D YOUNG & CO

PATENT NEWSLETTER

February 2009

EVERY CLOUD HAS A SILVER LINING...

There has been a significant reduction in the value of the GB Pound versus the Euro, and also with respect to the US Dollar and the Yen over the last six months. Initially commentators were suggesting that this might be a short term blip as a result of speculation. However, commentators are now suggesting that this is much more likely to be a general realignment that will endure.

The exchange rates at 22 January 2009 compared to the exchange rates one, two, three and four years ago and the percentage changes are set out in the table below and in the accompanying chart on page two of this newsletter. It can be seen that the US dollar and the Yen have strengthened with respect to both the GB Pound and the Euro. The Euro has in turn strengthened with respect to the GB Pound.

SO WHAT DOES THIS MEAN IN PRACTICE?

Firstly, it is more important than ever for all IP rights owners to have a well thought out International IP strategy, both as regards where to obtain and enforce IP rights and how and where to handle the obtaining and enforcement of those rights. We at D Young & Co are very experienced in advising on this, and we work closely with our clients to maximise the return for their IP investment.

For example, for UK and Euro-zone rights owners, we advise on the choices to be made with regard to strategy and budgets, given that unit costs outside Europe, and in particular unit costs outside the UK, have increased significantly in Euro and, in particular, in GB Pound terms.

For US and Japanese rights owners, the cost of obtaining European and UK rights and also of enforcing those rights has reduced.

Indeed, given that D Young & Co is UK-based within the GB Pound area, the cost of the services of D Young & Co have reduced significantly with respect to practices based in

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YEAR	GBP/EURO	YR ON YR (%)	GBP/US$	YR ON YR (%)	GBP/YEN	YR ON YR (%)
22 Jan 09	1.06	-20.90	1.37	-30.10	121.93	-41.79
22 Jan 08	1.34	-12.42	1.96	-1.01	209.45	-12.83
22 Jan 07	1.53	5.52	1.98	10.61	240.28	17.42
22 Jan 06	1.45	1.40	1.79	-4.43	204.64	6.03
21 Jan 05	1.43		1.87		193.01	

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EDITORIAL
ACT NOW TO AVOID EPO FEE INCREASES

Despite the current economic situation, the EPO is pushing ahead with the further fee increases scheduled for EP applications filed or entering the EP regional phase on or after 1 April 2009. The increases include:

- An excess claims fee of €500 for the 51st and each subsequent claim, rather than the current amount of €200 (claims 16-50 will continue to cost €200 each);
- An excess page charge of €12 for the 36th and each additional page (which replaces the printing fee of €12 for the 36th and each additional page payable at grant for currently pending applications), and
- A new "Designation fee for one or more Contracting States designated" of €500, which replaces the individual designation fee of €80 per state currently payable if less than 7 states are designated.

If you think that these changes may adversely affect an EP application to be filed or to enter the EP regional phase on or after 1 April 2009 (e.g. if the application is large and/or has a lot of claims and/or you would normally designate less than 7 states) you may wish to consider filing the EP application or entering the EP regional phase before 1 April 2009. It should be noted that for a PCT application entering the EP regional phase, it would be necessary to request and be granted early regional phase entry to bring forward EP regional phase entry to a date earlier than the 31 month date.

For further details please see the EPO Fee Changes article on the D Young & Co website at: *www.dyoung.com/Publications/EPOfeechanges.pdf* or contact your usual correspondent at D Young & Co.

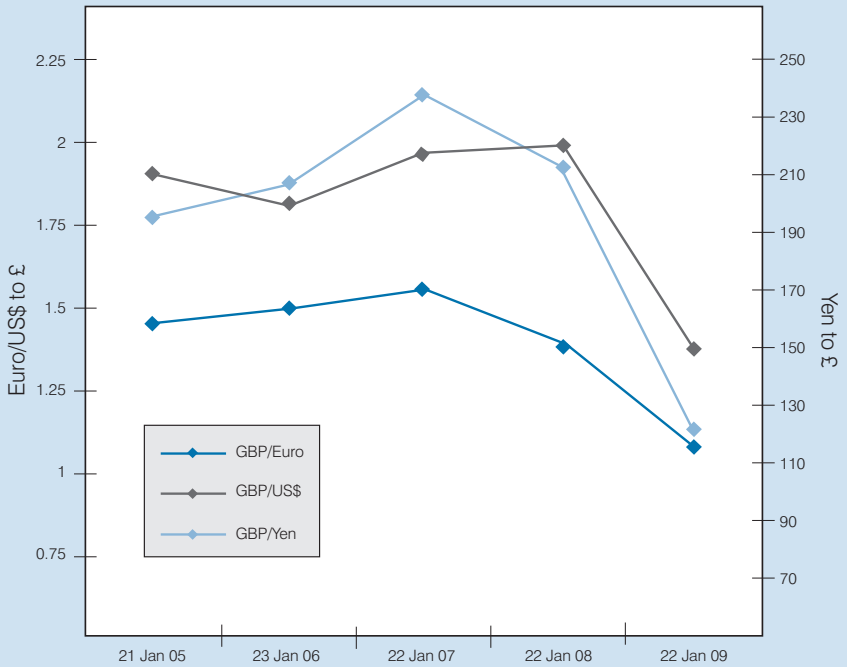
EVERY CLOUD HAS A SILVER LINING...
[CONTINUED FROM COVER PAGE]

