An introduction to European intellectual property rights

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1. Patents

1.1 Patentable inventions

The requirements for patentable inventions are set out in Article 52 of the European Patent Convention (EPC). Patentability requires that the invention is new, involves an inventive step and is susceptible of industrial application. An 'invention' is not defined. However, it is clear from EPO case law that inventions must have a concrete and technical character and this is consistent with the non-exhaustive list of 'non-inventions' in Article 52(2) EPC including: discoveries, scientific theories, aesthetic creations, business methods and programs for computers. The exclusion of business methods and programs for computers in particular has given rise to an important body of case law (both at the EPO and in the national courts) concerning the scope of these exclusions. Of greater relevance to pharmaceutical patenting are the exceptions to patentability set out in Article 53 EPC, namely that European patents shall not be granted: if their exploitation would be contrary to *ordre public* or morality, for plant or animal varieties or essentially biological processes for the production of plants or animals and methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body (in contrast to other jurisdictions such as the United States, where patents for methods of treatment are allowed).

The exclusion of inventions the exploitation of which would be contrary to *ordre public* or morality (defined by the Technical Board of Appeal in *Harvard/Onco-mouse* T356/93 as "not in conformity with the conventionally accepted standards of conduct pertaining to this culture") and for plant and animal varieties and essentially biological processes has been considered further in the context of the Biotechnology Directive 98/44/EC (see below). The decision of the Court of Justice of the European Union (CJEU) in *Brüstle v Greenpeace* (case C34/10) gave a broad interpretation of the term 'human embryo' and clarified that a process involving the removal of a stem cell from a human embryo at the blastocyst stage, entailing the destruction of the embryo, is not patentable subject matter. The EPO subsequently issued new examination guidelines in line with the CJEU's ruling (even though the EPO is not formally bound to follow the EPO[1]). However, the impact of this decision is mitigated to a considerable extent by the availability of technologies that

avoid the destruction of human embryos in the production of pluripotent stem cells and also by the other barriers to entry in this highly complex area of biotechnology.[1]

The methods for treatment by surgery or therapy and diagnostic methods set out in Article 53(c) EPC are excluded from patentability as a matter of policy (ie, to protect clinicians and veterinarians from falling foul of patent laws). Previously, this exclusion was expressed on the basis that such methods are not susceptible to industrial application. However, this fiction has been corrected by EPC 2000. The scope of this exclusion, which is to be interpreted narrowly, has been considered in a number of EPO cases (summarised in the EPO Guidelines for Examination).

Importantly, the exclusion of Article 53(c) EPC does not apply to products for use in such methods and thus pharmaceutical products may be patented for multiple uses (ie, a patentable invention may reside in the product itself or the use of a known product for a new medical use). This is set out in the terms of Article 54(4) EPC, which states that the fact that a product may be part of the state of the art "shall not exclude the patentability of any substance or composition … for use in a method referred to in Article 53(c) EPC, provided that its use for any such method is not comprised in the state of the art". Whereas such second (or further) medical use claims were previously only permitted when drafted in the 'Swiss' style (eg, the use of X in the manufacture of a medicament for the treatment of Y), after the implementation of EPC 2000 this has no longer been necessary and indeed such claims are no longer accepted by the EPO (although old Swiss-style claims remain valid and enforceable).

The patentability of known products for medical use is not restricted to new therapeutic indications. The EPO has held that novelty may also reside in a new dosage regime or means of administration. However, the new use must satisfy the inventive step requirement and must be more than a mere discovery about an already known use. This distinction has been considered by both the EPO and the national courts.

1.2 Industrial application

As indicated above, patents shall only be granted for inventions that are susceptible to industrial application, defined in Article 57 EPC to mean inventions that "can be made or used in any kind of industry, including agriculture". Relative to the other requirements of patentability set out in Article 52 EPC, there is a paucity of decisions on industrial application. This is unsurprising as the term 'industry' is construed broadly and in most areas of technology the mere fact that a patent is worth applying for is of itself an indication that the invention has industrial value. However, for biotechnology inventions in particular the threshold may be harder to satisfy (ie, if the practical use to which the new technology will be put has not been identified at the date of the application).

