

### mewburn ellis llp's review of recent developments in ip law

Like software products, the according of a year to the product of a Diplomatic Conference to revise an international treaty sometimes only serves to emphasise how long it has taken to implement the decisions of that Conference. However, as indicated in the last issue, "EPC 2000" is now a reality, and the most significant reform of European Patent Law since the introduction of the EPC itself in 1977 will occur at the latest by the end of 2007. As it was, the final ratification needed to tip the balance came from an unexpected source. Most commentators had expected Malta to become the 15th state to ratify or accede to EPC 2000 following its accession to the EU in 2005. However, while Malta has yet to accede, Greece ratified in December and so set the implementation timetable in motion.

The Organising Committee for the London Olympic Games in 2012 has certainly been quick off the mark in acting to ensure that the highly lucrative IP rights associated with the Olympic games are protected. Although the existing provisions of the Olympic Symbol Protection Act implement the minimal level of protection for the Olympic symbols, the new Act dealing with specific provisions required for hosting of the games strengthens this protection by effectively creating further statutory trade marks in combinations of words that suggest association with the Olympic Games in London.

#### contents

2-3	EPC2000
3	Cross-Border Patent Enforcement in Europe and Forum for Validity
4-6	Experimental Use Exemption in the Pharmaceutical and Biotech Industries
6	Serbia and Montenegro
7	Trade Marks and the London Olympics
8-9	Artists' Resale Rights
9	No SPCs for New Formulations
10-11	Top Tips & In-House News

Slipped into a Directive on Medicinal Products for Human Use in 2004 was the provision of a further potential exemption to patent infringement. This exemption for certain forms of experimental use has, due to its similarity to the "Bolar" provisions in the US, been dubbed EU-Bolar, but there are significant differences in the scope of the two exemptions.

One of the more controversial European Directives in the field of Intellectual Property has been the requirement on states to introduce an "Artists' Resale Right". This adaption from the French *droit de suite* was lauded by artists as providing "proper reward" and criticised by the art trade in equal measure as likely to significantly reduce the number of sales in the EU, and particularly in Europe's foremost art market, London. It is therefore somewhat ironic that the Directive has been fully implemented by the UK (albeit a few weeks late), but remains unimplemented in countries such as France where it was originally much less controversial.

SXH

## 2007 summer course on the european patent

Our popular course will take place from 4th to 15th June 2007, followed by an optional visit to the European Patent Office (EPO) in München on 18th June.

This two-week course, aimed at practitioners from Japan and other Asian countries, provides

an in-depth study of the legal and practical aspects of working with the European Patent Convention (EPC) and the EPO. Recent attendees have commented favourably on the emphasis we place on practical advice and case studies.

For further information, please refer to our website - [www.mewburn.com](http://www.mewburn.com).

As mentioned in the previous issue of the Newsletter, the changes to the EPC introduced by the Diplomatic Conference held in 2000 ("EPC2000") will come into force on 13th December 2007 at the latest. However, the exact effect of many of the changes will not be finalised until after the corresponding changes to the Rules of the EPC have been confirmed by the Administrative Council of the EPO. It is expected that these will be finalised at the meeting in December 2006. Accordingly, whilst we set out the major expected changes below, we will comment in more detail on the various changes in future issues.

## date of implementation

The 13th December 2007 date was set by the ratification of EPC2000 by Greece on 13th December 2005 when they became the 15th state to ratify. If all contracting states to the EPC ratify EPC2000 before 13th September 2007, EPC2000 will come into effect 3 months from the date of the last ratification. As all those states which have not yet ratified are required to do so by 13th December 2007, and will cease to be parties to the EPC if they fail to ratify by that deadline, it is possible that earlier implementation will take place.

## major changes

### *late priority claims and filing date requirements*

To bring the EPC into conformity with the Patent Law Treaty, changes are introduced to the requirements for obtaining a date of filing and claiming priority.

An applicant will be able to make a claim to priority up to 16 months after the filing date of the earliest priority claim on an application, replacing the current requirement that all priority claims are made on filing. It will also be possible to file an application with a claim to priority up to 14 months from the filing date of the earliest priority application, provided that the applicant can show that they exercised all due care in attempting to meet the standard 12 month priority period.

It will also be possible to claim priority from a filing in a country which is not party to the Paris Convention, but is a member of the WTO (overturning decisions *G2/02* and *G3/02*).

