Although plans for the unitary European patent and unified European patents court continued to progress during 2014 the situation at the end of the year was, at first glance, quite similar to that at the beginning.

The Rules of Procedure for the Court are still in draft form (17th draft and counting); the vast majority of countries have yet to ratify the agreement (with the UK, Germany and at least 5 further countries needed to ratify before the agreement can come into force); and the EPO have yet to announce the intended level of the renewal fees for the new unitary patent.

However, significant developments do include the beginning of recruitment of the judges for the Unitary Court, the issuing of the Advocate General’s opinion on the outstanding Spanish CJEU challenge to the unitary package, and the release of what is thought to be a near-final draft of those Rules of Procedure (any further tweaks are likely to be minor); the majority of the EPO provisions relating to the running of the unitary system have also been finalised. See page 2 for a summary.

On the trade marks side, the latest developments in examination practice relating to colour marks are explained in this issue (see page 13) and some interesting recent court decisions are also summarised, on page 12.

We hope you will enjoy reading MewsNews.
A lot of progress has been made in 2014 with the European Unitary Package – the European Unitary Patent (EUP) and Unified Patent Court (UPC). However, the scale of implementing such a system also became apparent in 2014, pushing the predicted date when the court will open its doors to “no earlier than the end of 2015” and more likely mid to late 2016.

The hurdles towards implementation are reducing in number and the political momentum behind the proposal has mostly continued from the initial signing of the Agreement at the start of 2013. This article provides a brief summary of the progress and changes that occurred in 2014.

RATIFICATIONS
After the solitary ratification by Austria of the Unitary Patent Court Agreement (“the Agreement”) in 2013, a further 5 European countries (including France) ratified in 2014. An additional 7 countries, including Germany and the UK, will need to ratify the Agreement before the UPC and EUP come into force.

The UK has passed the law initiating the first steps of ratification, while Germany is drafting changes to its law to enable ratification. It is likely that either or both of Germany and the UK will hold back ratification until the UPC is ready to open its doors from a practical perspective.

Ireland are due to hold a referendum on ratification, probably in May 2015. Meanwhile, the Czech Republic reportedly will not initially ratify the Agreement. It is reported that the Czech Republic believe that the quality of machine translations are not of sufficient quality to enable many in the Czech Republic to understand the translation.

OPT-OUT FEE FOR UPC AND RENEWAL FEE FOR EUP
The various fee levels for the UPC and EUP are keenly anticipated. In particular, there has been a lot of discussion on:

(i) how much will it cost to opt out “traditional” European patents from jurisdiction of the UPC; and
(ii) how much will it cost to renew an EUP.

All traditional European patents will automatically fall under the jurisdiction of the UPC, even if they were granted before the UPC comes into force, unless the patent proprietor requested to opt-out (and pay a fee). There were rumours that the opt-out fee would be an enormous €30,000 per patent. However, it is currently thought that the opt-out fee will be small to reflect administrative costs. A fee of, say, €100 will still create a large bill for patent proprietors wishing to opt-out a significant proportion of a large European patent portfolio.

The EPO are responsible for deciding the renewal fees of the EUP. As mentioned last year, the fee level is likely to be equivalent to renewal fees in around 5 or 6 countries. The EPO will announce the level of fees around mid-2015, having run several renewal fee simulations.

SPANISH CHALLENGE AT THE CJEU
A remaining uncertainty is the legal challenge brought by Spain at the Court of Justice of the European Union (CJEU). Spain believe the Agreement contravenes European Union law. However, Advocate General Bot has given his opinion that the challenge should be dismissed and has further encouraged more countries to ratify as soon as possible. The CJEU often follows the Advocate General’s opinions, although it is not bound by their opinion in any way. The CJEU publish its decision later this year.

DRAFT RULES
The 17th draft Rules of Procedure of the Unified Patent Court were published in October 2014 and discussed in a public meeting. It is thought that the Rules will not significantly change, bringing further certainty to how the court will operate. The 17th draft Rules sees the reinstatement of a previously deleted Rule relating to bifurcated procedures where a counterclaim for revocation is sent to the central division court, while the infringement proceedings remain in the local division court and not stayed. In these circumstances, new Rule 40(b) specifies that the revocation action will be accelerated and the central division will endeavour to set a date for the oral hearing on revocation action before the date of the oral hearing of the infringement action.

Meanwhile, the Rules relating to the EUP were approved in principle by the EPO Select Committee (aside from financial issues) in their latest meeting. There has also been progress on the Rules relating to the European Patent Litigation Certificate, a certificate enabling European Patent Attorneys to represent parties in the UPC.

WHAT’S LEFT TO DO?
A considerable amount of work remains on the practical aspects of the UPC and EUP, such as procuring and establishing the IT systems, selecting and training judges, and picking suitable locations for the court. Preparation of these aspects is likely to be time-consuming (and hence the delay to implementation of the UPC). However, it is hoped that preparations can be concluded by the end of 2015.

In addition, the committees working on the UPC and EUP are looking to finalise all the draft Rules around mid-2015, including setting of fees. The level of EUP renewal fees, in particular, will have a large influence of the uptake of the EUP.

Keep an eye on our website for further updates on the progress of the unitary patent package during 2015.

Joseph Lenthall
Following a decision from the governing body of the EPO in 2013 (previously reported here), two changes to the EPO rules came into force during 2014.

**(1) RULE 36(1) EPC – TIME LIMIT FOR FILING DIVISIONAL APPLICATIONS**

In 2010, the EPO brought in restrictions that meant an applicant wishing to file a divisional application had to ensure not only that the parent application was still pending, but also that either (i) the first substantive office action from the Examining Division had been issued no more than 24 months earlier, or (ii) a new non-unity objection from the Examining Division had been issued no more than 24 months earlier.

Starting 1 April 2014, requirements (i) and (ii) have been abolished for all applications pending before the EPO as of 1 April 2014, including those pending applications whose 24-month time limits had already expired.

