

Welcome to the latest edition of Mewsnews, which features highlights of a few of the items of news and developments in European and UK intellectual property. If you would like more information on any of the topics covered, or on a specific area of interest, please get in touch with your regular Mewburn Ellis LLP contact.

### diagnostic methods

The President of the EPO has asked the Enlarged Board of Appeal to consider questions concerning the allowability of claims relating to methods of diagnosis following conflicting decisions of two Boards of Appeal.

“Diagnostic methods practised on the human or animal body” are excluded from patentability under Article 52(4) EPC. The two Boards of Appeal in the conflicting decisions agree that the reason for this exclusion is to protect practitioners who carry out such methods as part of a medical treatment from being inhibited by patents. However, the two decisions give greatly different scope to the exclusion.

The application in **T385/86** related to a method of measuring conditions inside the human body using local magnetic resonance. The Board found that this was a method of data collection, providing only interim results rather than a final diagnosis, and as such did not fall within the exclusion.

The Board in T385/86 held that a method of diagnosis had to include **all of the steps** involved in reaching a medical diagnosis, namely the steps of data collection, detecting a deviation from the norm (a symptom) and attributing the deviation to a particular medical picture. They also found that both the data and the deviation from the norm had to be directly discernable from the body.

**T964/99** related to a non-invasive method of extracting a metabolite (e.g. glucose) from the human body. In contrast to T385/86 and the line of case law developed from it, the Board found that the EPC was meant to exclude from patentability methods practised on the living human or animal body comprising **any one step** which relates to diagnosis or which is of value for the purpose of diagnosis. Metabolite sampling was found to be such a step, and thus the application was refused.

Under T385/86, the exclusion of methods of diagnosis from patentability would apply in only a small number of cases. Methods that could be described as mere “data gathering” would be allowed, as would methods of collecting a sample, since this would not even go as far as providing data. If the reasoning of T385/86 were applied, the application which was the subject of T964/99 would almost certainly have been allowed.

However, a strict application of this approach would not exclude typical diagnostic methods such as percussion, auscultation or palpitation, since they do not give rise to immediate diagnosis. These manual methods are seemingly exactly the sort of activity

which should be excluded from patentability under policy considerations.

T964/99 explicitly rejects the approach of T385/86 and excludes from patentability methods which include even one step relating to an essential diagnostic activity and carried out on the human or animal body. This brings the test for methods of diagnosis into line with the test for therapeutic and surgical methods. The Board in T964/99 stated that the reasoning was not intended to exclude NMR methods and the like from patentability, since these methods only define steps which concern the internal control and operation of a technical device, and no specific step of diagnostic character can be recognised. Hence, the method which was the subject of T385/86 would presumably still be allowable under the reasoning of T964/99.

Even so, it remains unclear how a specific step of diagnostic character is to be recognised, particularly when the patent application discloses non-diagnostic applications of the method. Some of the questions addressed to the Enlarged Board of Appeal are aimed at clarifying this point.

At present, it does not appear that the pending decisions will affect the patentability of laboratory tests on tissue samples, which are likely to remain allowable on the basis that they are not carried out on the human or animal body.

However, applications relating to methods of taking measurements or taking samples from the body are likely to be affected by the outcome of the Enlarged Board of Appeal decision and first instance proceedings relating to such cases will be postponed.

### eu enforcement directive

The EU Enforcement Directive was passed on 29th April 2004. This Directive implements a minimum standard of sanctions for intellectual property infringement, and seeks to adopt “best practice” from existing measures across the EU countries.

## pct news

Serbia and Montenegro (YU) has withdrawn its reservation under revised Article 22(1) PCT and, for all PCT applications **filed** on or after 1st January 2004, the deadline for entering the national phase is now 30 months from the priority date.

As a result of this move, the only remaining “reservation countries” are those for which regional protection can also be obtained (through the EPO or the ARIPO). Thus there is no longer any need to file a Demand by 19 months from the priority date solely to delay the national/regional phase.

