The plans for the unitary European patent and unified European patents court continued to progress during 2013 with the Rules of Procedure being drafted (and re-drafted) and the participating States starting to make plans for ratification.

So far, only one country (Austria) has ratified the treaty, so we are still some way short of the necessary 13 ratifications – but it is now expected that the unitary patent “package” could become a reality some time in 2015. Commentators now await with great interest the announcement by the EPO of the proposed renewal fees, the level of which will be a key factor in the attractiveness of the new ‘unitary European patent’. More information on the progress of the unitary system can be found on page 2 of this newsletter.

The other major development in European patent world in 2013 was the EPO’s dramatic change of position on divisional applications.

After holding an open consultation with users (in the form of an online questionnaire) - and sifting through a huge number of responses - the EPO finally decided to scrap the much-hated deadlines (introduced in October 2010) for filing divisional applications. From 1 April 2014 it will once again be possible to file a divisional application from any pending European application.

More information on the upcoming EPO rule changes can be found on page 5.

The UK courts had another fairly busy year including the Supreme Court which, somewhat unusually, heard two patents cases in 2013. A round-up of these and a few other interesting patents cases is on page 12 of this newsletter. Meanwhile, the Patents County Court got a new name (the Intellectual Property Enterprise Court) and a new judge (Richard Hacon).

A hot topic in trade mark circles has been the significant expansion of the group of possible generic top level domains (gTLDs) for websites. This has raised concerns about possible increased abuse of trade mark rights. This is discussed in more detail on page 15 of this newsletter.

Also discussed in this issue of MewsNews are patents for plant products (page 8) and ‘personalised’ medicines (page 9), the issue of exhaustion of copyright in light of the UsedSoft decision in the CJEU (page 13), and much more.

Mewburn Ellis News

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THE EUROPEAN UNITARY PATENT PACKAGE
IN 2013

In December 2012, a European “unitary patent package” was approved by the European Parliament and the European Council. The package will establish:

(i) a single patent right across most EU countries - the European Unitary Patent or “EUP”; and
(ii) a centralised European patent litigation forum - the European Unified Patents Court or “UPC”.

The UPC will not only have jurisdiction over European Unitary Patents, but also “traditional” European patents granted by the European Patent Office (EPO).

The unitary patent package was discussed in last year’s MewsNews Review. This article discusses the developments to the EUP and the UPC in 2013, what still needs to be done, and some important aspects to consider before the package is implemented, which is currently thought likely to be in 2015.

For more information about the package, please see our information sheet or ask your normal Mewburn Ellis contact.

WHEN WILL THE PACKAGE COME INTO EFFECT?
The approval of the package in December 2012 was only the first step towards making the EUP and the UPC a reality.

The EUP is linked with the UPC and the EUP will only come into effect when the UPC also comes into force.

The Agreement on the UPC was signed by most of the EU countries in February 2013, thus starting the ratification process needed for both the EUP and the UPC to come into effect. The Agreement to the UPC needs to be ratified by 13 of the EU countries (including the UK, France and Germany) before it comes into force.

Austria was the first country to ratify on 6 August 2013. However, ratification in other countries is taking significantly longer. For example, Denmark and Ireland will each hold a referendum in 2014. The UK has started the ratification process, while France has started the ratification process under an accelerated procedure. As yet, there is no information about ratification in Germany.

In addition to ratification, time is required to establish the infrastructure for the EUP and UPC. The Rules of Procedure of the UPC and EUP are still in draft form. Judges for the Court need to be selected and trained: over 1300 expressions of interest to be a judge had been received by the end of 2013.

Furthermore a key piece of European legislation, the Brussels I Regulation on Jurisdiction and the Recognition and Enforcement of Judgements (Regulation EU 1215/2012), will need to be amended to accommodate the presence of the UPC. There is a proposal for such an amendment of Brussels I, but it is unlikely to take effect before January 2015.

Given the factors above and despite the progress made this year, it is likely that the package will not come into force before 2015.

WHO’S IN AND WHO’S OUT?
The package will cover only those EU countries that ratify the UPC agreement.

So, if 20 EU countries have ratified the agreement by the time it is in force, then a EUP will cover those 20 EU countries and the UPC will have jurisdiction in those 20 EU countries. 25 of the 28 current EU countries initially agreed to participate in the Unitary patent package, with the notable exceptions of Italy and Spain.

Italy and Spain initially opposed the package, primarily over the language provisions.

Spain remains opposed to the package and has an on-going legal challenge at the Court of Justice of the European Union (CJEU). However, Italy has signed the UPC Agreement. As a result, the UPC could decide Italian patents granted by the EPO (although a EUP won’t cover Italy).

Poland was initially interested in the package, but did not sign the UPC agreement as a result of an economical study on the effect of the participating in the package.

In addition, Croatia joined the EU after the package was agreed (in July 2013), and so were not an EU country when the package was agreed. Spain, Poland, and Croatia can all join the package (and Italy can join the EUP) at a later date, if they wish to do so.

HOW WILL THE UNITARY EUROPEAN PATENT WORK?
Once the package is in force, all patent applications granted at the EPO will have the potential to become a EUP.

The European Patent Office will be responsible for the administration of the EUP and one of the most talked about aspects of the EUP is the level
of the renewal fee set by the EPO. If the renewal fee is too high, the EUP will be unattractive to patent owners. On the other hand, if the renewal fee is too low, countries may not sign up to the package because of potential revenue loss.

The EPO’s Select Committee will decide the level of renewal fees in 2014.

The EPO President, Benoit Battistelli, has been reported to have said at the IP Summit in Paris in December 2013 that “They [the renewal fees] will be higher than would hope, but lower than some might fear.” It is thought that the renewal fee level will be equivalent to renewal fees in around 5 or 6 countries.

There has also been concern over the so-called “Maltese Problem”. The EUP will be a single right covering all participating EU countries. However, the EUP cannot cover countries that were not designated in the original European patent application.

Malta only joined the European Patent Convention in July 2007, and around 30% of pending European patent applications do not cover Malta. As a result, any European patent application that does not cover Malta cannot become a EUP if Malta ratifies the package.

A potential solution is for Malta to delay ratification until an acceptably low number of European applications filed before July 2007 are pending. The same conundrum will occur if Croatia joins and ratifies the UPC agreement.

JURISDICTION OF THE UPC AND OPTING OUT

As mentioned above, the UPC will have jurisdiction over all EUPs and all ‘traditional’ European patents covering a participating EU country. ‘Traditional’ European patents are patents granted from European patent applications and validated in one or more EPC countries under the current ‘validation’ system.

The UPC will automatically have jurisdiction over traditional European patents that are already granted, as well as traditional European patents that are granted in the future. As a result, all traditional European patents for all participating EU countries will eventually be enforced and challenged in the UPC when the UPC Agreement comes into force.

However, traditional European patent proprietors (but not holders of a EUP) will have the option to opt out of jurisdiction of the UPC in the first 7 years of the UPC existence. This opt out period may be extended to 14 years after review by the UPC. The traditional European patent proprietor can opt out at any time during the 7 year period so long as there are no pending proceedings and the opt out lasts for the lifetime of the patent.

The proprietor must actively opt-out each European patent by filing a form with the UPC. A fee will be due for each patent that is opted out - this fee has not yet been set. Hence, owners of large patent portfolios could be hit with a sizeable fee when the UPC comes into existence. There has been some discussion about applying a single fee for each proprietor (independent of the number of patents) when the system first comes into effect. The draft Rules of Procedure also provide for a ‘sunrise’ period to allow an opt-out to be registered before the UPC comes into effect, thus avoiding a deluge of opt-out requests when the UPC first opens its doors.

Once opted-out, the traditional European patent proprietor has a chance to opt back into the jurisdiction of the UPC (for example, to initiate central infringement proceedings) so long as national proceedings have not been initiated.

THE UNIFIED PATENTS COURT PROCEDURE

The Rules of Procedure of the UPC will govern the details of the UPC. The 15th version of the Rules was released for public consultation ending in October 2013.

The Draft Rules set out a detailed time scale for proceedings at the UPC. It is the aim of the UPC to conclude actions in about 12 months. The actions will involve an initial Written Procedure lasting 6 to 8 months, followed by an Interim Conference with one of the judges, and concluded with a short (typically 1 day) oral hearing. This will be welcome news for those who are frustrated by the often long EPO Opposition and Appeal proceedings.

One of the controversial aspects remains the possibility for revocation and infringement proceedings to be heard by separate courts, so-called ‘bifurcation’ of proceedings. Bifurcation will be at the discretion of the courts, but the bifurcated revocation and infringement proceedings should run in parallel unless there is a stay.

