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Events

6-8 December 2010

Developing IP Strategies for Crystalline Forms Conference

Neil Nachshen is speaking at Pharma IQ's Developing IP Strategies for Crystalline Forms conference. Neil's talk is entitled 'The Value (or Not) of Crystal Form Patents in Europe'.

Kit Wong and Tim Russell will be leading a pre-conference workshop on Optimising International Patent Protection For Crystalline Forms - How to Draft Your Crystalline Form Patent Application - Adopting Best Practice Strategies.

10-11 Feburary 2011

Vaccine Research and Innovation 2011

Catherine Mallalieu and Simon O'Brien will be speaking at this conference in London, which will explore global opportunities in vaccine research and development, and is designed to implement successful strategies and innovative technologies to develop more effective vaccines.

23-24 February 2011

Stem Cells 2011

As part of this conference in London, Robert Dempster and Simon O'Brien will be leading a workshop entitled 'Practical Steps and Strategies for Obtaining Patent Protection for Stem Cells'. This interactive session will provide practical tips on drafting, filing and prosecution strategy for stem cell patent applications in order to provide flexibility and maximise protection in each jurisdiction.

For more information: www.dyoung.com/events

Editorial

As the temperature drops in the United Kingdom, the festive season is once more upon us.

2010 was an exciting year for D Young & Co with our rebrand in April; and we are now looking forward to 2011 and to welcoming Ian Starr and Tamsin Holman to the firm in our new IP Dispute Resolution and Litigation Practice in January. See the article on page three for more information.

We hope you enjoy this edition of the newsletter and wish you Season's Greetings and a Prosperous New Year.

Editor:
Aylsa Williams

Article 01

The Big Chill
The Effects of Hypothermia and Xenon as a Clinical Treatment

Advances are made by pushing boundaries

British television channel BBC2's recent Horizon program *Back from the Dead* provided a fascinating insight into how an accidental discovery led to dramatic developments in the clinical treatment of ischemia and other traumatic events to which the body may be subjected.

The program documented the remarkable story of a Norwegian skier, 29 year old Anna Bagenholme, who was involved in a serious skiing accident 11 years ago in the Kjolen mountains in northern Norway. Whilst skiing with a friend, Anna fell down a ravine and was dragged under the ice. She remained trapped for nearly an hour, during which time her heart stopped beating and her body temperature fell to as low as 13.7 °C. Rescuers eventually came to her assistance and airlifted Anna to hospital in Tronsø, over 280 miles away. By the time she received emergency treatment at the hospital, Anna's heart had not beaten for almost 3 hours and there were no signs of electrical activity in the brain. However, once on cardiopulmonary bypass, Anna was gradually warmed up and her heart began to beat again. Against all the odds, Anna eventually made a full recovery. Physicians attribute her astonishing recovery to the body's ability to shut down under conditions of severe hypothermia, thereby preventing neural damage to the brain. The key to Anna's survival was that her brain was cooled to a low enough temperature to reduce its requirement for oxygen before her heart stopped beating. In other words, by the time her heart had stopped, the extreme hypothermia to which she was subjected had already served to protect her brain from permanent neural damage.

Although the neuroprotective effects of cooling were well known, this story provides an extreme example of how effective hypothermia can be in a real life clinical situation. In the light of this, physicians then began to speculate whether artificially induced hypothermia could be used to protect patients against neural damage in circumstances where the body is subjected to traumatic events, eg, during surgery.

Studies carried out by Dr John Elefteriades and his team at Yale New Haven Hospital, Connecticut documented the progress of a 59 year old male who underwent an operation to remove a potentially life threatening aortic aneurysm. During the surgical procedure, the patient's body temperature was lowered to 18°C to achieve what is known as deep hypothermic circulatory arrest. This reduces the metabolic requirements of the brain to 12.5 % of normal levels, thereby creating a narrow window during which the surgical team could cut off the blood supply to the brain and repair the aorta. During this period the patient is effectively in limbo between life and death; the heart stops, the blood is stationary and there is no sign of electrical activity in the brain.

Once the surgical procedure was complete, full bypass was resumed and the body was gradually warmed up. The operation was a success and strengthened the growing belief that hypothermia could be a very effective clinical treatment.

Pioneering research is also investigating whether hypothermia can be used in true emergency situations, eg, in the treatment of trauma patients in Accident & Emergency departments of hospitals. Studies by Dr Hasan Alam and his team at Massachusetts General are investigating whether trauma patients suffering major blood loss can be subjected to rapid hypothermia by the infusion of cold saline to reduce the body temperature to as low as 10-15 °C. Whilst this research is still at a very early stage, it is hoped that this type of intervention may be able to significantly affect survival rates, whilst minimising long term neural damage.

