

Medical use patents in Europe – EPO and UK approaches

Introduction

Medical treatment methods are not patentable in Europe. This is specified in Art 52(4) EPC1973 and repeated in Art 53(c) EPC2000.

Under EPC1973 inventions to be patentable must be ‘susceptible of industrial application’. Art 52(4) provides the fiction that medical methods are not so susceptible, but this does not extend to products for use in such methods.

Art 54(5) provides a special statutory exception for medicinal products to the normal novelty rules. Even if such a product is itself not new it is patentable for use in any medical method provided ‘its use for any (medical treatment) method is not comprised in the state of the art’.

Normally ‘for use’ claims are not limiting for novelty purposes. A new use for a known thing must be patented as a method or process. But as a new therapeutic use for a known compound may not be patented as such this exception was required.

Unfortunately Art 54(5) EPC1973 was held by the EPO (and the UK Courts) only to apply to discovery of a first medical use. Once any medical use is known the proviso to Art 54(5) is invoked.

It accordingly became necessary to consider patentability of second and subsequent medical uses separately. Initially these were not considered protectable but by the exercise of some ingenuity and convoluted analysis the EPO recognised the validity of the so-called ‘Swiss’ form of claim.

The UK Courts against their ‘better view’ but in the interests of conformity followed. There still remains some divergence however on the extent to which such claims may be extended to cover more than the new indication itself e.g. a new dosage regime.

In the meantime EPC2000 came into force on December 13 2007. It introduces some possibly significant changes.

Art 52 includes the requirement that patents should be granted ‘in all fields of technology’.

Art 53 (c) EPC2000 removes the fiction about industrial applicability. It simply declares that patents may not be granted for medical methods. This is a matter of public policy.

Art 54(4) EPC2000 is in similar form to Art 54(5) EPC 1973 but perhaps significantly in the proviso now refers to any ‘such’ method.

But even more significantly new Art 54(5) provides at least for novelty of second and subsequent medical uses, and is perhaps broader.

The possible implications of these changes for the UK in particular are discussed below.

EPO practice:

It has become well established at the EPO that where an invention resides in the use of a known product for a new medical use it is protectable notwithstanding that the product itself is old. This applies to first, second and subsequent medical uses. But while the position of a first medical use is clear from Art 54(5) EPC1973, this was not so for second and subsequent uses.

This presented the EPO with a dilemma which was resolved by the Enlarged Board of Appeal in G0005/83 (**Eisai**) and related cases.

The EPO accepted that Art 54(5) by relaxing the usual novelty rules enables the inventor of a first medical use to obtain purpose-limited product protection for a known substance or composition.

But for second and subsequent medical uses it held that Art 54(5) no longer applies. The prior identification of any medical use is enough to invoke the proviso.

The EBA accordingly considered the position of claims to the use of a substance for the preparation of a medicament for a newly identified use which were being accepted by the Swiss Patent Office.

It held that these are 'clearly directed to inventions which are susceptible of industrial application' under Art 57 EPC and do not conflict with Art 52(4).

It recognised that there 'might be a problem' concerning novelty where the medicament concerned was not in any way different from a known medicament. This was an understatement. The medicament itself was clearly not new and the inventor could not benefit from the novelty exception of Art 54(5).

The EBA got around this by pointing out that in the case of a purpose-limited claim for a first medical use under Art 54(5) the required novelty for the medicament concerned is, in effect, derived from the new medical use.

It accordingly considered that it was justifiable 'by analogy' similarly to derive the novelty for a process which forms the subject-matter of a 'Swiss' form of claim from the new therapeutic use of the medicament.

It held that this applies 'irrespective of the fact whether a pharmaceutical use of the medicament was already known or not'. So Swiss form claims may be used equally to protect first, second and subsequent medical uses.

It emphasised that this 'special approach to the derivation of novelty' could only be applied to claims to the use of substances or compositions intended for use in a method referred to in Art 52(4) EPC.

It held that the intention of Art 52(4) was only to free from restraint non-commercial and non-industrial medical and veterinary activities. It 'seemed appropriate' to take a 'special view' of the concept of the 'state of the art' defined in Art 54(5) EPC to prevent this exclusion from 'going beyond its proper limits'.

The EBA concluded that Art 54(5) EPC did not exclude second (and further) medical indications from patent protection 'other than by a purpose-limited product claim'.

Nor could any intention to exclude second (and further) medical indications generally be deduced from the terms of the EPC nor from the legislative history.

It accordingly held it legitimate to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application even in a case where the process of manufacture as such did not differ from known processes using the same active ingredient.

In short where any product is found to have a new pharmaceutical activity the invention is protectable by the well-established 'Swiss' form directed to the use of the product for the preparation of a medicament for use in the new therapy.

In October 2004 the EPO Technical Board of Appeal in T1020/03 in a comprehensive review and analysis of G0005/83 went even further. It concluded that protection is not limited to new indications. It may extend to protecting a product for use in any novel and inventive therapy.

