EDITORIAL

DISCOVERY AND INVENTION: WHERE IS THE BOUNDARY BETWEEN THEM AND SHOULD WE CARE?

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> *A simple discovery cannot constitute a patentable invention. One of the main difficulties regarding patenting in biotechnology, is the ability to distinguish between a simple discovery which is not patentable and an invention as such, which is patentable.*[1]

> *What should be debated now, [Professor Steve] Jones says, is not the issue of patenting DNA, 'but the … argument about whether DNA is a discovery or an invention.'* [2]

This opinion is common among popular writers about intellectual property, in Europe at least. I well remember (but have not been able to trace) a *Guardian* leader in the last decade of the last millennium in which it featured prominently. 'We have forgotten the fundamental rule of patenting, that inventions are patentable, and discoveries are not' (or words to that effect).

But is this right? If you think it is, you may quote me Article 52 of the European Patent Convention:

> *Patentable inventions*
>
> *(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.*
>
> *(2) The following in particular shall* ***not*** *be regarded as inventions within the meaning of paragraph 1:*
>
> *(a)* ***discoveries****, scientific theories and mathematical methods…[emphasis added]*[3]

I respond with the corresponding US Statute, 35 USC:

> *§101. Inventions patentable*[4]
>
> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

This is qualified by the preceding section:

> *§100. Definitions*[5]
>
> *(a) The term* ***'invention' means invention or discovery*** *… [emphasis added]*

To this I add the power given to the US Congress under Article 1, Section 8 of the Constitution:

> *To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and* ***Discoveries*** *…*[6]

This apparent conflict of authorities suggests three possibilities:

(1) The laws of the United States and Europe are completely different in this respect.

(2) Discovery' and 'invention' mean quite different things in the two territories.

(3) The difference between 'discovery' and 'invention' is not an important feature of patent law.

I wish to argue for the third proposition.

1) 'Ethical Aspects of Patenting Inventions Involving Human Stem Cells', Opinion of the European Group on Ethics in Science and New Technologies, No 16, 7 May 2002, available at http://ec.europa.eu/european_group_ethics/docs/avis16_en.pdf.

2) *The Guardian*, 27 November 1997, http://www.guardian.co.uk/science/1997/nov/27/genetics.

3) http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar52.html.

4) http://www.law.cornell.edu/uscode/35/usc_sec_35_00000101----000-.html.

5) http://www.law.cornell.edu/uscode/35/usc_sec_35_00000100----000-.html.

6) http://www.usconstitution.net/xconst_A1Sec8.html.

As a practitioner, I say, on the basis of experience, that this is simply false. There are significant differences between the laws of Europe and the United States – in the law of novelty, for example. Disclosure by the inventor, in Europe (but not in the United States) generally invalidates a subsequent patent. Some things (plant varieties, business methods, computer programs as such) are specifically excluded from patenting in Europe but may often be patented in the United States. But we seek in vain for an example of something which is patentable in the United States, but not in Europe, solely because it is a 'discovery' rather than an 'invention'. If you disagree, please offer a counter-example.

This raises the preliminary question (which perhaps should have been dealt with before) of the normal meaning of the words 'discovery' and 'invention'. For 'discovery' from the dictionary[7] I select (from several less apt alternatives):

> *1. The act of uncovering or fact of becoming uncovered … 3. The finding out or bringing to light of that which was previously unknown.*

'Invention' has more possible options:

> *1. The act of coming upon or finding; discovery* [!] *2. The act of devising, contriving or making up; fabrication. 3. Contrivance or production of a new method, of an art, kind of instrument, etc, previously unknown; origination, introduction.*[8]

Now, if we are talking about the normal use of words, it is clear that, in common usage, 'discovery' and 'invention' overlap. So it is difficult to draw a clear line between them and insist that this will be the fundamental distinction between what is patentable and what is not.