Now, a divisional application can be filed at any time up until the grant or refusal of the parent application.

Alongside this change, the EPO introduced an additional fee for filing a divisional application from an application which is itself a divisional application. Starting at €210 for a second generation divisional application, the fee increases by €210 per generation up to a maximum of €840 for fifth and subsequent generation divisional applications.

It is thought that the eradication of the 24-month time limits is a welcome change for applicants and their representatives. Many considered the 24-month time limit to be too short to decide whether a divisional application was actually wanted or needed.

This rule change also reduces the burden involved in monitoring divisional time limits (especially for large patent families).

**(2) RULE 164 EPC – ADDITIONAL SEARCHES FOR EURO-PCT APPLICATIONS**

When a lack of unity is found during a search of the claims, the EPO searches the first-mentioned invention.

Those who file their application directly at the EPO are invited to pay one or more additional search fee(s) if they want to pursue one of the other invention(s). Unsearched inventions must be pursued in a divisional application, because the EPO requires that the claims relate to searched subject-matter. The alternative route – European regional phase of a PCT application (Euro-PCT) – is slightly more complex. The changes to Rule 164 EPC, which entered into force on 1 November 2014, aim to bring the two routes (Euro-PCT and Euro-direct) into greater harmony.

When the EPO as the International Searching Authority (ISA) makes a finding of lack of unity on a PCT application, the applicant is invited to pay one or more further (international) search fees to have further invention(s) searched.

Old Rule 164 EPC provided no additional opportunity during the European regional phase to have the other inventions searched. Under new Rule 164, if an applicant files claims for examination that relate to a previously unsearched invention, the EPO will invite the applicant to pay, within a period of two months, an additional search fee for each further invention he wishes to have searched. If an additional search is carried out, the results of the additional search will accompany the first communication from the Examining Division.

If the EPO was not the ISA for the PCT application, a supplementary search is carried out when that application enters the European phase. If this supplementary search finds that the claims lack unity (either in agreement with the opinion of the ISA, or otherwise) the first-mentioned invention is searched.

Under old Rule 164 EPC, applicants were given no opportunity to have other inventions searched under these circumstances. New Rule 164 EPC, however, provides the applicant with a two-month period to pay additional search fee(s) for any other invention that he wants the EPO to search. The supplementary search report is drawn up for all inventions for which a fee has been paid.

It is expected that the changes to Rule 164 will allow applicants using the PCT system greater flexibility in deciding how to achieve protection for their inventions in Europe in a cost-effective manner.

Elizabeth Lambert
UK PATENT BOX TO SHRINK

BACKGROUND
The UK Government has been keen to encourage innovation for many years. As a result, a wide variety of Government funded or supported schemes exist for providing such encouragement - be it in the form of grants, networks, or simply tax benefits.

A recently introduced example is the Patent Box, which gives tax relief for profits derived from patented inventions. Starting in April 2013, it has proved popular - the system is generous, and many companies have found the UK a more attractive marketplace because of it.

However, the UK system was scrutinised by international organisations and found to be, perhaps, TOO generous. As a result, an agreement was reached and the UK Patent Box will, from 2016, be changed.

CHANGES - AND CONSEQUENCES
The exact changes that will be made to the legislation are not yet known. What we do know is that the system will be less generous. There will probably be greater limits on which patents (and accordingly which products) are Patent Box eligible. There will also probably be some shift in the way the tax relief is calculated. At the moment relief takes tax on Patent Box eligible profits down to 10% - it is possible that there will also be some change to that.

We also know that entry into the current (probably more generous) Patent Box scheme will be closed soon. We currently have a date of June 2016 for that closure.

Furthermore, we know that the present Patent Box benefits will be terminated for companies who have entered the system. We currently have a date of June 2021 for that termination.

Accordingly, now more than ever, companies who are paying corporation tax in the UK should consider investigating the Patent Box. Entry into the Patent Box system before June 2016 is vital in order to reap the benefits until June 2021.

Once that date is gone, we will have to rely on the new scheme. Once more details emerge we will have a better feel for just how much the scheme will be limited - but for now, we should take advantage of the present system while we can.

Please get in touch with your usual Mewburn contact if you want more information about the Patent Box, or any of the other innovation/IP related support schemes available.

Matthew Smith

STAYS OF UK PATENT LITIGATION PROCEEDINGS PENDING THE OUTCOME OF EPO OPPOSITION PROCEEDINGS

Recent decisions of the UK Patents Court (Actavis v Pharmacia (2014)) develop the approach of the UK courts to the question of whether, and in what circumstances, the court will grant a stay of UK patent litigation pending the outcome of EPO opposition proceedings. This is of interest to patent owners seeking to enforce their patents while EPO opposition proceedings are pending. It is also of interest to parties seeking to “clear the way” of troublesome patents, by relatively fast national revocation proceedings in addition to EPO opposition proceedings, in order to launch a competing product.

BACKGROUND - VIRGIN V ZODIAC
In patent litigation between Virgin and Contour (which became Zodiac), relating to flat-bed seats for airliners, the Court of Appeal reached a final determination of patent infringement based on the scope of the patent as granted. However, subsequently, the Board of Appeal in EPO opposition proceedings maintained the patent in an amended form. In this amended form, the patent was not infringed by Zodiac. The effect of amendment of the patent in EPO opposition proceedings is that the scope of the patent is considered to have been the amended scope as from the date of grant. Therefore the question arose: was Virgin still entitled to damages from Zodiac, in view of the final decision of the UK courts on the question of infringement, or was Zodiac now able to rely on the retrospective amendment of the patent as a defence to the requirement to pay damages? There was previous case law from the Court of Appeal (Unilin v Berry (2007)) that had decided that in these circumstances the alleged infringer must still pay damages.