This should eliminate any advantage of one action being decided significantly before the other action, particularly as the Draft Rules specify that the decision to bifurcate will be made at the end of the Written Procedure. So the written arguments and counter-arguments for infringement and revocation will have been submitted to the Court, and both actions will have progressed significantly through the proceedings, before bifurcation occurs.

When the infringement and revocation proceedings are bifurcated, the Court may stay one of the proceedings pending the outcome of the other proceedings.

The Draft Rules specify that infringement proceedings will be stayed where there is a high likelihood that the relevant claims will be found invalid following a counterclaim for revocation.

WHAT SHOULD PATENT APPLICANTS AND PROPRIETORS BE CONSIDERING AT THIS STAGE?

The first aspect to consider at this stage is whether or not a EUP would be an attractive option for currently pending European patent applications. There are potential benefits to having a EUP at least delaying prosecution until the package comes into force so that the option is available.

In particular, the EPO has recently announced a repeal of its divisional time limit Rule. The new Rule is effective from 1 April 2014 and allows a divisional application to be filed up to the day before grant (or refusal or withdrawal) of the application. As a result, European divisional applications can be filed from 1 April 2014 from pending European patent applications even where the ‘old’ divisional application deadline has already passed. Such divisional applications could grant after the Unitary patent package comes into effect, thus permitting an EUP to be granted on the divisional application.

Of course, the level of the EUP renewal fees will influence many and so the announcement later this year is keenly anticipated.
The second aspect to consider at this stage is whether or not to opt-out “traditional” European patents from the jurisdiction of the UPC. Single enforcement litigation covering multiple jurisdictions is attractive, but some may fear the uncertainty of costs and quality of a new system. Accordingly, it seems prudent to opt-out of the system initially, unless the opt out fee is prohibitively high.

Again, the announcement on the fee structure and level will be made later this year and is keenly anticipated.

CONCLUSIONS
The unitary patent package has overcome many hurdles to get to the present stage. A lot of hard work is still required for the package to come into force. However, political momentum is with the system and it is likely to become a reality in 2015.

Patent applicants and proprietors can start to consider strategy to maximise the system when it comes into effect. The latest news on the unitary patent package can be found on the Mewburn Ellis website or by asking your normal Mewburn Ellis contact.

Joseph Lenthall
UPCOMING RULE CHANGES AT THE EPO

As widely reported, the European Patent Office has decided to change the regulations regarding the deadline for filing divisional applications, specifically, to abolish the current deadlines. Hence, from 1 April 2014, it will once again be possible to file a divisional application from any pending application.

New Rule 36 EPC will apply to all divisional applications filed on or after 1 April 2014. This means that a divisional application will be possible based on any application that is pending on or after that date, even if a deadline for filing divisional applications under the current regulations had already been set or indeed had passed. Thus, for many applications, the “window” for filing divisional applications will re-open.

There will be an additional filing fee for second and subsequent generation divisional applications (i.e. divisionals of an application that is already a divisional application). The amount of this fee has not yet been set, but it is thought that it will be based on the current filing fee (115 Euro for online filing) and will not be excessive.

In addition to the new divisional rules, the Administrative Council also voted to amend the rules relating to the supplementary search procedures for PCT applications entering the European regional phase. Under the new rule, applicants will be given the opportunity to pay additional search fees to have additional subject matter searched, in cases where the application is found to lack unity at the supplementary European search stage.

The EPO performs a supplementary European search on all PCT applications entering the European regional phase (‘Euro-PCT’ applications), for which the EPO did not act as international search authority. Under current Rule 164 EPC, when the EPO finds a lack of unity when performing the supplementary search only the invention first mentioned in the claims is searched. There is no opportunity to choose a different invention to be searched or to pay additional fees to have the other invention(s) searched. In contrast, if the EPO finds a lack of unity during the European search on a direct EP application, the applicant is given the opportunity to pay further search fees. This was seen by many as being unfair on Euro-PCT applicants (particularly those who do not use the EPO as international search authority) and so the new rule will be very welcome.

Under the new rule, if a supplementary search is performed and a lack of unity is found, the EPO will search the first invention and will invite payment of further search fees in respect of any further invention(s) which the applicant wishes to be searched. Furthermore, in cases where no supplementary search is performed (i.e. where the EPO was the international search authority), if claims are presented for examination which relate to an invention which was not searched in the international phase (perhaps because a lack of unity was raised in the international search but no additional search fees were paid, or perhaps because the claims have been significantly changed on entry to the regional phase), the applicant will be given the opportunity to pay further fee(s) for a search on those inventions. This should make the Euro-PCT procedure much more flexible for applicants. These changes will come into force on 1 November 2014.

If you would like any further information, or advice about how these changes might affect you, please ask your usual Mewburn contact.

Julie Carlisle
Over the last year or so, the concept colloquially known as “poisonous divisionals” or “poisonous priority” has been a hot topic for analysis and debate. It is a large topic that includes a number of pieces of legislation, opinions, and arguments.

This article aims to provide a broad overview of the current position at the EPO and in the UK courts.

For those who are not familiar with the terms “poisonous divisionals” and “poisonous priority”, they are used to describe the stance that claims of an application (or patent) that are not fully entitled to priority can lack novelty over the disclosure of a later-filed and later published divisional application or priority application in the same patent family, respectively, under Art. 54(3) EPC or S.2(3) of the UK Patents Act.

As an example, consider a first (parent) application EPA claiming priority from an earlier national application in which the claims of EPA are only partially entitled to the claimed priority date, because the claim of EP recites a numerical range 1-10 and the priority application has the range 4.2-8.3. Each of EPA and the priority application has an example using a value 5.5.

Later, a divisional application EPD is filed, which is given the filing and priority dates of EPA and has identical description to EPA. EPD has an identical description to EPA.

The “poisonous divisional” theory says that on publication, EPD can be used as novelty-only prior art against EPA for any subject-matter for which the claims of EPA lack novelty over the disclosure of a later-filed and later published divisional application or priority application in the same patent family, respectively, under Art. 54(3) EPC or S.2(3) of the UK Patents Act.

Commentators and practitioners have been awaiting a decision that confirms whether or not the EPO or the UK courts would accept that a divisional or priority application could be used as prior art against a member of its own patent family using the “poisonous” theory.

There are also broader questions about whether the fate of an application should rightly rest on whether or not it is divided, or whether the priority application is allowed to publish after the filing of the application.

This year, we have seen that at least some members of the EPO and in the UK courts consider that a divisional application and a priority application, respectively, can be “poisonous”.

In late 2013, the Board in T1496/11 held that claim 1 of the patent lacked novelty over its divisional application. Correspondingly, in Nestec SA & Ors v Dualit Ltd & Ors [2013] EWHC 923 (Pat), the UK High Court concluded that the claims of a patent were not entitled to priority. The priority application had been allowed to publish, and therefore the claims of the patent in suit were found not novel over the published priority document.

The application of the “poisonous” approach depends to a large extent on whether or not the claims of the patent application (or patent) are entitled to priority; that is, whether the claims of the application (or patent) relate to “the same invention” as that of the priority document. G2/98 is a decision of the EPO’s Enlarged Board of Appeal concerning the requirement for the “same invention” in a priority document and a later application for a valid priority claim to be accorded. [This decision was also cited in the ruling of the UK court in Nestec v Dualit.]

In G2/98, the Enlarged Board said that multiple priorities could be allowed for a definition in a claim using a generic term/formula, provided that it “gives rise to the claiming of a limited number of clearly defined alternative subject-matters”. The meaning of “a limited number of clearly defined alternative subject-matters” has been the subject of
IN FOCUS

Of course, no issue arises if the EP application is identical to the priority application. Therefore it is always advisable to retain all of the disclosure from the priority application in the later application, including all explicitly-recited ranges and sub-ranges. This at least allows the possibility of later amendment to priority-entitled subject-matter.

In some cases, it might be possible, before filing the application, to abandon the priority filing and re-file a new priority case to include the new subject-matter (taking into account any risks relating to intervening art).

Alternatively, it might be useful to write claims explicitly in two parts in the manner “subject-matter fully entitled to priority OR subject-matter not fully entitled to priority”, to try to persuade a Board that there are a “limited number of clearly defined alternative subject-matters” in the claim.

In view of the different approaches taken as regards partial priority, the question of whether a divisional or priority application will be permitted to form part of the state of the art is presently rather difficult to predict. Such objections appear to be arising during the examination procedure as well as in oppositions before the EPO, and have also been raised in post-grant UK revocation proceedings.

Perhaps it is not unreasonable to speculate that a referral to the Enlarged Board of Appeal on this topic might (and probably should) arise in the near future.