This is all very well. Nevertheless, the distinction that is attempted between 'discovery' and 'invention' need not be meaningless. English patent law has many precedents referring to the unpatentability of 'discoveries'.[9] Note, however, that they are always referred to as '*mere* discoveries' (*emphasis added*). This is not just a conventional epithet, but an important qualifier. An invention, under the old British law, was defined as '*a manner of new manufacture* …'.[10] That is to say, it was a new process or thing – something substantial, not something abstract. A discovery, on the other hand, is 'merely' new knowledge, and no more. It may sound unnatural to regard something like Newton's Law of Universal Gravitation as 'mere' and hence unworthy of protection, while a metal tag on the end of a shoelace might qualify for a patent – but there it is. Knowledge, as such, is not patentable – you need a new and useful product or process. No longer need it be a 'manner of manufacture' but there is typically an analogous requirement – that it be 'capable of industrial application'.[11]

If we are to follow European usage (and ignore American practice) we can make a serviceable distinction between the two. For (European) patent purposes, a discovery is new knowledge: an invention is a new process or thing. A 'mere discovery' is not patentable because it is not associated with a patentable new process or thing. Finding out how something works is not patentable. The thing is not new; the process by which it works is not new. All that is new is the understanding of how it works – bare knowledge.

7) Shorter Oxford English Dictionary, 3rd edn, revised 1964.

8) Note also that 'invention' is from the Latin *invenire*, 'to come upon, find'.

9) For example, *re Genentech Inc.'s Patent* [1989] RPC 147 (CA), and cases there cited.

10) '*… the subject of letters patent and grant of privilege within Section 6 of the Statute of Monopolies, 1623* …' (UK Patents Act 1949, section 101).

11) TRIPs Article 27.1: http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5. Actually, TRIPs imposes minimum standards – countries are also free to patent things that are not industrially applicable, if they so choose (also, as a practical matter, they have considerable freedom to decide for themselves what is industially applicable and what is not).

However, many discoveries are not 'mere'. Many new discoveries immediately suggest 'new processes or things'. These are frequently patentable. As Lord Hoffmann said in *Biogen v Medeva*:[12]

> *Whenever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge.*

The idea is not patentable: the practical result may be. When you find out how something works, that may immediately suggest new ways of doing things. The fact that *once the idea is known* the new process or thing, and its likely benefits, directly or obviously follow is not relevant.[13]

So why is so much made of the alleged vital distinction between 'discovery' and 'invention'? Quite simply because there is a common (and entirely rational) view that some things should not be patented. As to what things, there is less agreement – and the reasons given are in some cases naïve and easily rebutted, in others very much stronger and more sophisticated. It is commonly held that only inventions and not discoveries should be patented. This is a strong motive to try to define as discoveries, not inventions, all things that one feels should not be patented. Genes are 'really' discoveries. Ditto algorithms:[14] so computer programs should not be patented – and so on.

I argue that this is generally a side issue. Take the patentability of genes. It is clear that to find out the sequence of a gene is knowledge, a discovery pure and simple. You cannot patent the gene itself as it occurs in Nature – your claim would not be new. However, knowing this sequence enables you to isolate it. The isolated gene is a new material that can be claimed as such.[15] You can also claim specific combinations of it with other DNA sequences, specific uses of it, and new organisms containing it. These are all 'inventions', though closely based on a 'discovery'.

The approach of seeking to limit undesired patenting by expanding the definition of 'discovery' is understandable but inadequate. Other weapons may be deployed. Patents are not to be granted (*inter alia*) for what is old,[16] obvious,[17] not properly disclosed,[18] or lacking support by the description (which should curb unreasonable extrapolation from the technology actually disclosed).[19] When these remedies fail, it may be time to try specific exclusions of certain subject-matter.

Let us concede that not everything 'technical' ought necessarily to be patentable. Despite the Universal Declaration of Human Rights,[20] we do not (most of us) subscribe to the view that the right to exclude others from using our inventions is fundamental. We are more pragmatic. If the clear view of society is that genes (or human beings, or 'life', or drugs, or computer programs, or business methods, and so on) should not be patentable, let the law say so. But it may not be easy or prudent to lay down general rules for deciding what kinds of subject-matter should or should not be patented.[21] For one thing, doing so presents an immediate challenge to the talents of patent attorneys, because the excluded areas have to be defined. A particular skill of patent attorneys is to test the limits of definitions. Thus the jurisprudence of the EPO has limited express exclusions from patentability (of computer programs, of 'plant varieties', of processes of medical treatment, for example) in ways which often surprise the naïve.