The case reached the UK Supreme Court. In Virgin v Zodiac (2013) [Virgin Atlantic Airways v Zodiac Seats [2013] UKSC 46], the Supreme Court decided that the decision of the Court of Appeal in Unilin v Berry (2007) was wrong. The outcome was that Zodiac was allowed to rely on the retrospective amendment of the patent at the EPO in order to avoid paying damages. It should be noted that if Zodiac had already paid damages to Virgin and the damages proceedings had been terminated, the decision in Virgin v Zodiac would not have made is possible for Zodiac to claw back the money paid.

The case reached the UK Supreme Court. In Virgin v Zodiac (2013) [Virgin Atlantic Airways v Zodiac Seats [2013] UKSC 46], the Supreme Court decided that the decision of the Court of Appeal in Unilin v Berry (2007) was wrong. The outcome was that Zodiac was allowed to rely on the retrospective amendment of the patent at the EPO in order to avoid paying damages. It should be noted that if Zodiac had already paid damages to Virgin and the damages proceedings had been terminated, the decision in Virgin v Zodiac would not have made is possible for Zodiac to claw back the money paid.
2. The Court of Appeal in IPCom v HTC are: whether or not to grant a stay of UK proceedings, as explained by the proceedings, and this was resisted by Actavis. The principles guiding UK designation of a European patent owned by Pharmacia relating this issue further. At issue in Actavis v Pharmacia (2014) [Actavis v Pharmacia [2014] EWHC 2265 (Pat) and [2014] EWHC 2611 (Pat)] considered this issue further. At issue in Actavis v Pharmacia is the validity of the UK designation of a European patent owned by Pharmacia relating to a dosage form of the drug pramipexole, with Actavis seeking to have the patent revoked in order to clear the way for marketing in the UK of a generic dosage form. Pharmacia requested a stay of the UK proceedings, and this was resisted by Actavis. The principles guiding whether or not to grant a stay of UK proceedings, as explained by the Court of Appeal in IPCom v HTC are:

1. The discretion, which is very wide indeed, should be exercised to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case.
2. The discretion is of the Patents Court, not of the Court of Appeal.

The Court of Appeal would not be justified in interfering with a first instance decision that accords with legal principle and has been reached by taking into account all the relevant, and only the relevant, circumstances.

3. Although neither the EPC nor the 1977 Act contains express provisions relating to automatic or discretionary stay of proceedings in national courts, they provide the context and condition the exercise of the discretion.

4. It should thus be remembered that the possibility of concurrent proceedings contesting the validity of a patent granted by the EPO is inherent in the system established by the EPC. It should also be remembered that national courts exercise exclusive jurisdiction on infringement issues.

5. If there are no other factors, a stay of the national proceedings is the default option. There is no purpose in pursuing two sets of proceedings simply because the Convention allows for it.

6. It is for the party resisting the grant of the stay to show why it should not be granted. Ultimately it is a question of where the balance of justice lies.

7. One important factor affecting the exercise of the discretion is the extent to which refusal of a stay will irrevocably deprive a party of any part of the benefit which the concurrent jurisdiction of the EPO and the national court is intended to confer. Thus, if allowing the national court to proceed might allow the patentee to obtain monetary compensation which is not repayable if the patent is subsequently revoked, this would be a weighty factor in favour of the grant of a stay. It may, however, be possible to mitigate the effect of this factor by the offer of suitable undertakings to repay.

8. The Patents Court judge is entitled to refuse a stay of the national proceedings where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO. It is true that it will not be possible to attain certainty everywhere until the EPO proceedings are finally resolved, but some certainty, sooner rather than later, and somewhere, such as in the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.

9. It is permissible to take account of the fact that resolution of the national proceedings, whilst not finally resolving everything, may, by deciding some important issues, promote settlement.

10. An important factor affecting the discretion will be the length of time that it will take for the respective proceedings in the national court and in the EPO to reach a conclusion. This is not an independent factor, but needs to be considered in conjunction with the prejudice which any party will suffer from the delay, and lack of certainty, and what the national proceedings can achieve in terms of certainty.

11. The public interest in dispelling the uncertainty surrounding the validity of monopoly rights conferred by the grant of a patent is also a factor to be considered.

12. In weighing the balance it is material to take into account the risk of wasted costs, but this factor will normally be outweighed by commercial factors concerned with early resolution.

13. The hearing of an application for a stay is not to become a mini-trial of the various factors affecting its grant or refusal. The parties’ assertions need to be examined critically, but at a relatively high level of generality.

At first, the judge in the Patents Court refused a stay of the UK proceedings. He noted that there was a fine balance between the parties’ competing considerations. Pharmacia had offered undertakings...
IN FOCUS

(a) to seek expedition of the EPO proceedings, (b) not to seek an injunction against Actavis or its customers until the determination of the EPO proceedings and (c) only to seek damages of 1% of Actavis’ net sales during the period from launch until the determination of the EPO proceedings if the patent is held valid both by the EPO and by the English courts. This was not enough for the judge to agree to a stay.

However, shortly afterwards, Pharmacia offered two additional undertakings in return for a stay of the proceedings. These were (d) not to seek an injunction based on the patent in the UK against Actavis or its customers during the life of the patent and (e) only to seek damages of 1% of Actavis’ net sales in the UK during the life of the patent if the patent is ultimately held valid by the EPO and valid and infringed by the English courts. The judge decided that these additional undertakings tipped the balance in favour of granting a stay of the UK proceedings, by addressing the concerns of Actavis that the granting of a stay would cause commercial uncertainty in view of the availability of injunctive relief and of damages at a normal level after conclusion of the EPO proceedings.

The direction of the decisions of the UK courts in relation to granting of stays is interesting. It shows that relatively complex sets of undertakings can be arranged in order to protect each side from adverse interim decisions and even to protect against conflicting decisions on validity as between the UK courts and the EPO. However, there must be a limit on what the patent owner or alleged infringer are prepared to offer as undertakings, in order for patents to retain their value and deterrent effect.