In order to obtain a filing date at the EPO, it is no longer necessary to provide a description. Instead a reference to a previously filed application (in any country and in any language) can be provided instead. A copy of the earlier application and, where appropriate, a translation into one of the official languages of the EPO must then be provided for the application to proceed.

Furthermore, it will no longer be necessary to file the application in a specified language. Applications may be filed in any language and a translation provided after filing.

### *specific provision for second medical use claims*

Although the EPC currently provides explicit basis for first medical use claims as being novel over prior disclosure of the chemical itself, the availability and scope of claims to use of the compound to treat a second medical indication is dependent on the case law of the Boards of Appeal (based on the decision in *G5/83*). New Art 54(5) formalises the novelty of such claims, and was specifically stated to be a codification of existing law in this area rather than a completely new provision (see the report on *T1020/03* in Newsletter issue 12).

### *automatic designation of all states*

Applications will, following the introduction of EPC2000, automatically designate all EPC states, although the applicant can withdraw a designation of a state at any time, and is not obliged to validate the application in all designated states. The consequential effect of this is that the prior art effect of unpublished European applications with an earlier priority date will change with the removal of the requirement for overlap in the designated states between the earlier application and the present application. However, the present requirement for overlapping states will continue to apply to any applications pending when EPC2000 comes into force.

It is thought that the Rules will be amended to remove the requirement for the payment of designation fees, although it is expected that the filing fee will rise accordingly.

Extension fees will still be payable if an applicant wishes to extend the effect of a European patent to any of the extension countries.

### *extension of "further processing"*

The availability of the EPO's "further processing" provisions will be significantly expanded to cover any "failure to observe a time limit vis-a-vis the EPO". This change will apply to all applications, regardless of when they were filed, as long as the time limit in question had not expired before the

## epc2000 (continued)

implementation date. Certain time periods, such as the priority time period, the appeal deadline, and a number of time limits for which grace periods are already available, are specifically excluded from this provision.

### central post-grant amendment

At present, post-grant amendment of a European patent (except in EPO Opposition proceedings) can only be achieved through application to the national patent offices in the countries in which the patent is validated. The criteria that must be satisfied in order to amend in each country varies, and the cost of amending a patent in several countries can be high.

Under EPC2000 the proprietor of a European patent can apply to the EPO to amend the patent after grant. The EPO will consider whether the amendments comply with the requirements of clarity (Art 84), added subject matter (Art 123(2)) and extension of protection (Art 123(3)). There will be no procedure for third parties to become involved in the amendment procedure, although it is thought that it will be possible to submit third party observations on a proposed amendment under Art 114. If the amendments are accepted, then the scope of the patent will be accordingly restricted in each of the countries for which it is

granted (subject to the fulfilment of validation requirements in each country). Following implementation, central post-grant amendment will be available for all EPAs, regardless of when they were granted.

### challenge to decisions of the board of appeal

At present, a decision of the Board of Appeal of the EPO is final and not open to challenge or review. Various attempts to have decisions reconsidered by the Enlarged Board of Appeal, by national courts or by the ECJ have failed. However, after the introduction of EPC 2000, it will be possible for a party to a decision of a Board of Appeal to file a petition for review of that decision by the Enlarged Board of Appeal. This procedure is only available under extremely limited circumstances, for example if the Board of Appeal included a person not appointed as a member of the Board, or the decision was affected by a "criminal act" as established by a competent court or authority. It is expected that such challenges will be limited.

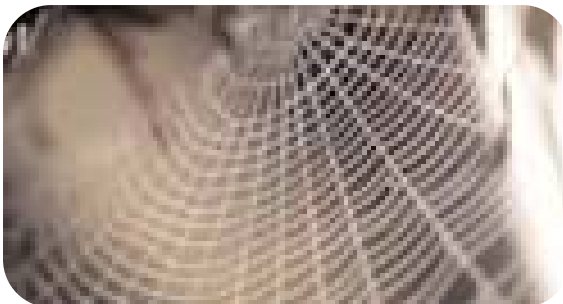
### other changes

A large proportion of the changes made by EPC2000 are to move the provisions of a number of Articles of the EPC into the Rules. This will allow these provisions to be changed by a decision of the Administrative Council of the EPO, rather than requiring the convening of a Diplomatic Conference. This will provide greater flexibility to the EPO to adapt the provisions of the EPC in, for example, procedural matters.