12) *Biogen Inc v Medeva Plc* [1996] UKHL 18 (31 October 1996) at paragraph 14.

13) A US Supreme Court case that is difficult to reconcile with this doctrine is *Parker v Flook* (437 US 584 (1978): http://laws.findlaw.com/us/437/584.html). Here a process claim was rejected on the grounds that it was no more than the application of a numerical formula to a specific process. It was said that the formula should be 'treated as known' and the process was unpatentable if, apart from the use of the formula, it was otherwise conventional. The decision has been strongly criticised, for example by Judge Rich, in *In re Bergy* (CCPA 1979). It is often used as a basis for saying that algorithms, 'laws of Nature' and the like are not patentable unless there is 'significant post-solution activity'. But no-one knows what that means. There were probably other good reasons for refusing the claims (they appear to cover purely mental processes, nor is it clear that the results produced by the claims were necessarily novel, even if the formula was).

14) To the contrary, Kronecker: '*God made the integers; all else is the work of man*'.

15) You need to be careful, however, that your claim has a useful scope. What is an 'isolated' DNA sequence? If it is read as meaning a sequence that is separate from a genome, or not connected to other functional DNA, then your claim may well be new, but not read on what you would have expected to be an infringement. See *Monsanto v Cargill* [2007] EWHC 2257.

16) EPC Article 52(1), http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar52.html. What is new is defined by Article 54, which could be amended in various ways (for example, to provide a 'grace period' for prior disclosures by an inventor).

17) EPC Article 56, http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar56.html.

18) EPC Article 83, http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar83.html.

19) EPC Article 84. http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar84.html. Note, however, that this weapon is difficult to bring to bear. Its scope is unclear; perhaps for this reason, only Patent Examiners are allowed to use it, it not being a ground of objection to a granted patent. This means that we have no court decisions, and the lack of clarity continues.

20) Article 27(2) '*Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*'

21) This may be why the US Supreme Court recently refused to do so: *Bilski et al v Kappos*, bb http://www.supremecourt.gov/opinions/09pdf/08-964.pdf http://www.supremecourt.gov/opinions/09pdf/08-964.pdf

There is a place for specific limitations of patentable subject-matter. There is also a place for other ways of limiting undesired effects from patents, and it may be that these will often be more effective in expressing the public will. These are not necessarily contrary to TRIPs.[22] Examples are: the right of private non-commercial use; the right of research on patented inventions; the right to grant compulsory licences under certain conditions; exempting doctors and pharmacists from patent infringement. The law on novelty (which differs considerably between, say, Europe and the United States) might be adjusted. To take 'genes' as a case in point: the law under the old UK Patents Act (1949) was that claims to a substance did not extend to that substance when found in Nature.[23] While that particular wording would not prevent claiming 'natural' genes *per se*, it might be provided that 'mere isolation' of a natural substance would not confer novelty.[24] A recent case in the New York District Court applied the old US doctrine that 'products of Nature' are not patentable[25] – a rule for which a good case may be made (for example on novelty grounds[26]). But let us leave aside unnecessary and fruitless arguments about whether something is 'really' a discovery or an invention. The question is whether it is (or should be) a *patentable* invention.

22) See TRIPs Article 30, Exceptions to Rights Conferred '*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*' Link at note 11 above.

23) UK Patents Act 1949, section 4.7.

24) I do not say that such an exclusion would be a good idea, only that it would make more sense than saying 'isolated genes are discoveries rather than inventions'.

25) You might say that this doctrine is the US expression of the fundamental truth that 'discoveries' are not patentable. But would this take you any further forward?

26) *Association for Molecular Pathology et al v USPTO* (the 'Myriad' case) at http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf. The defendants of course argued that in any case *isolated* genes were not 'products of Nature'. This point might reach the Supreme Court.