Matthew Naylor

OF BROCCOLI, TOMATOES, AND WATERMELONS:
PLANT SCIENCE ROUND-UP

The patentability of plants has been the subject of much discussion in Europe in recent years, following decisions by the Enlarged Board of Appeal in the “Broccoli” and “Tomatoes” cases. Those decisions (G2/07 and G1/08) related to the provision of the European Patent Convention which excludes “essentially biological processes for the production of plants and animals” from patent protection (Article 53(b) EPC). The Enlarged Board clarified that “essentially biological processes” were those that contained or consisted of the steps of sexually crossing the whole genomes of plants and subsequently selecting plants, so methods that involved these steps were not patentable. The Enlarged Board did state that methods in which a gene or trait is inserted into the genome by genetic engineering are not “essentially biological process” and are therefore patentable. However, so called “SMART” breeding methods (Selection with Markers and Advanced Reproduction Technologies) using genetic markers such as SNPs are excluded from patentability.

In both the Broccoli and Tomatoes cases, the claims to methods of producing improved plants (using SNP based selection, or through selection by extending the time in which fruit was left on the plate) were considered to relate to unpatentable subject matter. However, the cases were referred back to the Enlarged Board (as G2/12 and G2/13, or Broccoli II and Tomatoes II), because they also included claims to the plant products of these methods (i.e. product claims, rather than method claims). The earlier decisions only related to essentially biological processes, and did not consider whether the products of essentially biological process, i.e. plants produced by crossing and selection methods, were also excluded. The oral hearing was held in October 2014, and we are waiting for the decision to be published.

In the meantime, another plant patent has been the subject of an Appeal at the EPO. Decision T1729/06 related to a Syngenta patent for seedless watermelons. The patent had claims to a method for producing seedless watermelons by using diploid watermelon plants as pollenizer plants for triploid watermelon plants, thereby producing lots of seedless fruits on the triploid watermelon plants.

The method related to the production of fruit on existing triploid watermelon plants, and did not lead to the production of new plants with a new genetic makeup. The Board of Appeal concluded that the method was therefore not excluded from patentability, because it was not an essentially biological process for the production of plants, because no plants were produced.

In coming to their decision the Board of Appeal looked back at the historical documentation that was prepared when the European Patent Convention was drafted.

They concluded that the legislators never intended for the entire class of horticultural or agricultural inventions to be excluded, only to exclude conventional plant breeding methods for the production of plants for which plant variety protection was available through the UPOV correction (International Union for the Protection of New Varieties of Plants). This decision by the Board of Appeal is not binding on the Enlarged Board of Appeal, so it does not allow us to predict the outcome of the new appeals in Broccoli II and Tomatoes II. However, the Enlarged Board are also likely to try to determine what the legislators had intended when they come to their decision, and may refer to the same documents. We expect to know more very soon.

Frances Salisbury
PARTHENOTES ARE NOT STEM CELLS, RULES CJEU

SUMMARY
In decision C 364/13 ISCO v. Comptroller handed down on 18 December 2014, the Court of Justice of the European Union (CJEU) decided that unfertilised human egg cells stimulated to divide and develop in a manner similar to early-stage development of a fertilised human egg are not excluded from patentability within the EU under the Directive on the Legal Protection of Biotechnological Inventions (Directive 98/44/EC, known as the “Biotech Directive”). This decision has implications for European Patents and applications at the EPO, and for national patents and applications in EU member states.

BACKGROUND
Biotechnology presents a challenge for patent law, in the need to provide a legal environment which promotes research and innovation in this sector which is of such economic and social importance, whilst taking due account of ethical concerns.

One of the aims of the Biotech Directive was to harmonise the application of provisions for excluding inventions considered to be contrary to ordre public or morality from patentability in the field of biotechnology within the EU. Article 6(2)(c) of the Biotech Directive provides that patents cannot be granted for inventions that relate to uses of human embryos for industrial or commercial purposes. However, the scope of this provision has been unclear.

Decision G 2/06 (Use of embryos/WARF) of the Enlarged Board of Appeal of the EPO related to application of the provisions of the European Patent Convention implementing Article 6(2)(c) of the Biotech Directive. Here, the exclusion was interpreted as preventing the grant of a patent for an invention which necessarily involved the use and destruction of a human embryo at the filing date of the application.

In its 2011 decision in C-34/10 Brüstle v. Greenpeace (Brüstle), the CJEU went further, finding that the provision should be interpreted as excluding from patentability all methods that necessarily involved destruction of a human embryo, whether this was a feature of the claimed invention or an inherent step, and irrespective of when such destruction takes place.

The decision in Brüstle had far-reaching consequences for the patentability of inventions relating to stem cells within the EU; even inventions which made use of long-established stem cell lines were excluded from patentability if at the time of filing the patent application the only way of generating those cell lines would necessarily have required the destruction of a human embryo. The exclusion was held to apply even if no further embryos were destroyed in working the invention.

After these decisions, the EPO adopted a practice of refusing patent applications for inventions relating to human embryonic stem cells which were filed before 10 January 2008, taken to be the earliest recorded date of publication of a method by which human embryonic stem cells could be obtained without destruction of an embryo.

Of relevance to the present ruling, the decision in Brüstle also sought to provide clarity as to what exactly constituted a “human embryo” within the meaning of Article 6(2)(c) of the Biotech Directive. It was decided that “human embryo” should be interpreted broadly, as including “any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenensis”.

With regard to parthenogenetically-stimulated human ova (parthenotes), the judgement reasoned that this matter should be excluded from patentability as it is “capable of commencing the process of development of a human being, just as an embryo created by fertilisation of an ovum can do so”. The inclusion of parthenotes in the definition of a “human embryo” was controversial as they are considered by many to be an ethical source of human stem cells, not requiring the destruction of a fertilised human egg.

INTERNATIONAL STEM CELL CORPORATION VS COMPTROLLER
The present case concerns two GB patent applications by International Stem Cell Corporation (ISCO), which relate to producing human embryonic stem cells from parthenotes, and synthetic corneal tissues produced from such stem cells.