The Horizon documentary also described recent research investigating the use of hypothermia in combination with conventional neuroprotective drugs. A study by Professor Marianne Thoresen at St Michael's Hospital in Bristol is investigating the use of cooling in neonatal subjects, in combination with xenon, another neuroprotective agent.

Xenon is an inert gas that has been recognised as an anaesthetic agent for many years. However, to date the widespread use of xenon as an anaesthetic in the clinic has been precluded by its high cost compared to other conventional anaesthetics.

Twelve years ago, researchers at Imperial College, London discovered more about the mechanism of action of xenon. In particular, research carried out by Professors Nick Franks and Mervyn Maze revealed that xenon targets the glutamate (NMDA) receptors and acts as an NMDA receptor antagonist. Moreover, as well as having anaesthetic properties, xenon was also shown to exhibit potent neuroprotective properties, with minimal side effects. This opened up the possibility of using xenon in a number of different therapeutic applications, eg, in the treatment of stroke, trauma and other ischemic insults which may give rise to neural damage. They went on to show that the combined use of xenon together with hypothermia was a particularly effective treatment in animals that had suffered damage.

Based on these experiments with animals, Professor Thoresen in Bristol has shown that premature babies subjected to oxygen deprivation during birth can be treated with a combination of hypothermia and xenon to prevent brain injury. Research suggests that xenon may supplement the neuroprotective effects of hypothermia, thereby leading to the possibility of further improved treatment regimens.

The Horizon story provides a rare example of how an accidental discovery can propel a relatively little known clinical technique into the spotlight. It is often the case that advances are made by pushing boundaries without a complete understanding of the underlying scientific mechanisms. Future research is likely to focus on the question of whether hypothermia, with or without other neuroprotectants, can be used to further manipulate the physiological limbo between life and death to clinical advantage.

Dr Zöe Clyde-Watson of D Young & Co has been involved in drafting and prosecuting a number of patent applications relating to various therapeutic applications of xenon, including its use as a neuroprotectant and its use in combination with hypothermia. These patents and applications stem from research undertaken by Professors Nick Franks and Mervyn Maze, and are in the name of Protexeon Limited (a spin-out from Imperial College), now a wholly owned subsidiary of Air Products, Inc.. See WO 00/76545; WO 01/08692, WO 03/092707, WO 04/012749, WO 05/34966 and WO 06/18655.

BBC2's Horizon program aired on 27 September 2010 and can be viewed at: http://bbc.in/bigchillhorizon

Author:
Zöe Clyde-Watson

Stop Press! D Young & Co Launches IP Dispute Resolution & Litigation Group

We are pleased to announce that the D Young & Co Dispute Resolution & Litigation Group will be launched in January 2011. The team will be lead by Ian Starr and Tamsin Holman, who join us from law firm, Ashurst, and we will be expanding the team in the new year.

We will become the first firm of patent and trade mark attorneys to establish a Legal Disciplinary Practice in the UK.

Jeremy Pennant, Partner and head of the trade mark team, comments:

"This development enables D Young & Co to expand our range of services, so that clients can resolve disputes and enforce their rights, without having to employ the services of a separate law firm. Increasingly, clients are requiring us to manage their contentious work, and we will now be able to offer court litigation services as well as the full range of alternative dispute resolution procedures.

The ability to do so as a single firm permits us to both strengthen and streamline the services offered to clients in a cost effective manner and to ensure continuity in the quality of service they have come to expect from D Young & Co.

Ian and Tamsin bring a wealth of knowledge and experience and we are excited at the prospect of their arrival. We will be recruiting further solicitors with the creation of this new team."

If you have any questions regarding our new IP litigation practice please contact Jeremy Pennant.

Author:
Jeremy Pennant

Useful links:

http://www.dyoung.com/news-ldp

IP Litigation on a Budget
New Patents County Court Rules

Twenty years ago the Patents County Court (PCC) was born into the UK judicial system. Intended to provide a low cost and simple forum to bring Intellectual Property (IP) litigation within the reach of small to medium-sized enterprises (SMEs), it has regularly been criticised for failing to achieve that aim. For most of its lifespan, the PCC has applied the same procedures as its big brother the High Court, meaning that there is little real difference between the two forums in terms of cost and complexity. While the PCC permits representation by solicitors and patent attorneys, thereby enabling a litigant to reduce their own representation costs, it was difficult for a litigant to prevent the other side incurring substantial costs. As a result, the losing party could be forced to bear the excessive legal costs of the winning party.