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1 Furthermore, in its recent judgment in *International Stem Cell Corporation* (C-364/13) the CJEU qualified its decision in *Brüstle* by ruling that in order to constitute a 'human embryo' a stimulated ovum must have "the inherent capacity to develop into a human being" and thus parthenotes are not automatically excluded from patentability following *Brüstle* (although it is still possible for national courts to prohibit the patentability of parthenotes).

The European, US and UK law of industrial application was reviewed by the UK courts in *Eli Lilly v Human Genome Sciences* (including an analysis of the following EPO case law: *Max-Planck* T870/04, *Johns Hopkins* T1329/04, *Genentech* T604/04, *ZymoGenetics* T898/05, *Bayer* T1452/06 and *Schering* T1165/06). A number of common principles were identified, including the propositions that 'industry' must be construed broadly, that the industrial application must be derivable from the patent application (read with common general knowledge), the need for a sound and concrete basis for recognising that the contribution could lead to practical application in industry and that "the patentee must make a full disclosure of his invention, including a practical use to which it can be put. It [is] not a hunting licence to find such a use". In this case, in which the invention was the identification using bioinformatics techniques of a novel protein (neutrokine-α) through its homology to the TNF superfamily, the court decided on the facts that an industrial application for the gene sequence had not been made plausible by the specification. Although the UK court (both at first instance and on appeal) approved the EPO's approach to industrial applicability, the EPO Technical Board of Appeal upheld the same patent – an example of different findings of fact leading to different results.

1.3 Novelty

Novelty is dealt with in Article 54 EPC, which provides that "an invention shall be considered to be new if it does not form part of the state of the art". The state of the art comprises everything made available to the public (anywhere in the world) whether by written or oral description, by use or in any other way before the filing or priority date of the application. After the entry into force of EPC 2000, for the assessment of novelty (but not obviousness) the state of the art includes the content of European patent applications having an earlier priority date but published after the application in question (ie, co-pending patent applications). A co-pending PCT application may also form part of the state of the art so long as it has been published in one of the official languages of the EPO or its translation into one of these languages has been filed with the EPO and published and the national fee has been paid.[2] Article 55 EPC provides a limited six-month 'grace period' for disclosures made in consequence of "an evident abuse in relation to the applicant or his legal predecessor" (eg, where the disclosure is made in breach of a duty of confidence owed to the inventor) or for disclosure of the invention at officially recognised international exhibitions.

The onus is on the party seeking to revoke the patent to prove that the disclosure or prior use was made available to the public before the priority date and further that a skilled person would have been able to put the prior art into practice in such a way as to carry out the invention. Interpretation of the disclosure is by reference to the knowledge of the skilled person in the field at the relevant date. Importantly, the purpose of the prior art disclosure is irrelevant for assessment of novelty and thus a disclosure in an unrelated technical field, which may be directed at a completely

2 Rule 165, Implementing Regulations to the Convention on the Grant of European Patents.

different technical problem, may still constitute an 'accidental' anticipation (even if the same disclosure would be irrelevant for assessment of inventive step).[3]

The test for novelty is a stringent one. For a disclosure or prior use to anticipate a claim it must disclose all of the features of the claim (ie, only if the invention disclosed by the prior art would infringe the claim in question, if performed post-grant, will it deprive that claim of novelty). The test is not simply that the prior product or process was available to the public but that the information conveyed by that product or process made the invention available. For example in *G2/88 MOBIL/Friction reducing additives*, the use of the additives in question, which were already known for one use, would necessarily have achieved the new use as well. Although the new use would have been inherent in the old use, this would not have been evident and so the novelty attack was rejected. Further, for a claim to be anticipated, it must be inevitable that following the disclosure of the prior art something within the scope of that claim will result. The test of 'inevitability' is strictly applied (*Union Carbide* T396/89).

One aspect of novelty that is of particular relevance to pharmaceutical inventions is where the novelty resides not in the product but in its use. As indicated above, 'second (or further) medical use' claims are permissible in Europe and provided that the other requirements of patentability are satisfied novelty may reside in a new indication, dosage regime or means of administering a known product. A second aspect of novelty that often arises in a pharmaceutical context is the patentability of a sub-group from within a previously disclosed class. The EPO approach is that the patented thing only lacks novelty if it is individually disclosed in the prior art, and this is not usually the case where a selection is made from more than one list (or, in the case of a '*Markush* formula', from one list of substituents at one position and another list of substituents at another position, etc).