Elizabeth Lambert
Food safety, security and nutrition are significant issues for today’s consumers. With increasing rates of obesity on the one hand, and food security issues associated with population growth, low incomes and global climate change on the other, the public has heightened awareness of the importance of availability, traceability, and nutritional content of food.

Modified Beneforté™ broccoli and Golden Rice are just two examples of modified crop species that are approved or being tested for human use. The improvement of crop species by genetic modification or modern breeding techniques remains a significant area of innovation, so it is important to consider how these developments can be protected.

Community plant variety rights (CPVRs) are available for the protection of individual plant varieties throughout the EU, provided these meet the required standards of being distinct, uniform, stable and new. Separately, European law requires that new plant varieties are registered on the National Listing before they can be marketed. Requirements for listing are similar to the requirements for CPVR protection (distinct, uniform, stable), and where a variety is covered by a CPVR, the right holder must consent to the registration.

Consistent with the limited exceptions to protection provided by IP rights generally, to ensure agricultural productivity is not adversely impacted by CPVRs farmers may use farm-saved seed of certain protected varieties on payment of a reasonable royalty to the right holder. Generally, CPVRs are useful protection for individual plant varieties ready for market, rather than for a plant characteristic that may be applicable across a range of plant types, or early stage technologies.

While individual plant varieties are excluded from patent protection, the European Patent Office (EPO) has confirmed that claims that encompass varieties can be patented. Also excluded from protection are “essentially biological processes for the production of plants”, and the scope of this exclusion was considered by the EPO’s Enlarged Board of Appeal (EBA) in 2010, in the Broccoli and Tomatoes cases.

The EBA concluded that methods that contain crossing and selection are in principle excluded from patentability, unless the crossing and selection steps contain within them a technical step “which introduces a trait into the genome or modifies a trait in the genome of the plant produced”.

In both cases, the methods (using selection by genetic markers or phenotype analysis) were excluded from patentability. The EBA indicated that methods applying “genetic engineering techniques” to plants were still patentable, but that “SMART (Selection with Markers and Advanced Reproductive Technologies) breeding” methods were excluded.

However, closer examination of the decision raises concerns about the extent of the exclusion. Methods are excluded if they “contain” crossing and selection steps, unless a technical step of modification is included “within” those crossing and selection steps (ie, not before), and the decision states that “claims should not, explicitly or implicitly, include the sexual crossing and selection process”.

So, on a strict interpretation, the decision may exclude even methods directed to improving a plant using genetic engineering if, as is likely to be the case in practice, achieving the desired plant includes a back-crossing and selection step, irrespective of whether that step is specified in the claim.

“Where gene transfer occurs from one variety into another without utilising a synthetic DNA construct, it is likely to be difficult to draft a valid claim that provides adequate protection.”

Furthermore, in both cases the resulting amended patents contained claims directed to the plants (or their products) produced by the excluded methods and the EBA is now asked whether claims to the plants themselves should also be excluded under the same provision. Allegations are made that by allowing such claims, essentially biological processes for their production are also indirectly protected. While exclusions to patentability are interpreted narrowly, and the exclusion refers only to processes, the EPO faces significant pressure to also exclude the products of such processes, from governmental and nongovernmental organisations.

EFFECTIVE PROTECTION

Given these current uncertainties, we must consider alternative approaches in addition to claiming methods of producing plants and the resulting plants themselves in order to protect plant-related inventions effectively.

One possibility is to claim nucleic or amino acid sequences. This strategy may be appropriate for genetically modified plants containing exogenous DNA. However, difficulties remain for obtaining approval to market transgenic crops in Europe, and there is significant consumer opposition to genetically modified foods, so modern breeding techniques are the commercially favoured approach.
In such techniques, where gene transfer occurs from one variety into another without utilising a synthetic DNA construct, it is likely to be difficult to draft a valid claim that provides adequate protection, particularly where the exact nature of the genetic information that has been transferred is not known.

A note of caution when considering this approach comes from case C-428/08 (Monsanto Technology LLC v Cefetra BV and others), in which Monsanto attempted to enforce a claim to a nucleic acid construct. Monsanto was unable to prevent the import of processed soy meal into Europe because the nucleic acid present in the product was no longer capable of performing its function.

However, such claims to biological material should still be enforceable against unprocessed plant products, such as seeds, where the claimed material is able to replicate or perform its function in the product. Claims to downstream products obtained from modified plants can also provide useful protection where the product is new as a result of the modification, such as having improved nutrient characteristics, for example a seed oil with increased levels of a particular fatty acid.

Similarly, claims directed to methods of preparation of these products using modified plants can be appropriate. Taking care to ensure that any claimed method (whether for producing a modified plant or for preparing a product from a modified plant) includes appropriate steps to attain the commercial product is key, to benefit from the protection that such process claims provide for the products directly obtained by the process.

Resolution of these uncertainties is expected to take some time while the EBA further considers the scope of the exclusion in the context of the patentability of plant products produced by essentially biological processes. Until then, applicants should aim to use a variety of the available claim types, providing a flexible approach to protecting their plant-related inventions.

This article has also been published in LSIPR
Frances Salisbury and Lindsey Woolley

PERSONALISED MEDICINE IN EUROPE – IS THE PATENT SYSTEM KEEPING UP?

In the not-so-distant past, obtaining patent protection for a new therapeutic drug (or the new use of a known drug) was simpler than it is today. The therapeutic landscape was comparatively unexplored, and our knowledge of disease pathology uninformed by the battery of molecular techniques available today. This lack of detailed information meant the factors to consider when assessing a new therapeutic application were relatively few and, consequently, the required analysis was relatively straightforward.

Fast-forwarding to today, the number and sophistication of the analytical techniques available mean that it is not uncommon for researchers to make discoveries beyond simply the disease(s) which a compound has the potential to treat. For example, the research may characterize the sub-set of patients in which a drug works best (or not at all).

Examples of this type of ‘personalised medicine’ abound in the scientific literature, and patients can be defined by, for example, genotype, SNPs, or protein markers. This allows targeted treatment of the best-responding patients while avoiding non-responders or those likely to suffer adverse effects.

In some cases, defining the patient group means the difference between clinical trial success and failure, enabling rational design of smaller trials with high success rates in defined patient sub-groups. The progression toward a personalised approach to therapeutics poses a challenge for the patent system: can it protect this type of contribution – which has such clear benefits for both patient and practitioner? And, if such protection is available, how should the patent office decide which ‘personalised medicine’ inventions meet the requirements for patentability?

In Europe, at least, the law has developed in a way that is generally favourable to patent applicants in the field of personalised medicine. The European Patent Office (EPO) has long recognized that a newly discovered medical use of a known agent is patentable over the earlier use of the same agent. Through successive decisions of the Boards of Appeal, this principle developed to the point where identifying a new class of patient treatable using a known drug or a new clinical situation constituted patentable subject matter.

Significantly, the Board in T1020/03 (a case handled by Mewburn Ellis partner, Adrian Brasnett) explicitly acknowledged that the investment in clinical trials to find new applications of therapies needed the reward of patent protection to justify it on economic grounds.

Following-on from the T1020/03 decision, the revised version of the EPC which came into force on 13 December 2007 brought with it, for the first time, explicit legal basis in the EPC for medical use inventions by way of a new “composition for use in a method for treatment” claim format. This new claim format defines a method of treating patients rather than obliquely referring to manufacturing drugs like the earlier “Swiss claim” format, and can be easily adapted to “test and treat” claims, in which analytical results are used to identify patients as being eligible for treatment.
The combined results of these changes means that, by defining markers or other clinical criteria by which patients can be selected for treatment, applicants can define a subset of patients who would not have been treated without the insight obtained through the analytical step. This definition can provide the basis for acknowledgement of novelty and inventive step.

The situation gets more complex in cases where the identified target patient group overlaps with the group of patients that the drug was already known or intended to treat. For example, a drug may already have received regulatory approval for treating a certain disease and may have been administered to a diverse population of patients with the disease. Naturally, inventors wish to obtain patents reflecting this advance, including claims directed to the drug for use in treating the disease in the well-responding patient subgroup.

However, the EPO has struggled with the question of whether treatment of the same disease in a newly-defined patient subgroup represents a genuinely new medical use of the drug, or whether such claims are merely the old medical use described in a different way (and therefore not novel).

To the advantage of applicants, the EPO has decided that it is possible to obtain personalised medicine patents under these circumstances. For example, if the former use was described only in theory, with no patients actually treated (or there was a poor or unknown response to the limited clinical use), then use of the drug for treating patients who have a biomarker indicative of good drug response may be considered novel when the biomarker is specified in the claim.