On 1 October 2010, the PCC was reborn. Strict limitations on the amount of legal costs which are recoverable by the winning party have been set out. Streamlined case management procedures have been put in place to reduce procedural complexity, to permit decisions to be reached more quickly and to prevent costs getting out of control. And a new judge, Colin Birss QC, has been appointed to herald in a new age of low cost patent litigation.

Cost Limitations

Under the new rules, the maximum costs recoverable by the winner in a liability action (for example a patent infringement case) will be £50,000. For a damages/account of profits inquiry the limitation will be £25,000. In addition, each procedural stage of an action is subject to its own limit. For example, the maximum legal costs recoverable in relation to attendance at a case management conference will be £2,500, while that of preparing for and attending trial and judgment (if required) will be £15,000.

The overall intention is to provide access to justice for SMEs and individuals for whom IP litigation has previously been unaffordable. The basic premise of the new cost limitations is that a cost-sensitive litigant should be able to access IP litigation without risking becoming liable for a crippling costs order should they lose the case.

However, the new cap on costs does not provide absolute certainty. Firstly, there is provision for parties who have behaved "unreasonably" to have additional cost orders awarded against them. Care must therefore be taken to ensure that the rules of the court are adhered to rigidly, and that pre-action behaviour is impeccable.

Secondly, should a decision of the PCC be subject to an appeal, the cost of the appeal before a higher court is unlikely to be subject to a cost cap. No procedural rules or directions have yet been made which could bind the Court of Appeal in controlling costs for such cases. It is not yet clear whether any such formal rules will be implemented, or whether the Court of Appeal will use its own discretion to control costs in its treatment of cases originating from the PCC.

Thirdly, should a litigant bring an action before the PCC, there is a possibility that the action could be transferred to the High Court. Under the new rules this would expose the litigant to the more complex and costly procedures of the High Court and to the risk associated with the absence of a cap for legal cost awards. To mitigate these issues, a new practice direction has been adopted which sets out guidance on the circumstances in which cases should be transferred. Consideration should be given to whether a party can only afford to bring or defend the claim in the PCC. Consideration should also be given to whether the claim is appropriate to be determined by the PCC having regard to the value of the claim, the complexity of the issues and the estimated length of the trial.

Where a transfer to the High Court is required, the practice direction also provides for the PCC to set terms for the transfer and to award reduced or no costs where it allows a litigant to withdraw from proceedings. These measures are intended to give a cost-sensitive litigant a reasonable degree of certainty about whether an action is likely to remain before the PCC, and to provide a path of retreat should the case be transferred to the High Court and therefore placed outside of the financial reach of the litigant.

Simplified Procedures

The other dimension to the new rules is that of a simplified and more tightly controlled procedure. This in itself should result in lower overall costs for litigants, as well as enabling justice to be dispensed more rapidly. Currently, there is little guidance available on what the new rules mean, but a revised PCC guide is likely to be available soon. The new procedures include the following:

- A requirement for statements of case made at the outset of proceedings to include all of the facts and arguments which are to be relied on, and for those statements of case to be verified by a person with actual knowledge of the facts. Further evidence or arguments will require the permission of the judge, and that will presumably be given only with good reason.

- A shortened timetable up to and including trial, including an early case management

conference at which the issues of the case will be identified and discussed. Extensions of the prescribed time periods require permission by the court and will only be granted for good reasons.

- At the case management conference the court will decide whether or not to order the collection of evidence by way of, for example, disclosure, experiments, witness statements and expert evidence. The default position will be that these forms of evidence will not be ordered unless the court considers that their benefit to the case is sufficient to justify the associated expense.

- Where possible, the court will reach a decision based on the statements of case and any oral submissions made by the parties. Where a trial cannot be avoided, cross-examination will be kept to a minimum and efforts will be made to ensure that trial lasts one or at most two days.

It is clear that these measures should lead to an improvement in the affordability of IP litigation, but it should not be forgotten that they may cause a reduction in the quality of justice dispensed by the court. One key concern is that of the lack of expert evidence, which is often a cornerstone of IP litigation. Without this, the court must be its own expert. The trade-off between cost and quality may be particularly problematic for disputes where one party requires the relative financial certainty of the PCC while the other party requires the greater legal certainty of the High Court.

In general, the new rules are likely to be good news for SMEs for whom litigation before a court was previously unaffordable. For larger companies for whom litigation was already viable, the benefits of a lower cost forum may be outweighed by a perceived risk of lower quality justice. Only time will tell whether the rejuvenated PCC will be a success with litigants. In the meantime, the inhabitants of the IP world will be watching with interest.