ISCO appealed the decision to refuse the applications on the basis that Brüstle should not be binding as its reasoning for including parthenotes in its definition of a human embryo was flawed, as these cells are not capable of developing into a human being.

Several lines of evidence were presented which demonstrated that parthenotes are incapable of developing to a viable human being due to inherent biological limitations which prevents their development beyond a blastocyst-like stage. By contrast to fertilised eggs, parthenotes do not contain any paternal DNA, which is required for the generation of extra-embryonic tissue necessary for normal embryonic development.

Whilst the Hearing Officer accepted that based on the evidence presented that parthenotes were not capable of ultimately developing into a human being, the decision to refuse the applications was upheld.
The findings of the CJEU in Brüstle were found to be in line with those of the referring court in that case, in that during the initial stages of cell division parthenotes go through the same developmental pathway as a fertilised oocyte. It was noted that the decision of the CJEU focussed on commencing of the process of development into a human, rather than completion of the process.

The Hearing Officer expressed sympathy with the Opinion of the Advocate General in Brüstle, which had suggested the definition of a “human embryo” should be based on capacity to ultimately produce a human being. However, it was noted that the CJEU had not considered this in its decision.

ISCO appealed this decision to the High Court of Justice (England and Wales). They argued that it was unclear as to whether the wording “capable of commencing the process of development of a human being” in the CJEU’s decision in Brüstle was intended to include matter which is capable of commencing a process of development of a human being even if the process cannot be completed so that it is incapable of leading to a human being. It was also noted that the evidence provided to the CJEU in Brüstle suggested that parthenotes did have the potential to develop to a human being.

The High Court decided that a further reference was justified, and referred the question: “Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term ‘human embryos’ in Article 6(2)(c) of Directive 98/44?”.

The Opinion of Advocate General Villalón in C 364/13 ISCO v. Comptroller issued in July 2014, and recommended that parthenotes should be excluded from the definition of a “human embryo” in the sense of Article 6(2)(c) of the Biotech Directive.

The Opinion remarked that to be considered a “human embryo” the process of development of a human being should not merely be commenced, but rather the process should be capable of resulting in a human being. It was further noted that genetic manipulation of a parthenote to render it capable of developing into a human being may be possible, and that the CJEU should answer the question referred to it to include such subject-matter in its definition of a “human embryo”.

The CJEU followed the Advocate General in answering the referred question as follows:

“Article 6(2)(c) of [the Biotech Directive] must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’, within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine.”

**IMPLICATIONS**

The ruling opens up the possibility of obtaining patent protection for inventions relating to certain types of stem cells within the EU.

The CJEU leaves it to the national courts to decide whether a parthenote has the inherent capacity of developing into a human being, based on the current state of scientific knowledge, affording flexibility as to the application of the ruling in anticipation of advancements in this field.

It should be noted that the ruling provides that certain narrowly-defined subject-matter is not a “human embryo”, rather than providing a clearer definition of what in fact is a “human embryo”. The reasoning does, however, appear to be sympathetic to the position that matter which is not inherently capable of developing to a human being should not be considered to be a “human embryo” within the meaning of Article 6(2)(c) of the Biotech Directive.

Whilst the decision does not overturn the broad exclusion of inventions relating to human stem cells following Brüstle, it can at least be viewed as a positive step for commercialisation of research in this field within the EU, which may in turn promote investment.

Adam Gregory

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1 Chung et al. Cell Stem Cell, 2(2) 113-117; 10 Jan 2008, Describes a single blastomere biopsy technique for obtaining hESCs without embryo destruction.

2 International Stem Cell Corporation (BL 0/316/12) 16 August 2012.
OLD DRUGS, NEW TRICKS: PATENT CONSIDERATIONS IN DRUG REPURPOSING

This article originally appeared in the Life Sciences Intellectual Property Review.

The drug discovery and development path for a New Chemical Entity (NCE) can take 10 to 15 years and cost 1 to 2 billion dollars. Repurposing is the practice of finding novel therapeutic indications for existing drugs. Typically the selected drug will have already been shown to be safe in patients, thereby significantly reducing the time it takes to bring the drug to market. Indeed it has been reported that repurposed agents are more than twice as likely across all disease indications to make it to market compared to NCEs. Furthermore, price support for a repurposed drug is in principle no different to an NCE, being likewise dependent on its substitutability and its clinical and economic advantages.

Policymakers, being aware of these benefits, have made efforts to encourage repurposing — for example the US National Institutes of Health (NIH) have programs aimed at utilising existing, partially developed therapeutic candidates in new disease indication. In the UK an “off-patent” drugs bill has been recently proposed with one of its aims being to give generic drug-makers new marketable indications for their products.

However even if the repurposed drug in question is “off-patent”, bringing it to market is still a considerable challenge, and such an investment requires a clear exclusivity strategy. Unfortunately, clarity is something which is in short supply when considering obtaining and enforcing patents in this field.

PATENTS – HISTORY AND FORMATS

In order to protect innovations in repurposing, “second medical use” patents are available in most territories, although notable exceptions exist, including the so-called “pharmacy of the world” India. The precise wording of such claims is a matter of national laws and a bewildering array of formats are used, examples of which are provided in Table 1. For example in Europe two claim formats have been permissible:

- “Use of substance X in the manufacture of a medicament for the treatment of disease Y” (Swiss-form claim);
- “Substance X for use in the treatment of condition Y (EPC2000 form claim)”

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</tr>
<tr>
<td>United Kingdom</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>France</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Singapore</td>
<td>Allowed for the first medical use only</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
</tr>
<tr>
<td>Australia</td>
<td>Only allowed if compound itself is novel</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Canada</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
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<td>yes</td>
<td>no</td>
</tr>
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<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Japan</td>
<td>Only allowed if compound itself is novel</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
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<td>no</td>
<td>no</td>
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</tr>
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<td>India</td>
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</table>
IN FOCUS

The Swiss-form of claim was first permitted in the EPO landmark Enlarged Board of Appeal (EBA) decision G5/83 which found that such claims could be granted “for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient”. As elsewhere the patentability of Swiss-form claims at the EPO is predicated critically on the new “purpose” (or “repurpose”) of the known medicament.