the Euro zone (to the tune of 20% over the last year). This offers our Japanese, US and Euro-zone clients all the advantages of prosecuting European patent applications in English with the quality and service provided by D Young & Co at substantially lower cost than a year ago (about 40%, 30% and 20%, respectively). So, even in these difficult and stormy times, there is a silver lining to the cloud.

If you have any questions, please do not hesitate to contact your usual correspondent at D Young & Co.

IAN HARRIS

PERCENTAGE CHANGE IN EXCHANGE RATES 2005 - 2009



UKIPO PRACTICE NOTICE UPDATE: PATENTABILITY OF COMPUTER PROGRAMS

Following the decision of the Court of Appeal in the Symbian case (as reported in our December 2008 newsletter), the Intellectual Property Office (IPO) for the UK has updated its Practice Notice on the patentability of computer programs. It should now be significantly easier to obtain patent protection in the UK for at least some computer-implemented inventions.

According to the IPO, the new Practice Notice should be read in conjunction with two earlier Practice Notices, the first dated 2 November 2006, which followed the decision from the Court of Appeal in Macrossan/Aerotel, and the second dated 7 February 2008, which followed the Astron Clinica decision from the Patents Court (as reported in our April 2008 newsletter). The Macrossan/Aerotel decision introduced a '4-step' test for determining statutory subject matter in the UK (see our June 2008 newsletter for more information regarding the 4-step test). This test was applied by the IPO in such a manner that it became rather difficult to obtain patent protection in the UK for software inventions (especially in comparison with the situation at the EPO).

The new Practice Notice indicates that the IPO will persevere with the 4-step test from Macrossan/Aerotel. However, the portion of the test that involves the question of whether the invention "solves a technical problem" will now receive a more liberal interpretation. In particular, following the decision in Symbian, the IPO recognises that an invention may fall within the scope of statutory subject matter even if it solely addresses a problem in programming.

The Practice Notice considers the Symbian decision as having "confirmed a line of UK case law dating back to the EPO Board of Appeal decision in Vicom" (from the early 1980's). This perhaps rather begs the question as to why practice had been allowed to depart from this line of case law, especially since even the Court of Appeal in Macrossan/Aerotel had considered itself specifically bound by the earlier case law.

The Practice Notice also states that the mere presence of a computer to implement an invention does not, in itself, represent a technical contribution that would necessarily avoid the computer program exclusion. It is observed that this approach to non-statutory subject matter is different from that adopted by the EPO. However, this difference has little practical impact, since the EPO will reject cases regarded as non-technical for lack of inventive step. Accordingly, there should be substantial similarity in terms of the overall result regarding what is, or is not, patentable in the UK and Europe.

One potential complication concerns mental acts, another category of excluded subject matter under UK and European law. According to the Practice Notice, if an act could be done without the aid of a computer, then implementing the act using a computer will fall foul of the mental act exclusion (and also the computer program exclusion). It remains to be seen how this particular aspect of the Practice Notice will be applied by Examiners.

In summary, the decision in Symbian and the issuance of the new Practice Notice should provide improved certainty and prospects for grant in the UK with regard to computer-implemented inventions.