The EPO have also indicated that reciting an active step of determining a patient’s biomarker status (e.g. genotype) will be considered to render a claim novel, since the step of testing the patient to determine the presence of the biomarker is new, even if the drug was previously used successfully for treating the same disease in the same type of patients.

Whilst specifying a particular genotype is a common way of defining a patient group, the new EP medical use claim format lends itself just as easily to defining sub-groups by responders, assays or patterns of administration. This approach was backed by the EPO’s Enlarged Board of Appeal in G2/08, where the Board explicitly confirmed the potential patentability of medical use claims where the pattern of administration was the only novel feature.

Altogether this means that, by performing follow-up patient studies, companies have the possibility of identifying patient sub-groups and obtaining personalised medicine patents. Such patents would effectively lengthen protection they have for treatment of key patient groups and so provide additional revenue to the companies. Moreover, both patients and healthcare providers would reap the benefits of better targeted treatment (viz reduced unnecessary / ineffective treatments).

Thus, applicants seeking European protection for inventions in the personalised medicine field are well placed to obtain useful protection, as is reflected by the increasing numbers of applications that define patient subgroups.

Thankfully then, it seems the European patent system is managing to keep pace with the fast-moving therapeutic field - to the advantage of innovator companies, healthcare providers and patients alike.

This article is also being published in LSIPR

Robert Andrews

SUPPLEMENTARY PROTECTION CERTIFICATES – AN UPDATE

A supplementary protection certificate (SPC) has the effect of extending the duration of the patent on which it is based, but only in respect of the product which is the subject of the SPC. “Product” refers to the active ingredient or combination of active ingredients in a medicinal product or plant protection product. An SPC must be based not only on a patent protecting the product, but also on a marketing authorisation for a medicinal, or plant protection product containing the “product”.

SPCs are granted on a country-by-country basis, by the national patent offices, who apply Europe-wide SPC legislation. On 12 December 2013, the Court of Justice of the European Union (CJEU) issued three judgments, in which answers were provided to questions which had been referred to the Court by national courts who were uncertain about the interpretation of the European legislation.

HOW MANY SPCS PER PATENT?

It was well established that a patent proprietor with several patents in respect of a product could not hope to extend all of those patents in respect of that product, but must choose which was to be the basis for the SPC. It was however less clear whether a patentee whose patent protected several different products could obtain an SPC for each of those products, based on that patent, or was limited to just one SPC per patent. The SPC law does not clearly exclude this possibility, and national patent offices, examining SPC applications had generally been prepared to grant multiple SPCs based on a single patent provided each SPC related to a different product. Uncertainty existed, though, because of incidental remarks made in a number of CJEU decisions. These seemed to imply that there might actually be a restriction to just one SPC per patent.

CJEU Case C-484/12 (Georgetown University v Octrooicentrum Nederland)

Because of this uncertainty, the Dutch Court of the Hague, considering Georgetown University’s appeal from a Dutch Patent Office rejection of their SPC application, sought guidance from the CJEU on this point. Georgetown’s patent related to a vaccine containing at least one recombinantly produced human papilloma virus (HPV) L1 protein or fragment. The various strains of HPV from which the protein might be derived were listed in one of the claims, while other claims specified preferred strains or preferred combinations of L1 proteins. On the basis of this patent, Georgetown had been granted an SPC in respect of a combination of four L1 proteins – those of HPV-6, HPV-11, HPV-16 and HPV-18. The SPC was based on a marketing authorisation for a vaccine containing all four proteins in combination.

As this marketing authorisation was the first, not only in respect of the combination of the four proteins, but also in respect of each individual protein, Georgetown also sought SPCs in respect of each
of these different products based on the same patent and marketing authorisation.

The Dutch Patent Office, operating a policy of ‘one SPC per patent’, refused the applications.

The CJEU distinguished the situation in this case from those in its earlier judgments and concluded that, “It is possible, in principle, on the basis of a patent which protects several different “products” to obtain several SPCs in relation to each of those different products, provided inter alia, that each of these products is “protected” as such by that basic patent” (emphasis added).

Georgetown were, therefore, able to have SPCs for the combination of four proteins and for the individual proteins, as all these products were “protected as such” by the patent. The Court was concerned that the patentee should be adequately compensated for their efforts and expense in bringing each of these patented products to the market, but also noted that all the SPCs would expire together, since all were based on the same first marketing authorisation.

They emphasised, however, that a patentee could not obtain a second SPC for the same product based on the same patent and on a later authorisation of a medicinal product containing it. In this case, Georgetown could not obtain a second SPC in respect of the HPV-16 L1 protein based on a later authorisation of the HPV-16 + HPV-18 combination.

**CJEU Case C-443/12 (Actavis Group PTC EHF and Actavis UK Ltd v Sanofi)**

By contrast, in a case where questions were referred by the UK Patents Court, the CJEU concluded that the patentee was precluded from obtaining two SPCs based on the same patent, even though it could be argued that the SPCs related to different products.

Sanofi was the holder of an SPC in respect of the anti-hypertensive drug, irbesartan, based on a European patent in respect of that drug and a marketing authorisation in respect of a medicinal product (Aprovel) containing irbesartan as sole active ingredient. The European patent contained claims in respect of irbesartan and described how irbesartan might be included in a pharmaceutical composition also containing other classes of active ingredient, such as a beta-blocker, calcium antagonist, diuretic, non-steroidal anti-inflammatory drug, or tranquilliser. One claim of the patent referred to a pharmaceutical composition containing irbesartan in combination with “a diuretic”. When Sanofi subsequently obtained a marketing authorisation in respect of Coaprov, a medicinal product containing both irbesartan and another active ingredient – hydrochlorothiazide, which is a diuretic, they applied for and were granted a UK SPC in respect of this new combination of active ingredients. The SPC was based on the same European patent, and the new authorisation, so had a later expiry date than the first SPC. Actavis sought to invalidate this SPC in order to bring their own combination product to the market after expiry of the SPC in respect of irbesartan by itself.

Here the CJEU took the view that the patent relied on did not protect hydrochlorothiazide “as such”. The core inventive concept of the patent was irbesartan and the judgment says, “It cannot be accepted that the holder of a basic patent … may obtain a new SPC, potentially for a longer period of protection, each time he places on the market ...

Sanofi had already had the benefit of one SPC — that for irbesartan itself, which could have been used to oppose marketing of a medicinal product containing irbesartan in combination with another active, and it was not appropriate for them to receive a second SPC, in respect of the same core invention, and based on the same patent.

The CJEU distinguished this situation from that where a later patent relates to an innovative combination of a previously patented (and authorised) active with another. In these circumstances it should be possible to obtain an SPC in respect of the patentable combination based on this later patent.

Presumably the Court’s conclusions would have been the same even if the known diuretic, hydrochlorothiazide, had been specifically named in the patent; the patent would still not have protected it “as such”. Thus, the court found it unnecessary to consider a further question referred to it by the UK Court relating to whether the specific combination of irbesartan and hydrochlorothiazide was “protected” by the patent, and in particular by the claim to the composition containing irbesartan and a diuretic.

**DOES THE BASIC PATENT PROTECT THE PRODUCT?**

**CJEU Case 493/12 (Eli Lilly and Company Ltd v Human Genome Sciences)**

Whether a specific compound within the ambit of a broad generic claim of a patent is a product protected by the patent, and so eligible for an SPC based on the patent was, however, considered in C-493/12.

Here Human Genome Sciences (HGS) were holder of a patent in respect of a protein, neutrokine-alpha, and their patent included broad claims to an antibody to that protein, but the antibody was defined entirely functionally, in terms of its binding to neutrokine-alpha. The patent contained no example of an antibody having been made or tested, and the patent did not contain any structural definition of antibodies that might function therapeutically.

HGS hoped to obtain an SPC based on this patent, and so extend the duration of their patent, by relying on Eli Lilly’s marketing authorisation...
in respect of a particular antibody – tabalumab. Eli Lilly argued that tabalumab was not “protected” by the patent, for SPC purposes, despite the fact that marketing tabalumab during the life of the patent would be an infringement of the patent. Tabalumab was not named or described in the patent.

Following earlier case law, the CJEU rejected the infringement test as a way of determining whether the product was protected, emphasizing that if a patent were to be suitable basis for an SPC the product must be “identified” in the claims of the patent, which tabalumab was not. They explained that a purely functional, rather than structural, definition of a product in a claim might suffice to protect the product, provided that the claim, when interpreted in light of the description, related “implicitly, but necessarily and specifically” to the active ingredient in question. The Court noted that the objective of the SPC law was to encourage research by providing an extra exclusivity period to cover investments put into such research. This objective would be defeated if a patentee were to be granted an SPC when (unlike the marketing authorisation holder) it had “failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients”.