The EPC 2000 form of claim was introduced in 2007, and was intended to match as closely as possible the scope of protection to the scope provided by a “Swiss type claim”. Later the EBA decided that Swiss-type claims were effectively redundant in view of the new law, and would no longer be permitted in new applications. However the very fact that the claims available to applicants are worded differently leads to uncertainty about their scope.

For example the UK courts have to-date treated Swiss-form claims as process claims whereas EPC 2000 claims are purpose-related product claims. Although in some respects the difference may be academic, for example because the product obtained directly from the process claimed under the Swiss-form claim may be protected in the same way as the product claimed under the equivalent EPC 2000 claim, in other contexts there may be key differences. For example it is questionable whether the Swiss-form claim actually requires that the recited drug be present in the final medicament (as is believed to be the case for the EPC 2000 form) or whether it could merely be present during the manufacture? The latter argument was rejected in one UK case, based on particular facts, but certainly remains arguable. The complex relationship between the claims has also lead to confusing practice at the EPO in respect of applicants pursuing protection for both types of claim. For example in one recent decision the EPO prohibited both types in the same application as the Board was not persuaded that the claims were treated differently by national courts whereas other Boards of appeal have allowed that the applicant had a legitimate interest in pursuing both types of claims, accepting that the protection offered was not identical.

PATENTABILITY

Irrespective of the format of the claim, a first hurdle for obtaining a patent for a new medical use for a substance is that the new use must be supported by evidence, in the application as-filed, that the substance is effective for the specified use. In some territories, such as the EPO, the burden is not a high one; rudimentary tests may suffice - full, detailed and rigorous testing of the drug for the proposed condition is not necessary as long as the teaching is plausible. By contrast in China, at least historically, examiners have required that the applications as filed provides more complete evidence of efficacy.

A second hurdle for applicants is to establish novelty and inventiveness over the previous use: for known drugs, there will usually be a considerable literature or history of testing in a therapeutic context. Again, the EPO and UK Courts have frequently adopted a pro-patentee approach when assessing novelty. An earlier medical use should not anticipate a – different - later one because, unlike other areas of patent law, the doctrine of inherency does not apply. Nevertheless there is a squeeze between these two requirements. In claims to medical uses, the term “for” is typically taken to mean not just ‘suitable and intended for’ but also imbues a requirement for a level of therapeutic efficacy. The effect of this is that such claims are generally regarded as novel over a mere proposal to administer the drug to patients in the manner claimed, because a mere proposal does not disclose that the treatment is efficacious. However the disclosure requirements placed on the application itself, and the potentially anticipatory prior art, should be a seamless fit: it cannot be argued by that experimental data provides support for a claimed use, but the same data does not anticipate it.

ENFORCEMENT

Obtaining claims of one type or another is however only the first challenge for applicants in this area. An arguably greater difficulty arises in seeking to enforce them to protect the new market created by approval of the known therapeutic for the new use. Purpose or intention can be a challenging concept when applied to a product or even an act but is nevertheless the defining technical feature of any form of second medical use claim. The supply chain from manufacture (of the drug substance) to distribution, labelling, prescription and final use is likely to involve multiple parties, possibly in multiple jurisdictions, who may have disparate knowledge or intention regarding the final purpose of the medicament.

Where a drug is produced or marketed by a party with label instructions which describe a patented use, or is clearly adapted for that patented use (perhaps in terms of dosage or administration route) it may not be difficult in practice to identify infringement.

However a particular challenge arises in “cross-label” use, whereby a medicament has regulatory approval for both a non-patented and patented indication, and a generic version is marketed (“skinny labelled”) for only the non-patented indication but then ultimately used for the patented indication. To make matters worse, off-label (including cross-label) may be officially sanctioned by authorities. For example the MHRA and NHS UK websites provide guidance to doctors regarding off-label prescribing, with little or no reference to patents or IP. The French National Assembly recently backed a draft bill to let doctors use drugs off label even where alternative drugs are approved. The FDA does not prohibit physicians from prescribing the drugs for off-label uses, including patented uses.
Patentees are unlikely to wish to sue doctors and patients, but it may be challenging to show direct infringement by any party higher in the supply chain. In the absence of evidence of constructive or actual knowledge or intention by these other parties, for example based on sales volumes or promotional literature, a court may simply find the “skinny label” is decisive that the medicament was not “intended for” the claimed medical use.

It such cases it may be possible for the patentee to show “indirect infringement”. Here it would be necessary to show that a party in the supply chain “knew”, or it would have been “obvious to a reasonable person in the circumstances”, that the products were to be used in an infringing manner. The developing case law in the UK around indirect (or “contributory”) infringement has been surprisingly pro-patentee allowing that even the knowledge or suspicion of probable infringement may be sufficient to find liability. Nevertheless difficulties remain when applying this to second medical use claims, particularly Swiss claims where the infringing act itself would seem to be focussed on the manufacture, rather than final use. In these cases it may be necessary to look at the possibility of “joint tortfeasorship” and seek to demonstrate that multiple parties in the chain were acting in a concerted fashion or common design to infringe the claims, but again this can provide evidentiary difficulties for patentees.

Another legal strategy for patentees trying to identify infringement in a supply chain is to show inducement of infringement, for example by suppliers seeking to influence health providers. However in the UK there is no tort in merely facilitating an infringing act and the evidentiary burden to demonstrating induction or procurement of such an act is likely to be high. Interesting the recent US Supreme Court decision of Limelight Networks, Inc. v. Akamai held that there can be no liability for induced infringement when there has been no direct infringement. Since the final health care providers in the chain may benefit from statutory defenses to infringement, or may not in any case perform all the required steps in a medical use claim, there is likely to be considerable challenges for patentees seeking to demonstrate inducement in the context of medical use claims.