SIMON DAVIES

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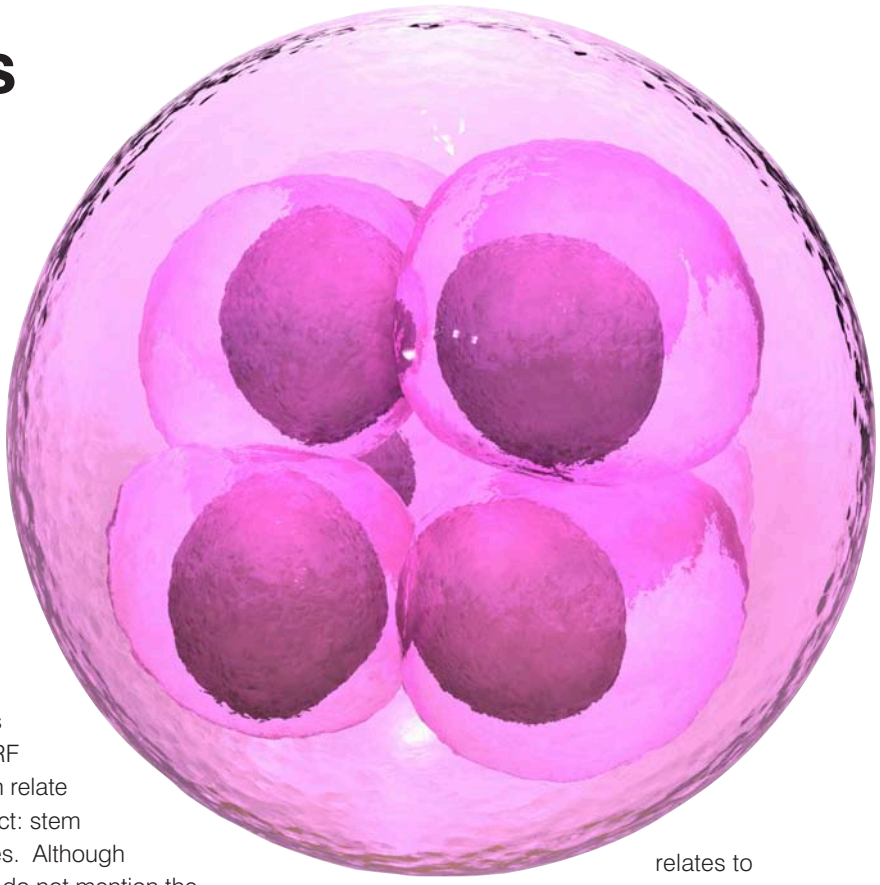
For print editions please contact rjd@dyoung.co.uk.

STEM CELLS PATENTS

EUROPEAN ENLARGED BOARD DECISION G2/06 ANSWERS ONE QUESTION BUT POSES SEVERAL OTHERS



The eagerly awaited Decision from the Enlarged Board of Appeal of the EPO on the Wisconsin Alumni Research Foundation (WARF) stem cell application was issued on 25 November 2008.

The Enlarged Board decided that under the European Patent Convention (EPC), it is not possible to grant a patent for an invention which necessarily involves the destruction of human embryos. Notably, however, in the last paragraph of the Decision, the Enlarged Board stressed that its decision does not concern the general question of human stem cell patentability.

Moreover, the answer to the question which the Decision does address gives rise to a multitude of further questions which will need to be addressed by future case law.

According to Rule 28c of the EPC, European patents shall not be granted in respect of biotechnological inventions which concern uses of human embryos for industrial or commercial purposes.

Rule 28 is a relatively new addition to European patent law: it was added just over 9 years ago in order to incorporate a European community directive (98/44/EC). Since its incorporation, the impact of Rule 28(c) on the patentability of stem cells has been the subject of much discussion.

It was generally hoped that some light would be shone on this issue by the referral to the Enlarged Board of Appeal of a series of questions relating to the patentability of stem cell cultures. The questions arose during appeal proceedings on a patent application filed by the Wisconsin Alumni Research Foundation (WARF).

The claims of the WARF application relate to a product: stem cell cultures. Although the claims do not mention the derivation of the cells, the only starting material disclosed in the application was pre-implantation (blastocyst) embryos, which are "spare" embryos arising from IVF procedures.

The Examining Division refused the application on the basis that the invention involved the direct and unavoidable use of human embryos. On appeal, the Technical Board of Appeal referred the matter to the Enlarged Board of its own motion, stating that it considers "the question of the patentability of human embryonic stem cells and of the condition therefore as being an outstandingly important point of law".

The four questions which were referred to the Enlarged Board, together with the corresponding answers provided by the Decision, are as follows:

Q1 Does Rule 28(c) EPC apply to an application filed before the entry into force of the rule? (1 September 1999).