SXH

## cross-border patent enforcement in europe and forum for validity

To prevent "forum-shopping" in litigation, and to safeguard rights, Council Regulation 44/2001 ("the Regulation"), replacing the Brussels Convention, provides rules for the forum in



which legal actions within Europe should be conducted. The basic principle is that all persons domiciled in a Member State should be only sued in the courts of that state, subject to some narrow exceptions. Two recent ECJ decisions have significantly clarified the application of these exceptions and the corresponding possibility of cross-border actions.

In *Roche v Primus* the ECJ held that, in the context of European patent infringement, the courts of a Member State do *not* have jurisdiction over other group company defendants domiciled in other countries. This abolished the "spider in the web" theory which had found favour with the Dutch courts.

In *GAT v LuK* the ECJ confirmed that the exclusive jurisdiction of the courts of the country of registration over validity of IP rights should apply in *all* matters concerning that right.

# experimental use exemption in the pharmaceutical and biotech industries

In the UK, “experimental use” in the pharmaceutical and biotech industries is exempt from infringement where the experimental act concerned falls within either of two provisions:

- (i) the general statutory experimental use defence for acts done for “experimental purposes relating to the subject matter of the invention”;

and, as of 31 October 2005

- (ii) the industry-specific so-called “EU Bolar” provision for acts done for gaining regulatory authorisation.

Whilst the UK courts have provided guidance on the interpretation of the general statutory defence (as relating only to acts carried out **on** the invention, not **using** the invention), there is a great deal of uncertainty surrounding the interpretation and scope of exemption provided by the newly implemented “EU Bolar” provision. Similar uncertainty surrounds the “EU Bolar” provisions implemented elsewhere in the EU and indeed the original Bolar exemption in the US following the decision last year of the US Supreme Court in *Merck v Integra*.

However, a consensus view appears to be emerging that the “EU Bolar” provision as set out in the EC Directive, and as implemented in the UK, is rather narrower than its US counterpart. Variation in implementation of the Directive in different EU member states means that the scope of the exemption varies quite widely across the EU. In some countries, such as Germany and France, the exemption is considerably broader than in the UK and mirrors the differences in scope of the general experimental use

exemptions between those countries.

## the US bolar exemption: the current position

The US Bolar exemption provides a safe harbour from infringement where an act is carried out in respect of “a **patented invention... solely** for uses **reasonably related** to the development and submission of information [to the FDA]”.

The provision does not limit exemption to a drug product, also covering medical devices, nor to a particular type of pharmaceutical, i.e. generic vs non-generic. The Supreme Court in *Merck v Integra* (2005) interpreted the provision to extend exemption to **all** uses that are **reasonably related**, for **any** information for the FDA, necessarily **including pre-clinical studies** that are appropriate for the FDA regulatory process. It also provided some guidelines on the scope of the exemption (see table 1).

Nonetheless, the interpretation and scope of the provision remains uncertain. Indeed, the Supreme Court explicitly did not express a view on exemption in respect of use of “research tools”.

For example, it is not clear whether pre-clinical screening of a patented compound to determine its potential as a candidate drug compound, or use of a patented compound to screen for other potential drug compounds, are exempted.

## US bolar

Exemption includes:

research where there is “**reasonable basis for believing** that a patented compound may work...to produce a particular physiological effect, **and** uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA”

in certain circumstances, “experimentation on drugs that are not ultimately the subject of an FDA submission” or “use of patented compounds in experiments that are not ultimately submitted to the FDA”.

Exemption excludes:

“basic scientific research on a particular compound, performed **without the intent to develop a particular drug** or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce”.

table 1

## experimental use exemption in the pharmaceutical and biotech industries (continued)

Comparative use where the patented compound is acting as a control is expected to fall within the safe harbour, whilst some commentators have suggested that the exemption also covers pre-clinical screening provided the screening is carried out in the reasonable belief that it may lead to a particular drug. Further, it is also unclear whether the safe harbour is available where some uses are “reasonably related” uses while others are not. It is likely that these uncertainties will remain pending clarificatory judgements from the US courts.

### the new “EU bolar” provision: the UK and other european countries

The “EU Bolar” provision of the recent EC “Medicines Directive”<sup>1</sup> had to be implemented into national laws of EU member states by 30 October 2005.

Article 10(6) of Directive 2004/27/EC provides that “Conducting the **necessary studies and trials** with a view to the application of paragraphs 1, 2, 3 and 4 [of Article 10] and the **consequential practical requirements** shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products [SPCs]”.