Author:
Gareth Scaddan

EPO Decision G2/08
End of the Swiss Claim Format for Second Medical Use Claims

Decision G2/08 heralds the end of the Swiss claim format for second medical use claims

As reported in our April 2010 newsletter, in decision G2/08, the Enlarged Board of Appeal held that where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, the claim may no longer have the format of a so-called Swiss-type claim[1]. The Board set a period of three months from the publication of decision G 2/08 in the Official Journal, after which period **future** applications are required to comply with this ruling.

G2/08 was published on 28 October 2010 and therefore the three-month period set by the Board will expire on **28 January 2011**. As a consequence, European patents will not be granted in respect of European patent applications having **a filing date or earliest priority date of later than 28 January 2011** if they contain Swiss-type claims.

So, for these future European applications, the Swiss-type claim as instituted by G5/83: "Use of a substance X in the manufacture of a medicament for the treatment of disease Y", will not be accepted. Instead, the new format introduced by EPC2000 can be used: "Substance X for use in the treatment of disease Y"[2].

However, when drafting applications which may be filed in jurisdictions other than Europe and where, eg, the EPC2000 claim format may not be approved, basis for both the Swiss-type format of claim and the EPC2000 format should ideally still be included in the application.

Please note that the ruling of G2/08 does not have retroactive effect and so does not apply to pending applications. Swiss-type claims will continue to be acceptable for applications which have a filing date or earliest priority date of 28 January 2011 or earlier.

Author:
Jo Bradley

Footnotes:

1. *D Young & Co patent newsletter, April 2010, Article 03: Dosage Regimes Patentable - Enlarged Board of Appeal Liberalises Law on Second Medical Use Claims. http://www.dyoung.com/patentnewsletter-apr10*

2. *Article 54(5) EPC2000*

The Green Channel
Is the New System Bearing Fruit?

On 12 May 2009 the UK Intellectual Property Office (UK IPO) introduced an accelerated system of examination for applications which relate to an invention which has an environmental benefit – a so called 'green' invention.

The system, referred to as the Green Channel, provides an incentive to applicants to file their applications for their 'green' invention with the UK IPO. All that the UK IPO required is a request in writing and an explanation of how the invention is environmentally friendly.

According to the UK IPO, the service is available to applicants who make a reasonable assertion that the invention has some environmental benefit. The UK IPO will not conduct any detailed investigation into these assertions, but will refuse requests if they are clearly unfounded, for example if the application relates to a perpetual motion machine.

Nearly 18 months on, has the system been successful in providing a quick route to grant for 'green' technology?

As of 22 October 2010, the UK IPO's website indicated that 136 applications for examination via the Green Channel have been published. Of these 136 applications, 33% were filed after the 12 May 2009 and so could arguably have been filed in response to the introduction of the system. The remaining 77% of applications of course relate to existing applications which were filed prior to the existence of the Green Channel. It is therefore quite possible that at the time that these applications were filed, the 'green' credentials of the invention may not necessarily have been envisaged.

This is perhaps evidenced by the fairly wide spread of technology sectors for which applications published under the Green Channel have been made. The chart on the right illustrates the distribution of the published Green Channel applications across the different IPC technology classifications.

As can be seen, although the area of mechanical engineering, lighting and heating contain a large proportion of the applications, applications have been made in each classification.

This perhaps shows the open-minded approach being taken by the UK IPO to the issue of whether an invention is 'green' or has an environmental benefit. Indeed, applications for accelerated examination via the Green Channel appear to have been accepted for inventions as diverse as insecticidal compositions and coffins. Therefore, it would appear that the UK IPO has not restricted the use of the Green Channel to those areas which have stereotypically been considered as 'green', eg, wind turbines, solar panels etc, but instead has given the system a much broader application.

The result of this is that there are many inventions which qualify for accelerated examination through the Green Channel, even though at first sight they would not necessarily seem appropriate.

The speed at which the examination process can be accelerated is also considerable. Some applications have been granted just four months after requesting entry into the Green Channel. This represents a significant improvement on the four and a half year limit given in the UK Patents Act for placing the application in order for acceptance.

In view of the potential speed at which grant can be obtained from the UK IPO, it should be remembered that the criteria for patentability have not been reduced, nor the standard of examination diluted. Thus, there is no reason to suspect that a patent granted through the Green Channel would not be as robust as one granted through normal examination.

More information
UK IPO website: http://bit.ly/greenchannel

This issue may be of relevance if considering using the granted GB patent as a platform for examination in other territories.

In this regard, it is worth remembering that the Patent Prosecution Highway (PPH) between the UK IPO and the United States Patent and Trademark Office (US PTO) has been extended indefinitely. As a result, applicants who wish their US application to undergo accelerated examination can potentially use a granted GB patent as a platform for US examination. Therefore, provided the UK patent has been granted with claims of a satisfactory commercial scope, any means of obtaining accelerated grant in the UK can potentially be 'exported' to the US through the PPH.