The old German law used to be that disclosure of a class entailed disclosure of all members of the class, so all members of that class lacked novelty. English law took a similar view but tempered by the concept of selection patents: a selected sub-class was patentable if it enjoyed an advantage (taught in the later patent) not enjoyed by other members of the main class. In recent years the German and UK courts have both rejected the old approach and adopted the 'individualised description' approach of the EPO (ie, distinguishing what is within the scope of the prior art from what has actually been taught). In doing so, the English court also rejected the rules previously applied to selection patents. In *Dr Reddy's v Eli Lilly* the UK Court of Appeal followed the EPO approach, summarised by Lord Justice Jacob as follows: "It regards what can fairly be regarded a mere arbitrary selection as obvious. If there is no more than an arbitrary selection then there is simply no technical contribution provided by the patentee."

The settled EPO jurisprudence that disclosure of a racemate is not (by itself) a novelty-destroying disclosure of the component enantiomers is now followed by

3 Note, however, that 'accidental' anticipations may be the subject of a disclaimer following G1/03. More recent EPO case law has clarified that where the subject matter to be disclaimed is disclosed in the patent (a so-called 'disclosed' disclaimer) the less stringent test set out in G2/10 is to be followed, ie, that after the amendment the skilled person must not be presented with new technical information.

national courts (although in the absence of particular difficulties in resolving the racemate, establishing 'inventive step' (see below) may be difficult).

1.4 Obviousness

Lack of inventive step (also referred to as 'obviousness') is the most common means of attacking the validity of a patent. The approach taken by the EPO to assessing inventive step (followed to a greater or lesser extent by most EPC countries) is the 'problem-solution approach' (ie, identify the 'closest prior art', establish the 'objective technical problem' and then ask whether the claimed invention would have been obvious to a skilled person starting from the closest prior art and the problem to be solved). The approach most commonly followed by the UK courts is the *Windsurfing* test (reformulated in *Pozzoli*), although in recent years the English courts have also shown a willingness to follow the EPO approach. Both are means of applying a structured approach in order to avoid an *ex post facto* analysis and in most cases the 'mechanics' of the approach followed is unlikely to result in a different outcome (save perhaps where identifying the problem is itself part of the invention); whatever the approach followed, the key question remains: 'Is the invention obvious to a person skilled in the art?'

It is established case law of the EPO that the question is whether the skilled person would have arrived at the invention in the expectation of the improvement or advantage actually achieved (not whether he could have done so). However, the weight to be attached to motivation and the expectation of success may vary from case to case.

Until the mid-2000s the English courts were widely perceived as being out of step with the rest of Europe in terms of the approach to obviousness, particularly as applied to pharmaceutical inventions. In recent years the English courts have been adopting a more patentee-friendly approach to 'secondary' patents, and patents to enantiomers, combinations, dosage regimes and new crystal forms have all been upheld, where in the past (until the mid-2000s) one would have expected that these patents would have been revoked for lack of inventive step (on the basis that they were 'obvious to try'). The English court is now more aligned with the rest of Europe in focusing its attention on what the skilled person would have done, taking into account considerations such as the motive to find a solution to a problem, alternative avenues of research, the effort involved and the expectation of success, rather than looking at what (with hindsight) he could have done.

A developing area of the law of obviousness (and one that overlaps with insufficiency issues – considered below) is that a patent which claims classes of things in respect of which no technical effect is disclosed, or where the technical effect is purely speculative, lacks an inventive step (so-called 'plausibility' obviousness). In *Conor v Angiotech*, the English House of Lords approved the European case law of *AGREVO* T939/92 and *Johns Hopkins* T1329/04, ie, that a specification must pass the threshold test of disclosing enough to make the invention plausible.