The “EU Bolar” exemption therefore is limited to use only in respect of gaining **regulatory approval** in the EU for: **generic medicinal products** under the “abridged” procedure (paragraphs 1 and 2 of Article 10) and for medicinal products that do not fall within the

definition of a generic medicinal product (paragraph 2) and so need further pre-clinical test or clinical trial data under the “hybrid-abridged” procedure (paragraphs 3 and 4 of Article 10) (i.e. “**bioequivalents**” and “**biosimilars**”).

In the UK, this Directive has been implemented almost word for word, with the general statutory experimental use defence remaining unchanged. General opinion is that the extent of exemption in respect of non-generics (e.g. “biosimilars”) is unclear, although it is widely considered that the exemption excludes innovative research. For example, the provision is not thought to exempt use in comparative studies for new drugs, unlike the expected position in the US. Neither is it thought to exempt use of, for example, a patented gene or protein sequence to screen for modulators of that molecule. Again, this may depart from the US position. How the “EU Bolar” provision has been/is being implemented in other EU member states varies. Consequently, although there is a minimum standard for exemption there are marked differences in the scope of the “Bolar” exemption across the EU (see table 2).

Although not an EU member state, Switzerland has also implemented a “Bolar-type” exemption which is not limited only to acts carried out for obtaining regulatory approval for generic products.

In most countries, the general statutory experimental defence has remained unchanged as in the UK. Different countries' approaches to exemption for experimental use, reflected by the national courts' interpretation of these existing defences, in general, is mirrored in the different implementation of the “EU Bolar” provision in these countries. Hungary and Poland already provide for broad “Bolar-type” exemption in their statutory experimental use provisions.

However, in Belgium the general statutory experimental use exemption has also been amended: it has been broadened to

#### Minimum scope similar to UK:

**Sweden**

**Belgium**

**Netherlands**

#### Broader scope than UK:

**Germany** - applies to **any application** submitted for regulatory approval, including the first application for an innovative product, and including for regulatory approval **outside of the EU**

**France** - applies to **any application** submitted for regulatory approval, including for innovative as well as generic products, although is limited to applications for regulatory approval **within the EEA only**

**Italy** - broader language than the Directive

table 2

continued on page 6

## experimental use exemption in the pharmaceutical and biotech industries (continued)

refer to “use for scientific purposes on **and/or with** the object of the patented invention”. This is intended to include not only acts carried out on the invention itself, but also all types of research use, including acts where the invention is used as a tool. Therefore, although limited exemption in respect of pharmaceutical and biotech experimental use is provided by the industry-specific “Bolar” exemption in Belgium, broader exemption is provided under the general experimental use provision. This appears to go further even than Hungary, Poland and Germany where both the “Bolar” exemption and/or general experimental exemption are of broad scope but are interpreted as not covering early stage pre-clinical research and use of research tools that are not necessary for (i.e. occur before) regulatory approval.

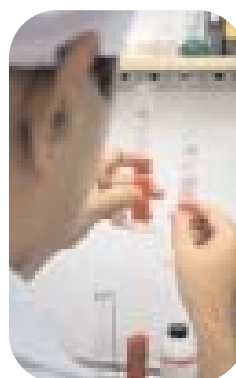
### conclusions

For the majority of EU countries, including the UK, the scope of the “Bolar” exemption is uncertain. The scope, however, does appear to be narrower than that available in the US, exemption being based on the principle of the use being “necessary” in respect of regulatory approval rather than “reasonably related” to regulatory approval as it is in the US. In these countries, whilst the scope of the general statutory defence is also far from decided such that it is not possible to be certain where the general exemption stops and the “Bolar” exemption starts, it is not expected to “fill the gap”. Following the implementation of the “EU Bolar” provision, the overall scope of experimental use exemption in several EU countries, such as Germany and France, remains broader than in the UK.

As in the US, uncertainty around the “EU Bolar” provision is likely to remain pending clarificatory judgements from the national courts and ultimately the European Court of Justice. It is highly advisable, therefore, to give careful consideration to the nature of any “experimental use” before relying on the “EU Bolar” exemption. At present, complete certainty as to exemption may only exist where the experimental use is necessary and conducted with a view to making an

application for regulatory approval of a generic medicinal product.

Although not binding, relevant national authorities have issued their views on the scope of the “EU Bolar” exemption. The UK Patent Office has issued guidelines on the scope of the exemption in the UK, which can be found at <http://www.patent.gov.uk/about/ippd/issues/pharmleg.htm>. These are broadly similar to those provided by the UK Medicines and Healthcare Products Regulatory Agency (MHRA).