Yes, Rule 28(c) EPC applies to all pending applications, including those filed before the entry into force of the rule. This is to be expected as Rule 28 was included to further define the boundaries of Article 53a EPC, which relates to morality, the satisfaction of which was already a requirement for patentability. This interpretation is reflected by the absence of any transitional provisions when Rule 28 was brought into effect.

Q2 If the answer to question 1 is yes, does Rule 28(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

Yes, based on their interpretation of the intentions of the legislators, the Enlarged Board concluded that Rule 28(c) should be construed broadly, thereby extending the exclusion to products whose isolation necessitated the direct and unavoidable use and destruction of human embryos. The term "invention" in Rule 28 is to be interpreted as relating to the technical teaching of the application as a whole as to how the invention is to be performed, and not merely to the invention as claimed.

The question to be answered, therefore, is not whether the claims involve a step involving the destruction of human embryos, but whether the act of performing the invention necessarily involves such a step. As the WARF patent application provides only one method for generating the stem cell cultures which are the subject-matter of the claim, it follows that in order to put the invention into effect, the skilled person would have to use that method which involves the destruction of a human embryo.

Q3 If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?

No answer is required since the answer given to both Questions 1 and 2 was "yes".

Q4 In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: e.g. derivation from available human embryonic cell lines)?

No, the Enlarged Board indicated that technical developments which became publicly available only after the filing date cannot be taken into consideration. Comparing the situation to an invention which is insufficiently disclosed in the application as filed, the matter cannot be rectified by the occurrence of subsequent technical developments, either by the applicant or by others. Any other conclusion would lead to legal uncertainty.

CONCLUSIONS

The Enlarged Board decision addresses the situation in which a product is made by a process which necessarily involves the use and destruction of human embryos. While this is of relevance to WARF's patent application which dates back to 1995, it is unlikely to be directly applicable to many later applications, as the technology moves forward and other sources of stem cells are developed.

It is therefore likely that, for patent applications filed after 1995, questions will arise which are unresolved by G2/06, for example:

Q1 If a stem cell culture can be made by two methods:
Method A - which involves the destruction of a human embryo and Method B - which does not involve the destruction of a human embryo
is the stem cell culture a patentable invention?

Q2 Is it only allowable when made by Method B?

Q3 If so, would the steps of method B have to appear in the claim to the product?

Q4 If not, would it be an infringement to make, use or sell a stem cell culture within the scope of the claim, made by method A?

As explained by the appellant in the WARF referral, the claimed stem cell cultures can now be made from established cell lines. This gives rise to further questions considering the Decision of the Enlarged Board, such as:

Q5 If a stem cell culture is made from an established cell line which was originally made by destroying a human embryo, is the stem cell culture still unpatentable?

Q6 How far back does the relationship extend?

Similarly, the position is unclear with regard to uses of the claimed stem cells and products derived therefrom. Considering the questions above:

Q8 If the stem cell culture is only patentable if made by method B, and it is necessary to include the steps of method B in the claim to the product, is it also necessary to include these steps in a claim directed to a use of the product, or a secondary product (e.g. cell line or tissue) made using the stem cell culture?

Q9 How far forward does the relationship extend?

The Decision of the Enlarged Board has therefore left a great degree of uncertainty on the patentability of stem cells in Europe. What is certain, however, is that the Decision is a blow for stem cell technology-based companies. Despite the indication from the Enlarged Board that the Decision does not concern the general question of human stem cell patentability, it will be seen as a negative indicator by potential investors. In these uncertain times, the Decision may dissuade companies from entering the sector and could steer investors to put their money elsewhere.

LOUISE HOLLIDAY

WHAT'S THE DAMAGE?
UK HIGH COURT RULES ON COST OF INTERIM INJUNCTIONS

In the recently decided case of Servier v Apotex, the UK High Court assessed the amount of damages due in a cross-undertaking by the French pharmaceutical company Servier to Canadian generics company Apotex, after Servier's initally obtained interim injunction to prevent Apotex marketing the drug perindopril had been discharged at full trial. The case provided useful guidance as to how UK judges assess the pharmaceutical market in order to quantify damages.

BACKGROUND

Servier developed and patented the anti-hypertensive pharmaceutical perindopril, which they sold under the trade mark COVERSYL. The basic patent and SPC protection for the compound itself expired in 2006. Servier obtained a further European patent for a specific crystalline form ("Form Alpha") of perindopril: this patent was upheld in opposition proceedings at the EPO.