CONCLUSION

Drug repurposing will be increasingly important for finding new cures in the years to come, so it is critically important that exclusivity strategies, including patent strategies, exist to provide incentives for companies to innovate in this area. If society is to benefit from new strategies, including patent strategies, exist to provide incentives for companies to innovate in this area. If society is to benefit from new cures in the years to come, so it is critically important that exclusivity strategies, including patent strategies, exist to provide incentives for companies to innovate in this area. It is therefore unlikely to progress.

Simon Kremer and Rachel Jones

4 Also called ‘repositioning’ (where the drug is diverted from its original utility)
Apple then filed an international application on the basis of the US registration and had varied success in different territories. In particular, the German designation was refused and, on appeal, the German court referred a number of questions to the CJEU.

The CJEU held that a representation which depicts the layout of a retail store by means of an integral collection of lines, curves and shapes, may constitute a trade mark provided that it is capable of distinguishing the products or services of one undertaking from those of another. Consequently, the layout of a retail outlet could potentially indicate origin, particularly if it departs significantly from the norms or customs of the economic sector.

It was found that there was no relevance as to whether the design contains an indication as to the size and proportions of the retail store it depicts. Provided none of the grounds for refusing registration applies, a sign depicting the layout of a store of a goods manufacturer may legitimately be registered for services as well as goods, where those services do not form an integral part of the offer for sale of those goods.

_Dalsouple Société Saumuroise Du Caoutchouc v Dalsouple Direct Ltd & Another [2014] EWCH 3963 (Ch)_

Dalsouple UK were the UK distributor of rubber flooring products manufactured by Dalsouple France. In 1998, Dalsouple UK obtained a UK registration for the mark DALSOPLE. Dalsouple France subsequently attempted to register DALSOPLE in the UK in 2011. Dalsouple UK opposed this application on the basis of its earlier registration which, in response, Dalsouple France applied to invalidate on the basis of bad faith, arguing that Dalsouple UK was its agent at the time of filing of the UK registration and had acted without their knowledge or consent.

The Hearing Officer, noting that any consent provided did not need to be in writing, found that Dalsouple France had in fact consented to the registration of the mark in the UK by Dalsouple UK. Accordingly, the application for invalidity failed.

An appeal was filed before the High Court, where the key issue was the consideration of ‘consent’. It was held that ‘consent’ had to be interpreted in the same way as ‘consent’ in the context of exhaustion of trade mark rights. Consequently, the test in _Zino Davidoff SA_ applied in this instance, namely that consent has to be expressed in an unequivocal manner, whether or not in writing. Whether an express statement of consent has been made must be determined as a matter of fact in accordance with normal English rules of procedure governing burden and standard of proof.

Consequently, based on the Hearing Officer’s finding of fact, it was held that there was an express oral statement of consent and thus an unequivocal demonstration of an intention to renounce Dalsouple France’s right to prevent Dalsouple UK registering the trade mark in the UK.

_Joined Cases C 581/13 P and C 582/13 P Intra-Presse SAS v OHIM (November 2014)_

This was an appeal to the CJEU on a number of grounds.

Firstly, the CJEU upheld the reasoning of the General Court in finding that there was no likelihood of confusion between the marks GOLDEN BALLS and BALLON D’OR. In particular, the General Court had held that the marks were visually and phonetically different and that there was, at most, only a weak, or even very weak, degree of conceptual similarity. The CJEU rejected this ground of appeal on the ground that it was in part unfounded and in part manifestly admissible.

Nevertheless, the CJEU held that the General Court was wrong in dismissing the Article 8(5) CTMR reputation ground of the opposition by simply referring to the above findings in the context of likelihood of confusion and concluding that, consequently, ‘the signs at issue lacked the requisite similarity for the purposes of applying Article 8(5)’.

In particular, the CJEU emphasised that the Court had consistently held that the degree of similarity required under the likelihood of confusion and the reputation grounds is different. The level of similarity under Article 8(5) reputation may be of a lower degree than that under the likelihood of confusion ground, provided it is sufficient for the relevant section of the public to make a connection between those marks, namely to establish a link between them.

Consequently, the Article 8(5) ground is only manifestly inapplicable where the General Court has ruled out any similarity between the marks. If there is some similarity, even faint, between the marks, then the General Court must carry out an overall assessment to determine whether a link would be made between them by the relevant public, taking into account other factors such as the reputation or recognition enjoyed by the earlier mark.

In this case, the General Court had found that there was a low degree of conceptual similarity between the marks and so did not rule out all possibility that the marks were similar. As a result, the General Court was wrong to dismiss the application of Article 8(5) without first carrying out an overall assessment of the marks to determine whether, despite the low level of similarity between them, the presence of other relevant factors meant that the relevant public would make a link between them.

The case was remitted to OHIM, which must now reassess whether Article 8(5) applied. 

Jacqueline Pang
A recent change in practice has implications on the scope of protection afforded to black and white marks registered in the UK and under the CTM system.

Previously, a trade mark application for a mark filed in black and white was considered to cover all possible colour variations, giving the broadest protection possible. However, this has changed, following the European Trade Mark and Design Network issuing a document called the Common Communication on the Common Practice of the Scope of Protection of Black and White Marks (“Common Practice”) on 15 April 2014.

Following the Common Practice, many trade mark offices across the European Community intend to interpret black and white marks differently in future. This change in practice may have significant impact on opposition and invalidity proceedings, on priority claims, and on whether a proprietor can prove genuine use of their mark.

THE PRINCIPLES OF IDENTITY BETWEEN MARKS

Two trade marks are considered to be identical where the later mark reproduces the earlier mark without any modification or addition, or where, viewed as a whole, the later mark contains differences so insignificant that they may go unnoticed by the average consumer.

The new Common Practice states that a black and white mark and a colour mark will only be considered to be identical if colour is an insignificant difference that a reasonably observant consumer would only notice upon side by side examination. It seems that a black and white mark will usually not be identical to the same mark in colour. The use of colour would need to be negligible to only be noticed on side by side examination.