Guidance on the extent of the experimental exemption in the UK may be close at hand, when the *Pfizer v Schwarz Pharma* case is heard. In May 2005, Pfizer sued Schwarz Pharma alleging that its phase III clinical trials of fesoterodine infringed one of its patents. This case will be followed

with interest and was heard in the Patents Court in July 2006.

<sup>1</sup> Directive 2001/83/EC as amended by 2004/27/EC for human use and Directive 2001/82/EC as amended by 2004/28/EC for veterinary use

LCW

## serbia and montenegro

The Union of Serbia and Montenegro was declared defunct by both republics in June 2006, following a referendum in Montenegro held under the terms of the original union deal brokered by the EU in 2003. Serbia and Montenegro was an extension state of the EPC from November 2004, “inheriting” this status from its predecessor, the Federal Republic of Yugoslavia.

Following the dissolution of the union, any patents or applications containing an extension to Serbia & Montenegro will extend to the Republic of Serbia (RS), which is the legal successor of Serbia & Montenegro into the Extension Agreement. The status with respect to the Montenegro is currently unclear.

# trade marks and the london olympics

As host country to the 2012 Olympic Games, the UK has already met the requirement to pass legislation protecting various words and logos that are connected with the Games.



The Olympic Symbol etc. (Protection) Act 1995 (the OSPA), has long been in force. More recently, the London Olympic Games and Paralympic Games Act 2006 (the 2006 Act) came into force in April 2006. The 2006 Act, like the OSPA, has an impact on the use of trade marks and applications to register trade marks.

The purpose of OSPA is to protect words, terms and symbols that are connected to any Olympic games, not just those to be held in London in 2012. Examples are the five ring logo, the Olympic motto and words such as "Olympic". One of the purposes of the 2006 Act is to protect the London 2012 brand in particular. The London Organising Committee of the Olympic Games Limited (LOCOG) will be able to prevent anybody, apart from official sponsors and partners, from using the London 2012 brand without permission. It is forbidden, without the permission of LOCOG, for anybody to create an association between any goods and services, or any business, and the London 2012 Games and/or the Paralympic Games.

LOCOG are the owners or licensees of various registered trade marks e.g. LONDON 2012 and LONDON 2012 (and Olympic five ring symbol device, as shown). Use of those registered marks by unauthorised parties may be registered trade mark infringement. Furthermore, OSPA provided an additional layer of protection whereby if, in the course of trade, a person uses the Olympic symbol, motto or any of the following: Olympiad, Olympiads, Olympian, Olympians, Olympic, Olympics, they infringe the OSPA. Yet another layer of protection is added by the 2006 Act.

The LOAR, created by the 2006 Act, is infringed if a person, in the course of trade uses in relation to any goods and services:

*"Any visual or verbal representations (of any kind) in a manner likely to create in the public mind an association between the London Olympics and the goods or services or the person who provides the goods or services."*

In order to establish whether the LOAR has been infringed, Courts can consider the use by the unauthorised person of particular "expressions". The 2006 Act contains two groups of these expressions. The use of any one of the four expressions in the first group (GAMES, 2012, TWO THOUSAND AND TWELVE, TWENTY TWELVE) with any of the seven expressions in the second group (GOLD, SILVER, BRONZE, LONDON, MEDALS, SPONSOR, SUMMER) is forbidden. The use of two or more of the expressions in the first group is also forbidden.

By way of example, the use of any of the following terms would be forbidden:

- (a) 2012 GAMES
- (b) LONDON GAMES
- (c) LONDON 2012
- (d) GOLD 2012.

The LOAR will not be infringed if the use is authorised by the LOCOG.

There are various exceptions to infringement of the LOAR. These include:

- the use by a person of his own name and address;
- use of indications concerning the kind, quality, quantity, intended purpose, value, geographical origin, time of production of goods or of rendering of services, or other characteristics of goods or services;
- the use of a representation which is necessary to indicate the intended purpose of a product or service.

In all instances, the use needs to be in accordance with honest practices in industrial or commercial matters.

Furthermore, the LOAR is not infringed by the use of a trade mark registered under The Trade Marks Act 1994. Note that this exception to infringement does not appear to apply to marks registered as Community Trade Marks. Moreover, this defence is likely to have little impact. If marks containing the prohibited expressions are already registered, the defence would appear to be available. However, for applications that have recently been filed or that may be filed in the future, it is reasonable to assume that LOCOG would oppose, on the basis of registered trade marks, applications containing some of the prohibited expressions - in particular, those containing "2012", "LONDON" and "GAMES".