It can be critical in the early stages of developing an invention to have adequate intellectual property protection in place to ensure that potential investors and collaborators are reassured regarding the exclusivity and value of the product they are interested in. Granted patents, as opposed to simply pending applications, provide a much stronger showing that the technology in question is an attractive investment. In view of this, quick grant of patent applications in major territories, such as the US, UK and Japan, can possibly provide additional security and confidence to investors when considering the development and commercialisation of new technology.

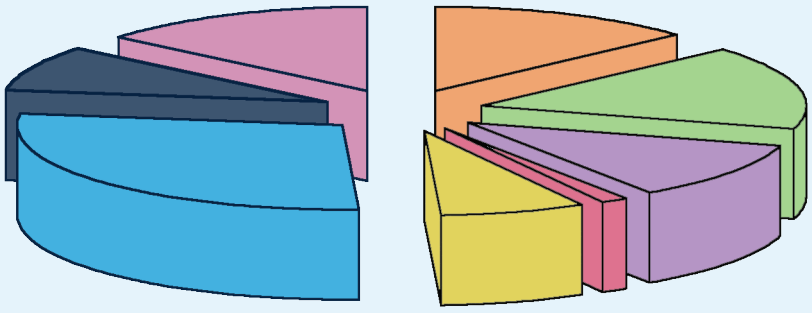
Bearing this in mind, the Green Channel of the UK IPO can potentially be used as an indirect means of obtaining accelerated examination before the US PTO. This could be invaluable for applicants who are still at the early stages of product development and require additional investment. Therefore, by combining the various systems introduced by different patent offices, applicants may be able to implement a patent strategy which may accelerate grant in one key territory by exploiting an accelerated system in another.

Given that it appears that the Green Channel is being generously applied by the UK IPO, it may be that it could be more widely harnessed by applicants than it is at present. Accelerated prosecution of their UK patent application would not only be highly advantageous for protecting the development and commercialisation of the invention on the UK market, but it may also provide a spring board to protection in other key markets.

If the Green Channel is intelligently combined with other incentive systems, such as the PPH, applicants can potentially obtain accelerated grant of equivalent patents in other key territories, notably the United States, which can provide a powerful incentive for securing development investment and funding.

Author:
Connor McConchie

Number of Green Channel Applications



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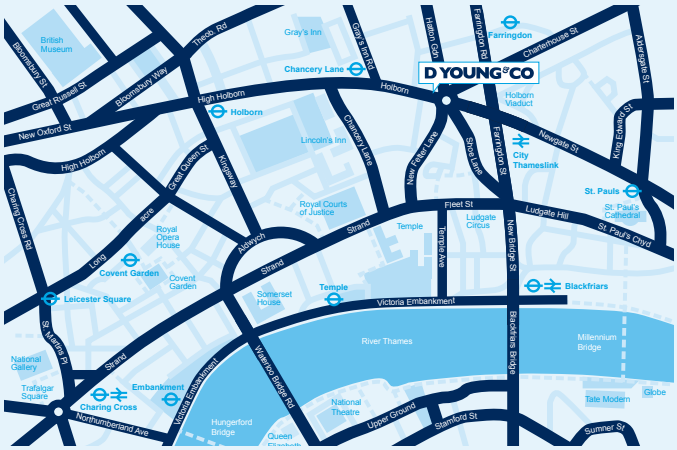

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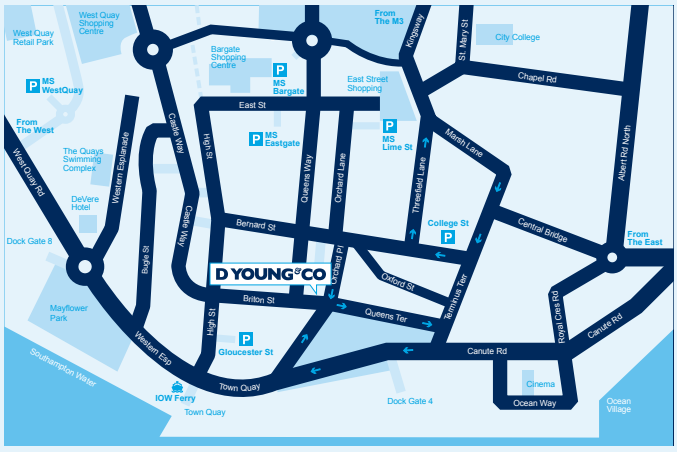

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