The examples below, taken from the Common Practice itself, demonstrate how the principles above will be applied. The following marks would be considered to be identical, as any differences between them are insignificant:

However, the following marks would be seen as having significant differences, and would therefore not be considered identical:

IDENTITY BETWEEN MARKS IN OPPOSITION AND INVALIDITY PROCEEDINGS

In the vast majority of cases, the changes outlined in the Common Practice would not have a significant impact on the eventual outcome of an opposition or invalidity action, as the two marks would still be considered similar. However, it is likely to impact the appropriate grounds of opposition or invalidity, and the ways in which an opposition or invalidity action is argued.

IDENTITY FOR THE PURPOSE OF PRIORITY CLAIMS

In some cases, applicants may wish to file an application for a colour mark in the UK or at the CTM Office (known as OHIM), whilst claiming priority from an earlier filed black and white mark in another territory. However, according to the new Common Practice, to claim priority, marks should now be the same in the strictest possible meaning.

This means that if the priority mark claims black and white, or is depicted in black and white, and the application is filed in a colour, the marks will not be identical and the priority claim will be rejected (unless the difference created by the colour change is insignificant).

GENUINE USE OF A BLACK AND WHITE MARK

For the purposes of proving use of an earlier mark in oppositions, invalidity proceedings, and non-use cancellation or revocation actions,
genuine use of a trade mark can include use in a form which does not alter what makes the mark distinctive (known as distinctive character).

The new Common Practice states that a change in colour does not alter distinctive character, as long as:
- The word/figurative elements coincide and are the main distinctive elements;
- The contrast of shades is respected;
- Colour or combinations of colours does not have distinctive character in itself;
- Colour is not one of the main contributors to the overall distinctiveness of the mark.

This is likely to make it much harder for proprietors to enforce or maintain a registration in black and white if they use their mark solely in colour, as colour will usually have distinctive character in itself, and can often contribute to a mark’s overall distinctiveness.

IMPLEMENTATION

The changes in practice have been implemented by most trade mark offices across the European Union, with the exception of the Swedish, Danish, Italian, French and Finnish trade mark offices. However, they have approached the changes in different ways.

OHIM implemented the change in practice on 2 June 2014, and will now apply the new interpretation of the scope of protection of black and white marks to all trade mark applications and proceedings (such as oppositions) filed after 2 June 2014, and to all trade mark applications and proceedings pending on 2 June 2014.

The changes were implemented by the UK Intellectual Property Office on 15 July 2014. Unlike at OHIM, the new interpretation of the scope of protection black and white marks will only be applied to trade mark applications and proceedings filed after the changes were implemented.

COMMENT

It should be noted that this is simply a statement of practice by the relevant trade mark offices, and not a change in the law. However, it does seem to be consistent with some more recent decisions from the higher courts in the European Community.

Trade mark proprietors who are concerned about the implications the new Common Practice will have on their trade marks should speak to their usual contact at Mewburn Ellis, or email news@mewburn.com for further information.

Rebecca Anderson

IN BRIEF

EPO

The EPO has signed an agreement on validation with the Tunisian Patent Office, which will eventually allow European patent applications and patents to take legal effect in Tunisia. The agreement still has to be ratified before it can enter into force.

The EPO has introduced a new scheme to improve legal certainty on pending patent applications. Under the “Early Certainty from Search” scheme, the EPO will aim to issue search reports and opinions within six months of filing, will prioritise the completion of examination which it has already started (over beginning work on new files) and will expedite grant in cases where a positive search opinion has been issued. In addition, it will prioritise processing of cases where substantiated third party observations have been filed. Oppositions and requests for limitation or revocation will also be given priority.

UK

The Intellectual Property Act 2014 came into force in the UK on 1 October 2014. The Act includes various changes to UK legislation, mainly in the areas of patents and designs. For more information, please visit our website.

As well as reducing the scope of the ‘Patent Box’ tax reduction scheme [see page 4], the UK government has also suspended funding for ‘IP Audits’ – applications filed after 31 January 2015 will no longer be accepted.

WARNING: FRAUDULENT INVOICES

The UK Intellectual Property Office and the European Patent Office have both issued fresh warnings that fraudulent invoices, purporting to be from the EPO, OHIM, or WIPO, are being sent to companies and individuals.

The fake invoices use names, abbreviations and/or logos which are very similar to those used by the official organisations and invite payment e.g. for the publication and/or registration of applications and patents. However, despite the misleading ‘official’ appearance of such invoices, the services offered by these firms are completely unrelated to the normal processing of patent, trade mark and design applications.


If you are in any doubt about a communication apparently received from an intellectual property office, feel free to ask your usual Mewburn contact for advice. UK-based companies can report receipt of fraudulent invoices directly to Action Fraud (operated by the City of London Police) using their online portal.

Further news items can be found on our website.
PERSONNEL NEWS

On 24 March 2014 our Manchester Office relocated to new premises at Manchester One, 53 Portland Street, Manchester.

Katherine Green and Sean Jauss both joined the partnership on 1 April 2014. Katherine is based in our Cambridge office and handles mostly biotech cases, with a particular emphasis on prosecution, opposition and appeal work at the EPO. Sean is Head of our Legal Team and advises a wide range of clients on all types of IP law, technology transfer and IP exploitation, and assists with due diligence and the preparation and negotiation of transactional agreements.

Jacqueline Pang passed her examinations and is now a qualified Trade Mark Attorney. Elizabeth Lambert and Paul Dunne passed the European Qualifying Examination and are now qualified European Patent Attorneys.

Mewburn Ellis LLP was again recognised in high-profile industry rankings and awards in 2014, including the Legal 500 and Chambers UK.

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EPC EXTENSION STATES

Bosnia and Herzegovina
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General enquiries: mail@mewburn.com
Website: www.mewburn.com

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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