KJM

# artists' resale rights

Amid some controversy, a new right for artists to royalties from the resale of their works came into force in the UK on 14th February 2006. The Artist's Resale Right Regulations 2006 implement Directive 2001/84/EC on the resale right for the benefit of the author of an original work of art. The Artist's Resale Right (known as *Droit de Suite* in France where a form of this right has existed since the 1920s) is intended to ensure that artists share in the economic success of their original works of art by receiving a share of subsequent sales of their works beyond the initial sale.

## what type of works are covered and for how long?

The resale right applies to any work of graphic or plastic art and lasts as long as copyright in the work subsists (presently 70 years following the death of the author of the work). Such works include not only paintings, but items such as glassware, sculptures and photographs. Certain authorised copies made in a limited number are also covered.

The resale right applies to *works* made before the Regulations came into force, but does not apply retrospectively to *sales* that preceded the Regulations.

## how much is payable?

The amount payable is calculated according to a tapering scale, reproduced below. However, the maximum royalty payable is capped at 12,500 euros. The sale price is calculated net of tax.

Portion of the sale price	Percentage amount
From 0 to 50,000 Euro	4%
From 50,000.01 to 200,000 Euro	3%
From 200,000.01 to 350,000 Euros	1%
From 350,000.01 to 500,000 Euro	0.5%
Exceeding 500,000 Euro	0.25%

For example, a painting sold for 200,000 Euro excluding VAT would attract a royalty of 6,500 Euro (4% of 50,000 Euro + 3% of 150,000 Euro).

## are all sales covered?

No. Sales are exempt in the following circumstances:

- (i) the first transfer of ownership from the author of the work;
- (ii) sales for less than 1,000 euros;
- (iii) sales where neither the buyer nor the seller (nor any agent of the buyer or seller) is acting in the course of a business of dealing in works of art (i.e. private sales); and
- (iv) sales where the seller previously acquired the work directly from the artist less than three years previously and the sale price does not exceed 10,000 euros.

However, the first transfer of ownership from the artist need not be a sale for money in order for any subsequent sale to be a 'resale'.

## who is liable to pay?

The following are jointly and severally liable to pay the royalty due in respect of a resale:

- (a) the seller; and
- (b) the agent of the seller, or where the seller has no agent, the agent of the buyer, or where there are no agents, the buyer.

Liability to pay arises on completion of the sale. However, payment may be withheld until evidence of entitlement to be paid is produced.

The Regulations provide for a right to obtain information necessary to secure payment of the resale royalty. The request for information must be made within three years of the sale

## who receives payment?

The artist is entitled to payment only if the individual is a national of an EEA state (i.e. the 25 EU member states plus Norway, Liechtenstein and Iceland) or one of 27 countries providing reciprocal rights to EEA nationals. These countries include Russia, Brazil, Turkey, Romania and Bulgaria.

## artists' resale rights (continued)

The resale right cannot be waived, assigned or charged. Although the resale right passes on the artist's death to his/her heirs, the UK has made use of a grace period until 1st January 2010, limiting the resale right to living artists. Therefore, an artist's heirs will not receive payment in respect of sales made before that date. Moreover, the grace period may be extended to 1st January 2012.

The UK has opted for collective management of the resale right, so only a collecting society may collect payment; the artist cannot do so directly. At present, The Design and Copyright Society (DACS) is the only collecting society managing resale rights in the UK.

### implementation elsewhere

Perhaps surprisingly considering its initial opposition to the Directive, the UK was one of the first to implement it. The other European countries to have implemented the Directive are mainly those in eastern Europe, while many key member states such as France and Germany have yet to do so.

### conclusions

The Artists' Resale Right has produced much debate among artists and art professionals alike. It may be too early to determine whether it will affect the volume of art sales in the UK or elsewhere in Europe. However, living artists in Europe now enjoy a further source of income as a result of this rather unusual IP right.

CSC

## no SPCs for new formulations

**A recent decision from the European Court of Justice (ECJ) has decided the issue of whether companies can claim extra protection for new formulations of known drugs.**

The decision relates to the award of Supplementary Protection Certificates (SPCs). An SPC allows the holder of a patent which covers a new drug to obtain an extra period of protection for that drug after the patent expires. The idea is to compensate the patent owner for the time spent obtaining market authorisation for the new drug - this time can eat up much of the usual 20 years of patent protection. Only one SPC may be granted for any one drug, even if the drug is covered by several patents.