Kathryn Nicholls

UK PATENTS CASES 2013

The UK Supreme Court, somewhat unusually, issued two patents decisions in 2013.

The first of these was Virgin v Zodiac ([2013] UKSC 46). This case was highly significant as it overturned the longstanding ‘Unilin principle’, which effectively preserved a patentee’s right to collect damages awarded for infringement of a patent claim, even if that claim was subsequently found to be invalid (i.e. in EPO opposition proceedings).

Notably, in the context of this judgement, the Supreme Court invited future tribunals to reconsider whether the guidelines for awarding stays or procedure in cases where EPO opposition proceedings are pending (as established in Glaxo v. Genentech) were correct. This invitation was subsequently answered, IPCom v HTC ([2013] EWCA Civ 1496).

Rather than scrapping the Glaxo guidelines, however, the Court of Appeal recast them into a new thirteen-point test and, essentially, said that judges must maintain the ability to exercise their discretion to grant a stay, based on the facts of any particular case.

The second Supreme Court patent decision, Schütz v Werit ([2013] UKSC 16), related to the existence or otherwise of a ‘right to repair’ and discussed the principles involved in deciding when ‘repairing’ becomes ‘making’ the product (and hence potentially infringing the patent for the product).

In their decision, the Court provided a five-part test to decide whether or not a person is ‘making’ a product within the meaning of s.60 of the UK Patents Act. The factors to be considered are:

1. Whether the replaced part is such a subsidiary part of the patented article that its replacement, when required, does not involve “making” the new article.
2. Whether the replaced part includes any aspect of the inventive concept of the patent.
3. Whether the replaced part is a free-standing item.
4. The nature of the work in replacing the part (for example, whether demolition or other improvement is involved).
5. A comparison of the value of the used article before and after replacement of the replaced part (to be used with caution).

This test was later followed by the High Court in Nestec v Dualit ([2013] EWHC 923 (Pat)). That case, also illustrated how a priority document may become prior art against its own later application (the so-called ‘poisonous priority’ problem – see page XX of this newsletter).

Other significant UK cases in 2013 included HTC v. Apple ([2013] EWCA Civ 451), where the exclusion from patentability of computer programs was considered. The Court in this case confirmed that an increase in the speed or reliability of the computer can be a valid "technical effect" for the purposes of determining whether the invention relates to a computer program as such.

The Court of Appeal also considered obviousness: in Novartis v Generics ([2012] EWCA Civ 1623), which confirmed that, in the absence of any difficulties or uncertainties involved in doing so, it was obvious to investigate and resolve the enantiomers of a (known) racemic drug in the expectation of producing a more active form of the drug; and in Generics v Yeda and Teva ([2013] EWCA Civ 925) it was confirmed that post-published experimental evidence has a role in confirming whether or not the patent makes it plausible that the relevant ‘technical problem’ has been solved - a party may therefore challenge the existence of a technical effect relied on by the patentee with post-published evidence.

Finally, in Sudarshan v. Clarian ([2013] EWCA Civ 919) the issue of unjustified threats was considered by the Court of Appeal, which confirmed that an unjustified threat to sue a manufacturer’s customers was actionable, even when that threat had not been communicated directly to those customers but only to the manufacturer.

For more information about any of these decisions, please ask your usual Mewburn contact.
EXHAUSTION OF COPYRIGHT

THE PRINCIPLE OF EXHAUSTION
The principle of exhaustion is an established international legal doctrine. It provides that a copyright owner’s right to control copies of their work “exhausts” on its first sale by the copyright owner or with their consent. The principle prevents the copyright owner’s right to control copies of their work from extending beyond the point at which they receive reasonable remuneration for the copy. Further, it allows the purchaser to have control over their copy, including the right to resell it free from interference by the copyright owner. In the UK we have codified this principle in national legislation. Sections 16(1)(b), 18(1) and 18(2) of the Copyright Designs and Patents Act 1988 (the CDPA) establish the copyright holder’s exclusive right to issue (i.e. distribute) copies of their work to the public and provide that infringement shall occur where a third party encroaches on this right. Section 18(3)(a) sets out the principle of exhaustion by stating that the subsequent distribution of copies of a work (such as selling on a purchased copy second-hand) will not infringe the rightholder’s distribution right.

The European Union (the EU) has further developed the principle of exhaustion, but primarily from the perspective of enshrining the free movement of goods throughout the EU and standardising the approach across EU Member States. This was achieved through EU Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society (the InfoSoc Directive). It was also achieved by Directive 2009/24/EC on the legal protection of computer programs (the Software Directive), which applied the principles of the InfoSoc Directive to computer programs, including games and software.

Article 4 of the InfoSoc Directive establishes the copyright holder’s distribution right and also the conditions of the right’s exhaustion on first sale or other transfer of ownership of the copies or of the original. Similar provisions are made specifically in relation to computer programs under Article 2 and 4 of the Software Directive. However, there are differences between the two Directives, which were particularly relevant in the consideration of the UsedSoft decision. Most notably, the absence in the Software Directive of recitals 28 and 29 of the InfoSoc Directive. Recital 28 states that protection relates to works incorporated in a tangible article (e.g. a CD-ROM) and that first sale exhausts the right to control resale of that object in the EU. Recital 29 specifically states that exhaustion does not arise in relation to services and on-line services. For a summary please refer to Table 1.

CASE ANALYSIS (USEDSOFT V ORACLE)

Background
Oracle International Corp. (Oracle) is a software company. It offered perpetual group licences of its Client-Server-Software (a database software) based on 25 users in exchange for a one-off payment. The licensee would receive the right to use the software, download a copy from Oracle’s website, store it on a server and allow the number of users permitted by the licence to access it by downloading it to their computer hard-drives. The perpetual licence also included a maintenance agreement, which enabled the licensees to download software updates and patches from Oracle’s website for the lifetime of the licence (i.e. forever).

Undertakings with fewer than 25 users often “hived off” what they considered to be excess user licences and sold them on to second-hand or used software companies such as the defendant in this case, UsedSoft GmbH (UsedSoft). UsedSoft would then resell these excess user licenses to their customers on the basis that the licence was still valid and the maintenance agreement element still effective. The purchaser of the second-hand licence could then download the software (and the on-going updates and patches) from Oracle’s website for the number of user licences they had bought.

In the German Regional Court (Munich) Oracle claimed that UsedSoft and its customers were infringing its exclusive rights under the German national law which had implemented the Software Directive. In particular, Oracle challenged UsedSoft on the grounds that by “permanently or temporarily reproducing Oracle’s computer program” and by “distributing the original program or copies thereof to the public without Oracle’s authorisation” UsedSoft and its customers were infringing Oracle’s exclusive rights of reproduction under Article 4(1)(a) and distribution under Article 4(1)(c). Further, Oracle argues that neither of the restricted acts had been excepted from infringement by either Article 5(1) (reproduction is necessary) or Article 4(2) (exhaustion). The court agreed with Oracle and granted them an injunction against UsedSoft’s continued activity. UsedSoft appealed to the German Federal Court (the Bundesgerichtshof). They decided to refer three questions on the application and interpretation of the Software Directive to the CJEU (refer to Table 2).

THE CJEU’S DECISION
The CJEU first established that the EU wide definition of a sale should be “an agreement by which a person, in return for payment, transfers to another person his rights of ownership on an item or tangible or intangible property belonging to him”. Despite Oracle’s use of the word “licence” and their insistence that it was a true software licence, the CJEU decided that concluding the grant of a perpetual licence with the right to reproduce the program for the purposes of its intended use. Having determined that Oracle was selling its software, rather than granting licences, the next issue considered by the CJEU was whether UsedSoft and their customers, having both relied on the exhaustion of distribution right in the copies of the software that they purchased from customers of Oracle, could be “lawful acquirers” under Article 5(1) thus allowing them to permanently or temporarily reproduce the program without authorisation from Oracle. The CJEU concluded that, as the right of distribution had been exhausted, it was impossible for the rightholder to object to any subsequent transfers of the software. Therefore, any second-hand acquirer must also be a lawful acquirer with the right to reproduce the program for the purposes of its intended use.