## the community trade mark (ctm) office joins the madrid protocol

On 1st October the CTM Office joined the Madrid Protocol. This means that a CTM can now be applied for as part of an “International Registration” (IR) via the Madrid Protocol and that a CTM application or registration can be used as the basis for an IR under the Madrid Protocol (i.e. as a home registration).

If an application for IR is already being filed (perhaps to cover for example Norway, Switzerland and the United States), the marginal cost of the CTM applied for via the Madrid Protocol will be less than a direct filing. Using this route may also be beneficial since the Madrid Protocol sets down time limits for issuing notices of refusal on an IR, so directly filed CTM applications may be given a lower priority.

If the CTM designation of an IR is refused, it can be converted to national designations under the Madrid Protocol for the countries not giving rise to the refusal (except for Malta, which is not in the Madrid Protocol). Conversion for a number of countries will be less costly than conversion of a direct CTM.

However, a directly filed CTM is not dependent on any other trade mark; an IR (and therefore the designations under it) is dependent on the “home” registration or application on which it is based for its first five years. If the “home” registration is invalidated or limited in the first five years, the IR will suffer the same consequences.

The IR, and consequently the designation of a CTM, cannot include any goods or services not in the “home” registration or application upon which the International registration is based. If protection is only required for the EU and there is no “home” application or registration already in existence, a directly filed CTM is more cost effective as regards filing and grant costs.

(The “safety net” of conversion to national applications is however much more costly than if the CTM were applied for via the Madrid Protocol). Costs are about the same for an IR designating the CTM as for a directly filed CTM if a UK trade mark already exists and coverage for just the EU is required, in which case the “safety net” of the IR is probably preferable.

However each set of circumstances needs to be looked at in its own right. There may be other cost considerations due to the number of classes, type of mark and countries of interest, as well as non-cost considerations. We can of course advise on this.

It is probably only advisable to base an IR on a CTM if you have an existing CTM registration that is strong. CTM applications are often opposed and sometimes objected to on absolute grounds. Any limitation or invalidation of the CTM on which an IR is based will have a knock-on effect on the IR.

The ability to designate the CTM under the Madrid Protocol is a very valuable and useful new route for trade mark protection; in some circumstances the ability to base an IR on a CTM may be helpful.

## european patents

Iceland joined the EPC on 1st November 2004. European Patent applications filed from that date will be able to designate Iceland. Lithuania will join the EPC on 1st December. European Patent applications filed from that date will be able to designate Lithuania, which will cease to be available as an Extension state from 1st December. PCT applications filed after the relevant dates will automatically designate these countries as part of a European Patent.

Malta has recently completed its parliamentary process and will soon become a contracting state to the EPC. It is anticipated that Latvia will become a contracting state in the near future. The accession of these countries will mean that all members of the Enlarged EU are contracting states to the EPC.

This information is simplified and must not be taken as a definitive statement of the law or practice. If you would like to receive our more detailed *Mewsletter*, please e-mail [mewsletter@mewburn.com](mailto:mewsletter@mewburn.com). For more information on Mewburn Ellis LLP and other intellectual property matters, please contact us or visit our website at [www.mewburn.com](http://www.mewburn.com).

Mewburn Ellis LLP is a Limited Liability Partnership registered in England (no. OC306749). Registered Office at York House, 23 Kingsway, London WC2B 6HP

**LONDON**  
York House  
23 Kingsway  
London WC2B 6HP  
**Tel: 020 7240 4405**  
Fax: 020 7240 9339

**BRISTOL**  
No. 1  
Redcliff Street  
Bristol BS1 6NP  
**Tel: 0117 926 6411**  
Fax: 0117 926 5692

**MANCHESTER**  
Bridgewater House  
Whitworth Street  
Manchester M1 6LT  
**Tel: 0161 247 7722**  
Fax: 0161 247 7766

**CAMBRIDGE**  
Newnham House  
Cambridge Business Park  
Cambridge CB4 0WZ  
**Tel: 01223 420383**  
Fax: 01223 423792

Email: [mail@mewburn.com](mailto:mail@mewburn.com)

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