An SPC can be granted for a specific active ingredient, or a new combination of active ingredients. In other words, it can be granted for a specific drug, or a new combination of known drugs.

In the recent case, the ECJ had to answer the question of whether a new formulation of a drug can be considered a "new combination of active ingredients". The answer was eagerly awaited by industry, as providing new and improved ways to deliver drugs is big business.

The new formulation in question was Gliadel, an implantable, disc-shaped wafer made of a



biodegradable polymer containing the anticancer drug carmustine (shown above). After surgery to remove a brain tumour, the wafer is implanted into the tumour site. The polymer then slowly degrades, gradually releasing the drug to kill any remaining tumour cells.

The patent owner, MIT, argued that the polymer should be considered an "active ingredient" because it was required to enable carmustine to act. In other words, the polymer was in part responsible for the improved effect of the new formulation, even though it did not itself have any therapeutic effect. The ECJ disagreed. They held that an "active ingredient" must be an ingredient that has a therapeutic effect in its own right.

Thus, following this decision, it appears that companies which develop new pharmaceutical formulations will not be able to obtain SPCs to extend the patent protection available for the new formulation beyond the usual patent term.

CPS

## top tips

### extended european search reports

In an effort to become more efficient and perhaps more “user-friendly”, the EPO now issues a detailed Searcher’s opinion together with the European Search Report (ESR). The combination of the opinion and ESR is known as the Extended European Search Report (EESR). An EESR will be issued for *all* European patent applications filed on and after 1st July 2006 (whether they are direct EPO filings or European regional phase applications of PCT filings).

#### the opinion

According to Rule 44a(1) EPC, the opinion included in the EESR shall indicate whether “the application and the invention to which it relates seem to meet the requirements of the European Patent Convention”. Consequently, the opinion outlines the Searcher’s objections to the application and/or the invention to which it relates, or it indicates that the Searcher believes the application meets the requirements for grant. In the former case, our experience so far is that the opinion usually deals with *all* the Searcher’s objections, rather than merely detailing any formal objections.

The opinion resembles an EPO examination report. However, there is no obligation to respond to it. Indeed, there is no sanction for not filing a response. Nonetheless, the applicant may voluntarily respond to the opinion by argument and/or by amendment of the application if so desired.

#### responding to the opinion

Where no response to the Searcher’s opinion is filed, then the first examination report during substantive examination usually simply refers to the Searcher’s opinion, and sets a deadline for filing a response. The applicant can thus choose to wait until the Examiner’s first communication issued before addressing the matters raised in the opinion.

However, our experience is that the Examiner’s first communication issues rapidly (usually within 1 to 2 months) after the EPO receive the examination fee or confirmation of the applicant’s desire to proceed to substantive examination. Therefore, where filing a response to the opinion is desirable, we advise filing the response before or at the same time

as paying the examination fee, or when confirming the applicant’s desire to proceed to substantive examination. Otherwise, there is the risk that the Examiner’s first communication may issue without taking account of the applicant’s response to the Searcher’s opinion, and it will simply refer to the opinion.



Although the provision of EESRs should reduce the previously long wait for the Examiner’s first communication, it does mean that when a positive opinion is received, it is advisable to consider at that time whether voluntary amendments or divisional applications are desirable.

Also, the Examiner’s first communication must take account of any response filed prior to the issuance of that first communication. Accordingly, if a response to the EESR is filed in time, the Examiner’s first communication should not

simply refer to the Searcher’s opinion. Where a response to the opinion is filed in time, it is anticipated that the Examiner’s first communication will be issued in the normal way, probably several months after the examination fee is paid or the applicant’s desire to proceed to substantive examination is confirmed.

#### partial european search reports

In the case of a partial ESR (issued for one invention in an application alleged to have multiple inventions), the Searcher’s opinion is not transmitted to the applicant until the ESR is finalised. The finalised ESR and the Searcher’s opinion on the *searched* claims are then issued as the EESR.

## top tips (continued)

### so what has changed?

#### *paying search and examination fees*

The respective fees for the search and the substantive examination have been altered to give relatively greater weight to the search fee, presumably since the Searcher's opinion is now included as part of the EESR. However, the deadline for filing a request for examination has not changed - it is still six months after the publication of the search report.