However, Apotex took the view that the crystalline form patent was nevertheless invalid and decided to launch its generic version of perindopril 'at risk' in the UK, rather than first applying to revoke the patent in the UK courts. Servier applied for and obtained an interim injunction to restrain Apotex's activities: the judge at the interim hearing accepted that Servier could suffer 'irreparable and unquantifiable harm' if Apotex were allowed to continue selling perindopril until full trial, whereas damages were considered an adequate remedy for Apotex should they succeed at full trial. As usual in the UK, Servier agreed a cross-undertaking to compensate Apotex for any losses they suffered while the interim injunction was pending.

The crystalline form patent was revoked at full trial by the High Court, and Servier's appeal to the Court of Appeal failed. The case then returned to the High Court for the assessment of damages due to Apotex under the cross-undertaking.

LEGAL PRINCIPLES

In his judgement Mr Justice Norris considered the approach to be taken in the assessment is to compensate Apotex, rather than to punish Servier. Essentially, the question to be answered was: what loss did the order of an interim injunction and its continuation until full trial cause to Apotex? The assessment was made as if the cross-undertaking had been a contract between the parties that Servier would not prevent Apotex from doing what the injunction prevented them from doing.

OPERATION OF THE PHARMACEUTICALS MARKET

Based on expert evidence, the judge found that, although the market in a given pharmaceutical product ultimately moves from the patent holder's monopoly to an entirely open market in an unprotected product, the transition between these states is not a smooth one: it includes periods of rapid price adjustment in response to an actual or rumoured new market entrant, and 'plateau' periods when the number of participants in the market is relatively stable. Furthermore, when a drug patent is in force but its validity is under challenge, any company bringing a competing generic onto the market does so at an enormous risk: the generic company may be liable to pay damages many times its profit margin on the drug should it ultimately be found to be infringing a valid drug patent. However, the rewards for operating as the only generic supplier during the 'at risk' period are higher, as other generic manufacturers may be unwilling to take the same risk: the risk-taker can consequently set a higher price during this period than in a fully open market.

Particularly during the 'at risk' period, pharmaceutical patent holders themselves frequently become manufacturers to a generic drug supplier, the original product (sometimes differently coloured or packaged) then being placed on the market in the name of the generic supplier (a so-called 'authorised generic'). This enables the patent holder to support its premium brand, make additional sales, and have some influence over the volume and price of generics.

In this case, the judge found there to be three market phases: an 'at risk' market which ended with the revocation decision from the High Court; a transition stage as some generics then came onto the market; and a fully open market. The judge ruled that Apotex had been kept out of the 'at risk' market and forced to participate in the transition stage as a new entrant along with the other generics, rather than as an established market participant.

CALCULATION OF DAMAGES

In assessing the financial consequences of the injunction, the judge considered it necessary to envisage the hypothetical market at the time Apotex launched 'at risk' had they not been restrained by the injunction, as well as identifying the market once the patent had been revoked. Two competing scenarios were considered: the first that Servier would have competed 'head to head' with Apotex in an attempt to preserve the position pending the validity of the patent being upheld; the second that Servier would have regarded the cause as essentially lost, operated on the practical basis of an open market and would also have supplied authorised generics. Based on expert evidence, the judge decided the first scenario was twice as likely to have happened as the second, and therefore calculated damages of two-thirds of the estimate (based on market share and price) of lost sales in the first scenario and one-third of those in the second. The final sum awarded to Apotex was £17.5 million.

CANADIAN PROCEEDINGS

While Mr Justice Norris was considering his judgement, the Canadian courts upheld a Canadian patent for perindopril held by a Servier-associated company, and which Apotex would have infringed in order to supply the UK market. On this basis, Servier applied to amend its case to dismiss Apotex's claim for damages. However, the UK judge dismissed the application as, in his view, it was filed too late in the proceedings.

LEGAL CONSEQUENCES

Although the assessment of damages in this case was fact-based, some legal guidance can also be derived from it. Firstly, parties need to consider what the market would have been at the time the injunction was granted, not just the state of the market once the proceedings are complete. Secondly, in view of the uncertainty inherent in such hypothetical markets, UK judges will not necessarily settle on one possible single market scenario, but are prepared to weigh up the likelihood of multiple scenarios and assess damages proportionally. These factors should be borne in mind by parties considering whether or not to apply for interim injunctions.

