sequences to a more general principle, long established in European patent laws, when applied to discoveries (emphasis added):

To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. \textit{Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.}

The Biotechnology Directive had a long and painful legislative history\textsuperscript{10} and Article 5(2) appeared when it became law to do no more than restate the position that had already been reached by the EPO. However in retrospect it can be seen that by enshrining in legislation the principle that an isolated DNA sequence is no mere discovery, excluded from patentability by Article 52(2) (a) EPC, (as is reflected also in Article 5(1) of the Directive), Article 5(2) of the Directive forced the analysis of claims to such sequences to take place in the context of inventive step and sufficiency (as well, on occasion, and in the light of subsequent developments unnecessarily and unhelpfully, industrial applicability).\textsuperscript{11} It is suggested that this is a more suitable framework within which to assess which alleged inventions merit the grant of a patent and if so what claim scope is appropriate.

**Exclusions from Patentability for Computer Implemented Inventions and Business Methods**

Although European practice differs considerably as between business methods and computer implemented inventions, because most patent applications for business methods are computer implemented it is convenient to consider the two together.

Recognising that much that would have been regarded as patentable previously should not be excluded from patentability simply because it happens to be implemented by means of computer program, the EPO has, after a protracted process of development of case law in its Boards of Appeal, adopted a narrow interpretation of the exclusion under Article 52(2) (c) EPC in the case of computer programs. This has allowed it to grant numerous patents for many computer-implemented inventions by focusing increasingly on the need for the invention to have ‘technical character’. Thus, as explained in the Guidelines for Examination in the EPO\textsuperscript{9}, the situation has been reached where ‘[a] computer program may be considered as an invention within the meaning of Article 52(1) if the program has the potential to bring about, when running on a computer, a further technical effect which goes beyond the normal physical interactions between the program and the computer.’

But the apparent exclusion of computer programs from patentability by the EPC had resulted for many years in sterile controversies as to what was, and what was not, a ‘computer program as such.’ This achieved nothing except confusion, and its effect was to distract attention in this field from analysing and developing the law as to the real issues that patent law is relatively comfortable addressing and which are met daily in other fields of industry – namely what is novel and not obvious over the prior art, and what is the legitimate scope of claim given the underlying contribution to the art. Thus, many of the objections of those in the computer programming community to many applications for computer program-related patents, once analysed, have been on the basis that they were obvious, or sought claims of over-broad scope given the inventive contribution. Such objections, which are often well founded, would be better addressed directly, rather than by seeking to use them to justify a broad interpretation of the Article 52(2) (c) exclusion when applied to computer programs. However, it was vociferous objections from many in the computer-programming community to many applications for computer program-related patents, once analysed, have been on the basis that they were obvious, or sought claims of over-broad scope given the inventive contribution. Such objections, which are often well founded, would be better addressed directly, rather than by seeking to use them to justify a broad interpretation of the Article 52(2) (c) exclusion when applied to computer programs. However, it was vociferous objections from many in the computer-programming community which led in 2005 to the failure of the initiative on the part of the European Commission to repeat its eventual success with the Biotechnology Directive with a Directive on computer-implemented inventions.

However, despite this setback the EPO and its Boards of Appeal persisted in refining their approach to examination for computer implemented inventions and have now established one which has become well settled\textsuperscript{13} and is explained in the Guidelines for Examination in the EPO.\textsuperscript{9}
Any claimed subject-matter defining or using technical means is an invention within the meaning of Article 52(1). If claimed subject-matter does not have a prima facie technical character, it should be rejected under Articles 52(2) and (3). If the subject-matter passes this prima facie test for technicality, the examiner should then proceed to the questions of novelty and inventive step. In assessing whether there is an inventive step, the examiner must establish an objective technical problem which has been overcome. The solution of that problem constitutes the invention's technical contribution to the art. The presence of such a technical contribution establishes that the claimed subject-matter has a technical character and therefore is indeed an invention within the meaning of Article 52(1). If no such objective technical problem is found, the claimed subject-matter does not satisfy at least the requirement for an inventive step because there can be no technical contribution to the art, and the claim is to be rejected on this ground.