However, the CJEU also concluded that where the computer program is sold as a bundle account purchase (as in this case) the “excess” accounts were not divisible from the bundle. In other words, the
IN COURT

TABLE 1: RELEVANT ARTICLES OF THE SOFTWARE DIRECTIVE

| Article 4(1)(a) | The rightholder of the computer program (either the natural person or persons who created the program or, where the legislation of the member state permits, the legal person designated as the rightholder by that legislation) shall have the right to do or to authorise (a) the permanent or temporary reproduction of the computer program by any means and in any form, in part or in whole; so far as loading, displaying, running, transmission or storage of the computer program necessitate such reproduction, such acts shall be subject to authorisation by the right holder. |
| Article 4(1)(c) | The right holder of the computer program shall have the right to do or to authorise any distribution to the public, including the rental, of the original computer program or copies thereof. |
| Article 4(2) | The first sale in the community of a copy of a program by the rightholder or with his consent shall exhaust the distribution right within the Community of that copy, with the exception of the right to control further rental of the program or a copy thereof. |
| Article 5(1) | In the absence of specific contractual provisions, the permanent or temporary reproduction of a computer program shall not require authorisation by the rightholder where they are necessary for the use of the computer program by the lawful acquirer in accordance with its intended purpose, including for error correction. |

TABLE 2: QUESTIONS REFERRED TO THE CJEU

| Question 1 | Is the person who can rely on exhaustion of the right to distribute a copy of a computer program a “lawful acquirer” within the meaning of Article 5(1) of D2009/24? |
| Question 2 | If yes, is the right to distribute a copy of a computer program exhausted in accordance with Article 4(2) D2009/24? |
| Question 3 | If yes, can a person who has acquired a “used” software licence for generating a program copy as a “lawful acquirer” under Art 5(1) and Art 4(2) D 2009/24 also rely on exhaustion of the right to distribute the copy of the computer program made by the first acquirer with the rightholder’s consent by downloading the program from the internet onto a data carrier if the first acquirer has erased his program copy or no longer uses it? |

fact that the transaction amounts to a sale applies to the group as a whole, but not to the individual accounts, which cannot be sold on individually. So although the principle behind the resale element of UsedSoft’s business model was legitimate on the basis that the principle of exhaustion applied, the sale applied solely to the bundle and it did not enable the original bundle accounts to be divided and sold separately.

Finally, the CJEU made a number of strong statements about the principles of equivalence between online and offline property. In particular, (1) that it made no difference in “this situation” whether the copy of the computer program was available to the customer by means of a download or a physical CD or DVD and (2) that the online transmission method was the “functional equivalent” of the supply of a material medium. To reinforce this attitude towards online-offline equivalence, the CJEU advised that, in practice, to avoid infringing the Article 4(1)(a) reproduction right by relying on the exhaustion principle, the original acquirer would have to make their own copy unusable on resale, just as it would be if the program was sold on in a tangible medium.

CASE IMPACT

The case has ramifications for the software community. Already some software providers are, or are being advised to, switch to fixed term licences - the intention being that granting licences for a set duration might enable companies to avoid “selling” copies of their software for the purposes of exhaustion.

There has also been speculation about how this decision could impact other digital media content such as eBooks and digital music, which are governed by the InfoSoc Directive rather than the Software Directive on which the UsedSoft decision centred. The provisions of recitals 28 and 29 to the InfoSoc Directive suggest that the principle of exhaustion should only apply to tangible media. As a result one could conclude that although the decision is relevant to the computer programs and video games covered by the Software Directive, the CJEU’s judgment should not be extended to include other forms of digital media. However, if we consider the CJEU’s commitment to the principles of online-offline equivalence throughout its judgment, its frank statement that the two directives must in principle have the same meaning and, finally, its establishment of an EU wide definition of “sale” to be applied to tangible and intangible property, it is reasonable to opine that, if given the opportunity, the CJEU will also interpret the InfoSoc Directive exhaustion provisions as applying to tangible and intangible property.

On this basis, therefore, the fact that the vast majority of other digital media is licensed in the same or similar manner to software (i.e. via perpetual licences with terms and conditions applied to use rather than outright sales) it is reasonable to infer that these licences will also amount to “sales” for the purposes of exhaustion.

THE TECHNOLOGICAL ISSUES SURROUNDING EXHAUSTION FOR INTANGIBLE DIGITAL MEDIA.

The practical technical issue facing software producers as a result of the UsedSoft decision (and potentially other forms of intangible media)
is how to practically ensure that the original acquirer’s copy becomes unusable on resale.

The CJEU has encouraged the use of Technical Protection Measures (TPMs). An earlier German decision (Bundesgerichtshof I ZR 178/08 - Half-Life 2; OLG Hamburg) determined that the use of TPMs would not prevent the exhaustion of rights in a copy. However, in this case the restrictive TPMs applied to the video game meant that only one user per copy could ever register an account. Thus a second-hand acquirer, though in possession of the tangible media (i.e. a CD-ROM) imprinted with the software, was unable to access the game, they were “locked-out”. In light of the UsedSoft decision one can reasonably anticipate that such restrictive TPMs, while still lawful, may be held by the CJEU to frustrate the principle of exhaustion. In fact, the use of TPMs to prevent the use of the software by a purchaser after the original acquirer sold it on, recently received a negative opinion on from Advocate General Sharpston in CJEU Case 355/12 Nintendo Co. Ltd, Nintendo of America Inc. and Nintendo of Europe GmbH v PC Box Srl and 9Net Srl (Nintendo v PC Box) referred to the CJEU by the Tribunale di Milano in Italy.

In this case Nintendo challenged PC Box (and 9Net Srl, the internet provider which hosts PC Box’s website) on the basis that its sale of mod chips and game copiers, which enable video games other than those manufactured by Nintendo to be played on Nintendo consoles, infringed Nintendo’s right under Article 6 of the InfoSoc Directive. Article 6 allows the copyright holder to put in place effective technological measures to prevent unauthorised acts in respect of its copyright works. AG Sharpston, however, concluded that, although the technological measures put in place by Nintendo did indeed achieve this, they also prevented authorised acts. She determined that there is unlikely to be any justification for protection of TPMs which prevent or limit acts outside of the rightholder’s authorisation. If this opinion is followed by the CJEU it should establish the boundaries for TPMs used in software as was advised in UsedSoft, and possibly for all digital media.

ECONOMIC IMPLICATIONS OF A SECOND-HAND DIGITAL MARKETPLACE

Beyond the legal ramifications resulting from the development of the principle of exhaustion to cover intangible goods, the creation of a second-hand digital media marketplace may also present significant economic issues. In the existing second-hand book market, for example, it is easy to identify the drop in value of a second hand copy – e.g. by the fact that the book looks “worn”. However, there is no truly comparative decrease in quality for a second hand digital file (unless as a result of corruption during the file transfer) so, in the absence of some distinguishing feature, a second hand copy will be perfectly identical to the original in all respects, except for price. In economic terms the competitive sale of homogeneous products that are perfect substitutes for each other is referred to as “pure price competition”. In this case, authors of digital works will be placed in direct competition with copies of their works which are identical in quality, but sold at a cheaper price or even swapped for free. Such a market place could be economically destabilising to the publishing industry.

DEVELOPMENT OF A SECOND-HAND DIGITAL MARKETPLACE

As we have discussed, the strength with which the CJEU has expressed its commitment to online-offline equivalence with respect to computer programs suggests that they may very well come to a similar conclusion on exhaustion in relation to digital media covered by the InfoSoc Directive. This will allow the development of a second hand digital media marketplace. The CJEU appears to envisage that the development of such a marketplace will require the application of appropriately targeted TPMs that ensure that once sold the original copies become unusable, while simultaneously not frustrating the effect of exhaustion on first sale or distribution. The use of appropriately targeted TPMs could also mitigate some of the impact of “pure price competition”.

In view of the progression of case law and in response to the 2011 Digital Opportunity A Review of Intellectual Property and Growth Report (aka the Hargreaves Review after the Report’s author Professor Ian Hargreaves), the UK Intellectual Property Office (the UKIPO) has proposed amendments to the CDPA. One of these amendments would create a private copying exception to permit an individual who has acquired a copy of a copyright work to make a further copy for non-commercial ends and to be entitled to transfer the original copy to another person, provided that he/she then destroys the duplicate or provided that the duplicate becomes unusable as a result of the function of a TPM. This amendment would be in keeping with the development or foreseeable development of copyright law, in particular in relation to exhaustion, following the UsedSoft decision.

CONCLUSION

It is generally recognised that the speed at which law and regulations move lags behind the development of technology, which has already moved into new formats such as “cloud”-based computing. How relevant will the legal issues surrounding digital files, whether as copies or originals be, when we stop “owning” copies of software on our hard drives and instead make use of such software via the cloud?

Spotify is an everyday example of cloud computing. Spotify enables users to “stream” Spotify’s online libraries of music. Once again, access to the media is via an online account, negating the need to buy and download music onto your own hard drive. Reliability of internet access is limiting step of cloud computing, but as the quality, speed, consistency and reliability of access improves, it is likely that we will increasingly migrate away from copies of digital files. But where will this leave the relevancy of the UsedSoft decision and the development of second hand digital markets? Probably limited to digital copies, but new thinking may change.