GARRETH DUNCAN

HANDS ACROSS THE SEA: TRILATERAL CO-OPERATION

In 1983 a Trilateral Co-operation was set up between the European Patent Office (EPO), the United States Patent Office (USPTO) and the Japanese Patent Office (JPO), with the objectives of:

- Improving the quality of examination processes and reducing the processing time of patent applications
- Improving the quality of incoming applications
- Developing common infrastructure and compatible data for electronic business systems and search tools;
- Solving common problems related to the protection of industrial property rights
- Harmonising practices of the three offices
- Promoting the dissemination of the technical information contained in patents
- Deepening awareness of the benefits of the patent system
- Exploiting the full potential of work performed by the other Trilateral Offices in search, examination, documentation and electronic tools.

Among the projects that have recently been implemented by the Trilateral Co-operation, and which provide potential benefits to applicants, are the following:

1. Electronic exchange of priority documents between the three Patent Offices. This allows for direct office-to-office transmission of priority documents and provides savings in terms of costs and time for both applicants and the Patent Offices.

2. The "Patent Prosecution Highway" which was set up with the aim of enabling patents to be obtained faster.

The Patent Prosecution Highway was initially set up in July 2006 as a pilot scheme between the USPTO and the JPO. According to the pilot scheme, when an initial patent application is filed in one of the two Patent Offices (i.e. the Office of First Filing or OFF) and the applicant receives a ruling from that office that at least one claim in the application is patentable, the applicant may request fast track examination of corresponding claims in a corresponding patent application in the other country (i.e. the Office of Second Filing or OSF). In January 2008 the pilot scheme between the USPTO and the JPO was made permanent and applications in the OSF which qualify for the fast track examination under this procedure were revised.

In September 2008 a similar pilot scheme was set up between the EPO and the USPTO and is to run for a period of one year which is extendable for an additional year, if necessary, in order to adequately assess the feasibility of the programme. It is the intention that, after the pilot period, the EPO and USPTO will decide whether and how the pilot scheme should be fully implemented.

A possible launch of the Patent Prosecution Highway between the EPO and the JPO is being looked at by those Patent Offices.

Although not a member of the Trilateral Co-operation, Korea has now set up a similar pilot Patent Prosecution Highway programme with the USPTO, this pilot programme starting on 28 January 2008 and running for a period of one year.

At the meeting of the Trilateral Co-operation members on 14 November 2008 they agreed:

- That they would enhance dialogue with the Korean Intellectual Property Office (KIPO) and the State Intellectual Property Office of the Peoples Republic if China (SIPO) towards developing a hybrid classification system that will be shared by the five offices.
- To accept Common Application Format applications in 2009. This will allow an applicant needing to file an application in more than one of the three offices to prepare a single application in the Common Application Format and for such an application to be accepted by each of the offices without the need for amendments related to formalities. This should provide cost savings to applicants in the filing and prosecution of patent applications before the offices of the trilateral members.

JIM TANNER

D YOUNG & CO PATENT GROUP

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OUT AND ABOUT

A PRACTICAL INTRODUCTION TO INTERNATIONAL PATENT LAW AND PRACTICE

26-27 March 2009

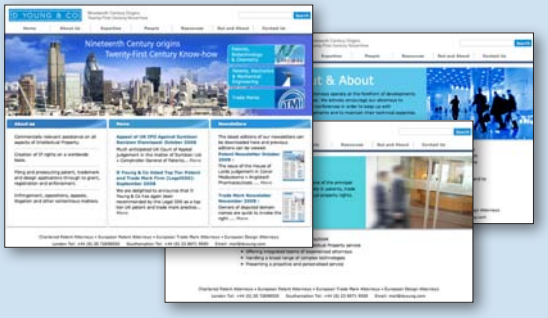
Simon Davies will be speaking at this Management Forum organised course, giving a one-stop, comprehensive and practical introduction to international patent law. For more information and/or to register, please visit the Management Forum website: www.management-forum.co.uk/ip/eventid/1045.

AIPLA 2009 SPRING MEETING

13-15 May 2009

Jonathan Jackson will be speaking on the subject of "A Practical Guide to the EP Patent System" at the AIPLA Spring meeting in San Diego, USA. For further details please visit the AIPLA website: http://www.aipla.org.

For further information on events attended by D Young & Co attorneys, please visit the events page on our website at: www.dyoung.com/out_and_about/events.htm.



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