In certain circumstances, such as withdrawal of an application before the substantive examination has actually begun, it has previously been possible to obtain a refund of the examination fee. However, the potential rapid issuance of the Examiner's first communication (particularly where no response is filed to the Searcher's opinion) may mean that the EPO now considers substantive examination to have begun when, after the issuance of the EESR, the examination fee is paid or the EPO is informed of the applicant's desire to proceed to the substantive examination. Therefore, in such circumstances, it may now prove more difficult to obtain a refund of the EPO examination fee.

#### *publication*

Although the ESR portion of the EESR is published together with the application (or as soon as practicable after publication of the application) the Searcher's opinion is not published. Thus, the appearance of published European patent applications will not change. However, once the application and the ESR have been formally published, the opinion will be made available for public inspection as part of the EPO file history, which is accessible on the internet.

#### *strategy*

The opinion will give the applicant, at a relatively earlier stage, an indication of the relative merits of the searched claims. This should help the applicant to decide how to proceed with the prosecution of the application. In particular, it should help the applicant decide whether to proceed with the application and incur the cost of the EPO examination fee.

For applicants desiring rapid grant of their European patent application, the provision of the Searcher's opinion provides an opportunity to address all of the initial objections to the application and/or the invention to which it relates, *before* entering substantive examination. If no additional objections are raised by the Examiner during substantive examination, then the prosecution of the application may be shortened significantly.

GPM

## in-house news

### personnel news

Since the last Mewsletter, Graham Forrest and Richard Clegg have joined the partnership. Graham has a degree in Biochemistry from the University of Oxford and a PhD in Molecular Biology from Imperial College, London. He joined Mewburn Ellis in 1999 and does patent work in biotechnology. Richard has a degree in Biochemistry from the University of Cambridge. He joined Mewburn Ellis in 2003 and does patent work, particularly in biotechnology and biochemistry, and designs work.

Lindsey Wooley and Sam Bailey have qualified as European Patent Attorneys. Graeme Moore and Jonathan Thwaite have qualified as UK Patent Attorneys.

### new website

Mewburn Ellis are pleased to announce the recent launch of their new website.

The revamped site offers many additional features but of course retains the same valuable library of information that has always been our hallmark. We hope that you will find the new site both easier on the eye and easier to navigate.

Please visit the site at <http://www.mewburn.com> as before.

If you experience any problems using the site or have any suggestions as to how it might be improved, please feel free to contact us at [mail@mewburn.com](mailto:mail@mewburn.com).

## useful information

### european patent convention (epc) contracting states

Austria	Hungary	Poland
Belgium	Iceland	Portugal
Bulgaria	Ireland	Romania
Cyprus	Italy	Slovakia
Czech Republic	Latvia	Slovenia
Denmark	Liechtenstein	Spain
Estonia	Lithuania	Sweden
Finland	Luxembourg	Switzerland
France	Monaco	Turkey
Germany	Netherlands	United Kingdom
Greece		

### epc extension countries

Albania	Macedonia
Bosnia & Herzegovina	Montenegro ?
Croatia	Serbia

### epo holiday dates 2006/7

25th - 26th December 2006	28th May 7th June
1st January 2007	15th August
6th April	3rd October
9th April	1st November
1st May	24th - 25th December
17th May	31st December

### eu member states (community trade mark and community designs)

Austria	Greece	Poland
Belgium	Hungary	Portugal
Cyprus	Ireland	Slovakia
Czech Republic	Italy	Slovenia
Denmark	Latvia	Spain
Estonia	Lithuania	Sweden
Finland	Luxembourg	United Kingdom
France	Malta	
Germany	Netherlands	

### ohim holiday dates 2006/7

25th - 31st December 2006	17th May 28th May
1st January 2007	15th August
6th April	12th October
9th April	1st November
1st May	6th December
9th May	24th - 31st December

### website addresses

UK Patent Office:

[www.patent.gov.uk](http://www.patent.gov.uk)

EPO:

[www.european-patent-office.org](http://www.european-patent-office.org)

World Intellectual Property Organisation (WIPO):

[www.wipo.org](http://www.wipo.org)

OHIM:

[www.oami.europa.eu](http://www.oami.europa.eu)

Mewburn Ellis LLP:

[www.mewburn.com](http://www.mewburn.com)

This information is simplified and must not be taken as a definitive statement of the law or practice. 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)

© Mewburn Ellis LLP 2006