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Emma Gallacher and Sean Jauss
ISSUES FOR TM OWNERS - NEW GTLDs

The core group of generic top-level domain names (gTLDs) such as .com, .info, .net and .org is set to expand significantly over the next few years. The process has already begun, as seven new gTLDs were made available to the general public on 29 January 2014, with many more set to follow in the coming months.

In 2008, the Internet Corporation for Assigned Names and Numbers (ICANN), the body responsible for managing domain names, began a process designed to introduce hundreds of new gTLDs. During the application window, which opened in January 2012, ICANN received around 1,930 applications for new gTLDs. These include brand names such as .amazon and .apple, geographic names such as .london and .amsterdam, and other more general names such as .app and .baby.

Around 230 of the new gTLD’s applied for were contested, meaning that more than one application was filed for the same name. The most popular included .app, .inc, and .home.

ICANN will not approve applications for names that are identical or would result in confusion, so these applications are unable to proceed until the conflict is resolved. In most cases this will be through mutual agreement between the parties or through an auction. Nevertheless, many uncontested gTLDs are now reaching the final stages of the process, with the first few having already been released, and many more expected to be available to the general public later in 2014.

With the introduction of hundreds of new generic top level domain names, many trade mark owners will be wondering how they can protect their rights and prevent any number of new domains containing their trade marks from being registered.

TRADE MARK CLEARINGHOUSE

Opened on 26 March 2013, the Trade Mark Clearinghouse allows trade mark owners to record their registered trade marks, marks validated by a court (e.g. UK passing off rights confirmed by a court), and marks protected by a statute or treaty (e.g. protected designations of origin). They can then take advantage of a pre-registration “Sunrise Period”, giving them an initial period of at least 30 days in which to register domains which correspond with their trade marks, before domains for each new gTLD are open to the general public.

To assist trade mark owners in preventing third parties from registering a domain name that is an identical match to a mark registered with the Clearinghouse, there is also going to be a Trade Mark Claims Service.

The potential registrant of such a domain will receive a warning notice. If they choose to continue with registering the domain, the trade mark owner will receive a notification so that they can decide whether to take further action. This could involve domain name dispute resolution (UDRP), an out-of-court dispute resolution mechanism designed to resolve cases of bad-faith and abusive use and/or registration of domain names, or the new Uniform Rapid Suspension (URS) discussed later in this article.

Trade mark owners should note that these notifications will only be triggered by exact matches and will only be sent for the first 90 days from the launch of the gTLD to the general public.

DOMAINS PROTECTED MARKS LIST

Larger domain registries are looking at offering their own protection mechanisms for trade mark owners.

Donuts Inc., a registry which applied for over 300 new gTLDs, has launched the Domains Protected Marks List to protect registered trade marks.

The protection offered is slightly broader than Clearinghouse and allows trade mark owners to record a range of different strings or combinations of words which correspond with their registered trade marks, providing the trade marks have first been registered in the Trade Mark Clearinghouse. The registered marks and related terms will then be blocked from being registered as domains. The block will apply across all of the gTLDs operated by Donuts Inc.

UNIFORM RAPID SUSPENSION

Trade mark owners will be able to continue using UDRP (Uniform Domain Name Dispute Resolution Policy) to pursue cases of cybersquatting. However, there will also be the option of URS (Uniform Rapid Suspension). This should enable trade mark owners to quickly and easily suspend a domain which infringes their trade mark. Within 24 hours of receiving a complaint, the registry operator will “lock” the domain and restrict any changes such as the transfer or deletion of the domain names. If the complaint is found to be justified, the domain could remain suspended for the remainder of its registration period.

COMMENT

As so many of the new gTLDs will be open to the general public, concerns have been raised as to a possible increase in abuse of trade mark rights. However, until the first few gTLDs are launched it will be difficult to fully anticipate the effect they will have. For the time being, trade mark owners should make themselves aware of the new processes in place to safeguard their rights. They should also consider monitoring the release of the new gTLDs to see whether any are particularly relevant to their area of interest. Rebecca Anderson
C-561/11 Fédération Cynologique Internationale v Federación Canina Internacional de Perros de Pura Raza (February 2013)

In this case, the CJEU confirmed that a Community Trade Mark (CTM) proprietor is able to bring infringement proceedings against a proprietor of a later registered CTM, without the need for the later mark to have been declared invalid beforehand.

The relevant sections of the CTM Regulations do not make a distinction on the basis of whether the third party is the proprietor of a registered CTM or not, therefore the CTM proprietor has an exclusive right to prevent “any third party” from using a sign liable to infringe its mark (emphasis added). The CJEU stressed that the exclusive rights afforded to a CTM proprietor are designed to protect the specific interests of that proprietor. If the proprietor were required to wait for the later mark to be declared invalid before preventing its use, the protection accorded to their CTM registration would be “significantly weakened.”

This is different from the position in the UK. Section 111(1) of the UK Trade Marks Act 1994 explicitly states that “A registered trade mark is not infringed by the use of another registered trade mark in relation to goods or services for which the latter is registered”.

Case T 437/11 and Case T 448/11 Golden Balls Ltd v OHIM – Intra-Presse (September 2013)

This case from the General Court considers the role of conceptual similarity in conflicts between trade marks, particularly where the two trade marks consist of words from different European languages.

In 2007, Golden Balls Ltd filed two CTM applications for the word mark GOLDEN BALLS. Intra-Presse opposed the applications under the provisions of Article 8(1)(b) and Article 8(5) CTMR, on the basis of their earlier CTM registration for the word mark BALLON D’OR. BALLON D’OR translates from French to English as “ball of gold” or “golden ball”. The Opposition Division rejected both oppositions in their entirety, however, the Board of Appeal partially upheld Intra-Presse’s appeals.

After finding that the marks GOLDEN BALLS and BALLON D’OR are visually and phonetically different, the General Court considered the Board of Appeal’s assessment that the signs at issue are conceptually identical or, at the least, extremely similar. The General Court held that, whilst the marks call to mind the same idea, overall the marks have, at most, a weak, or even very weak, degree of conceptual similarity.

The General Court stressed the importance of considering the two different languages which the words originate from. Whilst a linguistic difference of this kind cannot automatically exclude the existence of conceptual similarity, it can potentially prevent an immediate conceptual comparison on the part of the average consumer, in so far as they are required to make a translation. Whether or not immediate conceptual comparison is possible will depend on a number of factors, including the linguistic knowledge of the relevant public, the degree of relationship between the languages concerned, and the actual words used.

T-417/12 SFC Jardibric v OHIM – Aqua Center Europa SA (October 2013)

This case concerns the limitation in consequence of acquiescence (Article 54 of the CTM Regulations).

In 1999, SFC Jardibric filed a CTM application for a figurative marking consisting of the words AQUA FLOW, surrounded by a black background. The application proceeded to registration in March 2001. In May 2009, Aqua Center Europa SA filed an application for a declaration of partial invalidity. This was based on an earlier Spanish national registration for a figurative mark consisting of the words VAQUA FLOW.

SFC Jardibric argued that Article 54(2) applied in this case. This states: “where the proprietor of an earlier national trade mark has acquiesced, for a period of five successive years, in the use of a later Community trade mark in the Member State in which the earlier trade mark is protected while being aware of such use, he is no longer entitled to apply for a declaration that the later trade mark is invalid or to oppose the use of the later trade mark”.

SFC Jardibric argued the starting point of the period of limitation in consequence of acquiescence started from the registration of the contested CTM. However, the General Court held that this was incorrect. In accordance with previous case law, the period of limitation in consequence of acquiescence starts to run from the time when the proprietor of the earlier trade mark is made aware of the use of the later Community trade mark.

Secondly, SFC Jardibric tried to rely on a previous commercial relationship with Aqua Center to prove acquiescence. Aqua Center had, for example, purchased goods sold under SFC Jardibric’s French trade mark registration for AQUA FLOW for several years with a view to marketing them in Spain. However, the General Court found that this did not prove that Aqua Center was aware of the CTM registration for AQUA FLOW specifically. It also did not prove that Aqua Center acquiesced to use of that CTM registration in Spain.

This case highlights that there is a fairly high burden of proof on the proprietor of the later mark when trying to rely on the limitation in consequence of acquiescence. Importantly, the proprietor must ensure that the evidence provided is from the relevant time frame, and also specific to the relevant territory. A finding that Article 54 applies will not be made on assumptions based on a history between the two parties.

C-383/12 Environmental Manufacturing v OHIM – Société Elnar Wolf (November 2013)

In this decision of 14 November 2013, the CJEU offered some further guidance on the requirements for showing detriment to distinctive character under Article 8(5) of the CTM Regulations. The decision
clarifies the requirements set out in the earlier decision in Intel, i.e. that in order to show detriment to the distinctive character of a mark, it must be shown that there is evidence of a change in the economic behaviour of the average consumer as a result of the use of the later mark, or there is a serious likelihood that such a change will occur in the future.