This thus focusses, where an alleged invention is computer implemented and thus passes a prima facie test for technicality, at an early stage of the examination process on the issue of inventive step, conflating this issue with that of excluded subject matter, and then excluding from the inventive step analysis anything non-technical, such as a business method. Thus a novel and innovative business method cannot be patented by claiming it when run on a computer. More importantly however, this approach allows an application to be rejected where viewed as a whole it represents a trivial and un inventive difference over the prior art, without the examiner being required to agonise over the almost philosophical question of whether the application is to a computer program ‘as such’.

Conclusion

After so many years of frustration at the legislative process in the EU which led to the Biotechnology Directive and with the slow development of the case law of the Boards of Appeal of the EPO and of European national courts that has sought to analyse what precisely is meant by the exclusions ‘as such’ in Article 52 EPC, it has come as a relief to many that we have now reached a stage at which the sterile consideration of such issues is deferred in favour of making the initial and the primary focus of analysis the traditional and well recognised concepts in patent law of novelty and inventive step. It is thus sad and ironic that just as this happened in Europe, the USA has been moving in the opposite direction. It may, given Supreme Court case law, be too late to stop the USA going down this unfruitful road which Europe has now exited, but it is to be hoped that it is not too late for other jurisdictions to think twice before doing so.

References

1. The Association for Molecular Pathology v Myriad Genetics Inc (Supreme Court 12-398 13 June 2013).
2. Genomic DNA includes sequences of amino acids which code for various proteins but which also include sequences of amino acids (introns) the function of which (if any) remains obscure but which do not code for proteins, whereas cDNA codes for a specific protein and any introns in the corresponding genomic sequence have been spliced out.
3. CLS Bank International v Alice Corporation Pty Ltd (CAFC 2011-1301 10 May 2013). This decision reflects a change of approach, in the light of the Supreme Court decision in Bilski v Kappos, on the part of the CAFC since the 1990s when the scope for using patents to protect computer programs, and latterly business methods, became more widely recognised and US law, as interpreted by the CAFC, became more permissive of such patenting – see In re Alappat, 33 F.3d 1526 (1994) (holding a computer program for a technique for reducing the jaggedness of computer displays and which was in essence an algorithm to be patentable subject matter), State Street Bank v Signature Financial Group, 149 F.3d 1368 (1998) (holding a portfolio management system to be in principle patentable) and AT&T Corp v Excel Communications, 172 F.3d 1352 (1999) (holding a method to take advantage of adding more data into a message record in order to provide appropriate billing for subscribers and which was in essence a mathematical algorithm to be patentable subject matter).
6. Section 101 provides that ‘[w]hoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new or useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title’, but the Supreme Court held in Mayo v Prometheus that ‘laws of nature, natural phenomena, and abstract ideas’ ‘are basic tools of scientific and technological work’ that lie beyond the domain of patent protection.
9. Guidelines for Examination in the EPO (April 2010) Part C Chapter IV-4, 2.3.1, 2.3.6.
The 1998 Directive was based on a proposal adopted by the Commission in 1996 but this had in turn been preceded by a similar, but abortive, proposal for such a measure which had been adopted by the Commission in 1988 but was rejected by the European Parliament in 1995.

Article 5(3) of the Biotechnology Directive provides that ‘[t]he industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application’ which in and of itself is uncontroversial. The Directive does not however mandate the application of a heightened standard of industrial applicability and in particular not a ‘specific, substantial and credible’ standard as was subsequently adopted by the European Patent Office. It has been suggested that the application of this standard in this area has caused collateral damage to the neighbouring legal standards of obviousness and sufficiency in European patent law. Thambisetty Siva, *Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability* (LSE Law and Society Working Paper, 06 March 2008), *Jurimetrics Journal*, 49 (2) (2009) 155-201.

Case G-3/08 *Programs for Computers* (EPO Enlarged Board of Appeal, 12 May 2010)