1.5 Insufficiency

Article 83 EPC sets out the requirement that "the application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art" and this corresponds to the ground for revocation at Article 100(b) EPC. This 'sufficiency' requirement is an important means of maintaining the balance between, on the one hand, encouraging investment in innovation and rewarding invention and, on the other hand, ensuring that others can work the invention after the patent has expired. In combination with Article 84 EPC, the requirement for clarity and that the claims are "supported by the description", Article 83 also addresses the policy requirement that the patentee is only entitled to claim the contribution he has made to the art and taught in the patent. As stated in *Genentech/Polypeptide* expression I T292/85 there is a "general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported or justified".

It is settled law that the disclosure of the application must be sufficient to enable the skilled person to perform the invention across the scope of the claim (eg, *EXXON/Fuel Oils* T409/91). However, where the patentee has taught a principle of general application, teaching one way of performing the invention may be enough, even if the claim is of broad scope. Put at its simplest, the claim scope needs to be commensurate with the technical contribution made.

As at the date of the application the skilled person, having read the application as a whole and in light of the common general knowledge, must be able to put the invention into practice without 'undue effort' (*Genentech/Human* t-PA T929/92). This will be assessed on the facts of the case but a degree of trial and error will be allowed so long as this does not require an inventive step.

It is difficult to point to material differences in the law of insufficiency as applied across Europe. Nevertheless, it remains the case that insufficiency attacks hit the mark with greater frequency in some countries (most notably the United Kingdom) than in others.

1.6 Inequitable conduct

The list of grounds for opposition set out in Article 100 EPC is exhaustive. Unlike in the United States and certain other jurisdictions, inequitable conduct is not a ground to revoke or render unenforceable a patent in Europe. The European Patent Convention does not deal with misrepresentation or fraud.

1.7 Patent infringement

Infringement requires first that a prohibited act is carried out whilst the patent is in force and in the territory of the patent. Furthermore, the product or process that is subject of the act must fall within the scope of the claims.

The infringing acts, which differ depending on whether the claim is for a product or a process, are set out in Article 25 of the Community Patent Convention.[4] Article

4 Although all signatory states did not ratify the Community Patent Convention and it never came into force, equivalent provisions are enacted in the laws of a number of European states and the Convention itself remains widely influential in judicial decision making.

25 defines the prohibited acts as:

(a) making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes;

(b) using a process which is the subject-matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the territories of the Contracting States;

(c) offering, putting on the market, using, or importing or stocking for these purposes the product obtained directly by a process which is the subject-matter of the patent.

In respect of infringement by offering (etc) the product obtained directly by a patented process, it is important to note that the requirement that the product is a direct result of the process has been strictly applied, severely curtailing the ability of patentees to take enforcement action where the process is performed abroad and then a product of that process is imported (ie, if the product has been further processed or altered in some way after performance of the claimed method, then its importation and sale in a patent protected country will not be an infringement). For example in the UK case of *Monsanto v Cargill*, the court held that the progeny of a genetically transformed plant were not the direct products of the claimed method for producing a genetically transformed plant.

As well as the primary acts of infringement identified above, Article 26 of the CPC provides for indirect infringement where a party supplies or offers to supply means relating to an essential element of the invention. However, unlike the primary acts of infringement for which knowledge or intention is irrelevant (save for offering a process for use), indirect infringement also requires the patentee to establish that the alleged infringer had the requisite knowledge (ie, that those means are suitable for putting and intended to put the invention into effect). For this requirement the objective knowledge of the reasonable person will suffice. The territorial requirements of indirect infringement also require close attention.

Of course, for there to be an infringement the relevant product or process must fall within the scope of the claims. The extent of protection conferred by the claims is determined by reference to Article 69 EPC and the Protocol on its interpretation. In essence this provides that the description and drawings shall be used to interpret the claims and that a balance must be struck between a very narrow 'literal' interpretation of the claims (that would not give fair protection to patentees) and a broad interpretation in which the claims serve only as a guideline (that would not give third parties a reasonable degree of certainty as to the extent of the patent).

How this guidance has been interpreted by the national courts differs. Whereas in most European countries non-literal infringement is considered by applying a 'doctrine of equivalents', in the UK there is no doctrine of equivalents and Article 69 EPC is satisfied by a 'purposive' construction of the claims.

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