In this recent decision, the CJEU held that this is an objective condition and therefore requires more than subjective evidence. The mere fact that consumers note the presence of a new mark similar to an earlier mark is not sufficient in itself to establish the existence of a detriment to the distinctive character of the earlier mark.

You do not need to show actual detriment, but can instead show that there is a serious risk of detriment, allowing the use of logical deductions. Nevertheless, such deductions must not be the result of mere suppositions, but instead must be founded on an analysis of the probabilities, taking into account the normal practice in the relevant commercial sector as well as all the circumstances of the particular case.

The judgement does not offer specific guidance on the type of objective evidence which will satisfy the Intel requirements, however, it suggests that there is a fairly high standard of proof. It seems that it will be insufficient simply to argue that use of the later mark will undermine the earlier mark’s ability to identify the goods for which it is registered as coming from the proprietor of that mark.

Rebecca Anderson

**SPECSAVERS – THE DECISION**

The Court of Justice of the European Union (CJEU) issued its decision in Case C-252/12 Specsavers International Healthcare Ltd and others v Asda Stores Ltd on 18 July 2013, an infringement action concerning advertising campaigns ran by the well-known UK supermarket, Asda (a subsidiary of Walmart), for its optical products that targeted the popular high-street opticians Specsavers.

The Court held, amongst other issues, that where a Community trade mark (CTM) was registered in black and white, the fact that it has been used extensively in a particular colour or combination of colours may be taken into account when considering the likelihood of confusion and unfair advantage in the context of infringement proceedings against a third party. Conversely, if the third party is itself associated with that particular colour or combination colours and uses the colour(s) in relation to the allegedly infringing sign, this should also be borne in mind.

**UK INTELLECTUAL PROPERTY OFFICE**

In light of this ruling, the UK Intellectual Property Office (UKIPO) released a Tribunal Practice Notice (TPN 1/2014) at the beginning of this year, stating that the judgement also applies to infringement proceedings concerning UK national marks.

Furthermore, the UKIPO extended the application of the decision to opposition and cancellation proceedings. This, in itself, is unsurprising given that the opposition, cancellation, and infringement provisions mirror each other, but the application of the findings of the CJEU to the opposition context is of note.

The TPN begins by explaining the key difference in the analysis of the likelihood of confusion in infringement and opposition proceedings: in the case of infringement, the question of likelihood of confusion centres on the earlier mark as registered (now also taking into account whether it has been used extensively in a particular colour(s)) compared with the later mark as used. However, in oppositions, the comparison is between the earlier mark as registered and the later mark as applied for, bearing in mind “all the circumstances in which the [latter] might be used” (emphasis added).

Consequently, where the earlier mark is registered in colour or, following Specsavers, where it has been shown that a particular colour(s) forms part of the distinctive character of the earlier mark even though it may have been registered in black and white, the actual or potential use of the later mark in the same colour(s) may be considered to be relevant.

Another corollary of this difference in approach is that, given that all normal and fair future potential uses of the later mark must be taken into account in opposition proceedings, any evidence relating to the existing use of the later mark in different colour(s) would seem to be irrelevant.

Where an earlier mark is registered in black and white and has not been used, or has been used in respect of colour(s) but the extent and consistency of such use is not sufficient to show that the colour(s) formed part of the distinctive character of the mark, colour will be irrelevant. The comparison, in that scenario, would be between the earlier mark as registered and the later mark as applied for.

**WHAT DOES THIS MEAN?**

As a result of the decision and the TPN, where an earlier mark, which has been relied upon as a basis for an infringement action or UK opposition or cancellation proceedings, is registered in black and white but has
been used extensively in another colour(s), evidence of extensive use of the mark in that colour(s) may be submitted to strengthen a likelihood of confusion or unfair advantage argument. The question then arises as to the nature and extent of this evidence: what should it consist of and how much is enough to show that the colour(s) have become part of the ‘distinctive character of the earlier mark’? Although this specific point has not yet been addressed by the Registry or the courts, it should not pose a significant problem. The question appears to be very similar to that of proving acquired distinctiveness of a mark, and the types of evidence and standards of proof applicable in that area of the law would seem to apply here also.

The judgement of the CJEU in Specsavers is very much limited to infringement proceedings and, in the absence of clarification from OHIM, it is not yet clear whether the decision also applies to opposition and cancellation proceedings concerning Community trade marks. Whilst it is not uncommon for the CJEU to phrase its judgements so that they apply only to the facts in a particular case, given that the opposition, infringement, and cancellation provisions mirror each other both in the UK and at OHIM, and principles developed in any one of these areas are generally seen to be automatically applicable to the others, there is no reason to believe that Specsavers would not apply to CTM opposition and cancellation proceedings too.

The decision from the CJEU and the clarification offered by the TPN should be welcomed. It recognises the commercial reality in which businesses operate, where trade marks may be tweaked or modified, including a change in their colours, every so often as part of a larger re-branding exercise. Furthermore, in accepting evidence that a particular colour(s) has come to be perceived by customers as part of the distinctive character of a mark, the Registry and courts are simply acknowledging and protecting what has already occurred in the ‘real world’ marketplace.

Jacqueline Pang

IN BRIEF

WIPO

Saudi Arabia (SA) joined the PCT on 3 August 2013 and the Islamic Republic of Iran (IR) joined no 4 October 2013, bringing the total number of PCT Contracting States to 148.

EPO

As well as the significant rule changes due to come into force in 2014 (see page 5), the EPO also announced in 2013 that it is changing its practice with regard to handwritten amendments. In the past, the EPO routinely accepted handwritten amendments to the specification but, as of 1 January 2014 this will no longer be permitted and all amendments will need to be typed.

The Enlarged Board of Appeal had five pending referrals by the end of 2013, including new questions relating to the ‘Tomatoes’ and ‘Broccoli’ cases (G2/12 and G2/13; essentially biological processes) and several questions on formal and procedural matters.

The EPO signed a validation agreement with the State Agency on Intellectual Property of the Republic of Moldova (AGEPI), which will allow European patent applications and patents to take legal effect in Moldova.

UK

The Patents County Court was re-named as the Intellectual Property Enterprise Court (IPEC) with effect from 1st October 2013. The court has also now been brought under the wing of the Chancery Division of the High Court of England and Wales; it is no longer a County Court. Following the promotion of Mr Justice Birss to the High Court, new judge Richard Hacon was appointed in to take over the renamed court.

A new Intellectual Property Bill has been going through the UK legislative process, having received its second reading in the House of Commons on 20 January 2014. The Bill includes various changes to the provisions relating to UK registered and unregistered designs, and also lays the framework for ratification and implementation of the Unitary Patent Package in the UK. Separately, changes to the exceptions to UK copyright infringement are being considered. These are likely to be put into law later in 2014, by a series of statutory instruments.

Further news items can be found on our website.

Mewburn Ellis is now on Twitter! Follow us on @MewburnEllisLLP.
PERSONNEL NEWS

Julie Carlisle, Tanis Keirstead, James Leach and Emily Hayes all joined the partnership on 1 April 2013. Julie is based in our London office and does patent work in the chemical and pharmaceutical fields, Tanis and Emily are based in our Cambridge office and specialise in life sciences, while James is based in our Manchester office and concentrates on patent work in the mechanical, electronic and software fields.

John Addiss, Emma Graham, Lauris Kemp, and Rachel Jones all recently passed their examinations and are now qualified European Patent Attorneys.

Emma Gallacher has joined the firm. Emma is a newly qualified solicitor and will be working with our legal team in Bristol.

Mewburn Ellis LLP was “highly rated for its patent expertise, particularly in the biotech and life sciences arenas” in Chambers & Partners 2014 legal guide and was once again listed as a top-tier London-based firm in the Legal 500 guide.

Mewburn Ellis LLP was also named as ‘Best UK IP Firm: Prosecution’ at the 2013 International Legal Alliance Summit & Awards (ILASA), was ranked as ‘highly recommended’ in the 2013 edition of IAM 1000: The World’s Leading Patent Practitioners, and was selected as ‘Biotech Patents Law Firm of the Year in England’ by Corporate INTL Magazine.

Mewburn Ellis LLP also featured in a recent World Trademark Review (WTR) report on ‘The World’s Leading Trademark Professionals’.

For more information, please visit our website.
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The Information in this newsletter is simplified and must not be taken as a definitive statement of law or practice. For more information on these and other intellectual property matters, please speak to your usual contact or e-mail mail@mewburn.com.

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