The Technical Board held this applies even if the invention resides in a new medical treatment method such as use of a known product for treating the same disease in a new way (such as a new dosage regimen).

It accepted that this involves treating as the basis for novelty and inventiveness under Art 54(5) EPC the very feature which Art 52(4) EPC specifies is not an invention capable of industrial application. It held that this 'logical discomfort' was in decision G0005/83 'assuaged' by applying a 'pure fiction to ensure the freedom of physicians (but not the freedom of suppliers)'.

The UK position

The UK Courts have not been prepared to go this far.

Before 1985 all attempts at securing protection for second and subsequent medical uses had failed.

S 2(6) PA77 which implements Art 54(5) EPC1973 provides that where an invention relates to a product for use in therapy the fact that the product forms part of the state of the art does not prevent the invention being taken to be new if the use of the product 'in any such method' is new.

This was interpreted as permitting patents for first medical use of a known substance but not subsequent uses. The words 'any such method' in s2(6) mean that once one

therapeutic use is known claims to further therapeutic uses in the form 'Compound X as an agent for disease Y' lack novelty according to conventional rules.

In 1985 in **Wyeth and Schering's Applications** [1985] RPC 545 the Patents Court sitting en banc considered these issues and various claim forms in depth.

While the Court thought that the 'better view' was that even claims in the Swiss form lacked novelty under conventional rules it decided that in the light of the decision in G0005/83 and in the interests of conformity the Swiss form of claim should be recognised as allowing a limited exception to classic novelty rules, enabling the protection of second and subsequent medical uses.

Subsequently the Court of Appeal has held that the exception is limited to protecting a new therapeutic purpose for which the known substance is used. Novelty must reside in the new second or subsequent therapeutic use. It is not available to protect a medical treatment method such as a new dosage regime or other procedure for use of the same drug and indication. **Bristol-Myers Squibb v Baker Norton Pharmaceuticals** ([2001] RPC 1).

In this case the drug Taxol was already known for treating cancer. The invention was the discovery that by changing the treatment from a 24 hour infusion to 3 hours a similar effect was obtained with less neutropenia. The Court held the claim was 'an unsuccessful attempt to monopolise the new method of treatment by drafting it along the lines of the Swiss-type claim'.

This view is not universally held by UK patent judges. Jacob J (as he then was) in **Merck & Co Inc's Patents** [2003] FSR 298 followed the Court of Appeal as he was obliged to do, but with 'regret'. He commented that 'patents are provided to encourage research. If new and non-obvious improved methods of administration of known drugs for known diseases are not patentable in principle-even with a Swiss form claim, then there will be less of a research incentive to find such methods'.

Nevertheless the law is as decided by the Court of Appeal unless and until it is changed by the House of Lords.

Or might EPC2000 as implemented by the UK Patents Act 2004 make a difference?

UK Patents Act 2004 implementing EPC 2000

Art 53(c) EPC2000 provides that medical methods are not patentable but that this does not apply to products 'for use in any of these methods'.

Art 54(4) EPC2000 is similar to old Art 54(5) but now refers to 'any **such** method' rather than simply 'any method'.

New Art 54(5) EPC2000 goes further and confirms that the patentability of a product for any '**specific** use' in a medical method is not excluded 'provided that **such use** is not comprised in the state of the art'.

These new articles vindicate and provide statutory support for the approaches of the EPO under EPC 1973 discussed above.

They have been implemented in the UK by s4A (3) and s4A (4) PA 2004 respectively. They came into effect on December 13 2007 and apply to all then pending and new applications.

S4A (3) is similar to s2 (6) PA 1977.

S4A (4) however is new. It provides that ‘in the case of an invention consisting of a substance or composition for a **specific** use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that **specific** use does not form part of the state of the art’.

The changes have the following important implications for the treatment of medical use claims in the UK:

1. Claims for second or subsequent medical uses may now take the form of a claims to a products limited by use such as ‘Compound X for use in the treatment of disease Y’.

2. Swiss- form claims may still be used but may become redundant.

3. The need for the UK Court in recognising Swiss form claims to go against its ‘better view’ based on conventional novelty rules in the interests of conformity is removed. There are now clear statutory grounds for recognising products for new medical uses as novel.

4. Providing this clean slate may open the way for the UK Courts to reconsider their objections to claims to the use of known products in new ways in known therapies. There seems no logical reason why the words ‘specific use in any such method’ and ‘if that specific use does not form part of the state of the art’ should be limited to new therapeutic indications only. Art 52 EPC2000 emphasises that inventions in ‘all fields of technology’ are patentable.

- 5 While the law and practice develop it may make sense at least to include claims in both the ‘Swiss’ and ‘use limited product’ forms in new EPO and national applications.

6. It should be assumed that claims to products not only for use in treating new diseases but also for use in new ways of treatment (like new dosage regimens) are possible.

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