D YOUNG & CO

PATENT NEWSLETTER

June 2009

EPO INTRODUCES CHANGES TO INCREASE "QUALITY" OF PATENTS GRANTED

From our previous bulletins, you will be aware that the European Patent Office (EPO) is introducing a time limit for filing divisional applications. In addition, the EPO has also recently announced a number of other changes of which you should be aware. These changes have been introduced by the EPO to increase the "quality" of the Patents that are granted.

APPLICATIONS CONTAINING A PLURALITY OF INDEPENDENT CLAIMS IN ONE CATEGORY - INTRODUCTION OF NEW RULE 62a EPC

As you know, a European patent application having more than one independent claim in any one category (where these independent claims cover similar subject matter) will not be allowed. This is because the EPO considers the claims to contravene Rule 43(2) EPC as not being concise.

However, for search reports issued on or after 1 April 2010, where the EPO considers the claims to contravene Rule 43(2) EPC, the EPO will ask the Applicant which independent claim he or she wishes to pursue. There will be a time limit set. If the Applicant does not respond within the time limit, the EPO will only search the first mentioned independent claim in one category. This time limit is excluded from further processing.

During substantive examination, it will be possible to argue that such a restriction was not applicable. However, given that the Search Examiner and the Substantive Examiner is typically the same person at the EPO, unless the arguments are very convincing, they are unlikely to be successful. This means that the Applicant will be required to restrict the claims to only those searched.

This change means that it is typically not advisable to file European patent applications having more than one independent claim in any category where these independent claims cover similar subject matter (unless they relate to one of the possibilities permitted under Rule 43(2) EPC). This is for two reasons. Firstly, there will be an additional Office Action issued, which may reduce the efficiency of the prosecution. Secondly, with excess claims fees being so high, the Applicant could waste a large amount of money in paying claims fees for claims that will need to be excised during prosecution.

RESPONSE TO THE EXTENDED SEARCH REPORT - INTRODUCTION OF NEW RULE 70a EPC

The EPO issues an opinion with the extended European search report which sets out any objections the examiner has to the application. At the moment, the Applicant may respond to this opinion including, where appropriate, the filing of amendments.

However, for extended European search reports issued on or after 1 April 2010, the EPO will make it compulsory to "respond" to such an opinion. Failure to respond in time will mean that the application is deemed withdrawn. The time limit for response depends on whether the Applicant has already paid the fee for substantive examination prior to the issuance of the search report. If substantive examination has not been requested prior to issuance of the search report, the response must be filed by the expiration of the

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time limit for requesting substantive examination. If substantive examination has been requested prior to the issuance of the search report, the response must be filed within the period specified for indicating whether the Applicant wishes to proceed further with the application. These periods are subject to further processing, should you need more time to respond.

It is not clear at present to what extent the Applicant must "respond" to the opinion. Recent discussions with the EPO seem to suggest that it is not sufficient to simply say "I do not agree with the Examiner". Instead the EPO expects Applicants to react to the objections raised in the opinion by making appropriate amendments or well-founded comments. The EPO will update the Guidelines for Examination shortly where the degree to which Applicants must "respond" will be made clear.

AMENDMENT OF THE EUROPEAN PATENT APPLICATION - AMENDMENT TO RULE 137 AND RULE 161 EPC

The EPO always requests basis for any amendments made to the European patent application. However, current Rule 137 EPC is being amended to make this mandatory on applications which have an extended European search report issued on or after 1 April 2010. If this information is not provided in enough detail for the Examining Division, a time limit of one month will be provided to provide this information.

The EPO has always had a very strict interpretation of added matter. However, this change seems to indicate that the Examiners will become more inclined to not look for any basis themselves, and will simply revert to the Applicant to provide such basis.

For European patent applications which are derived from PCT applications, the EPO allows the European patent application to be amended once in response to a letter from the EPO issued under Rule 161 EPC. This letter is issued soon after filing of the European application. Presently, the Applicant may or may not respond to this letter.

However, for applications having a letter under Rule 161 EPC issued on or after 1 April 2010, this procedure changes. Where the EPO acts as the International Search Authority (ISR) and, where appropriate, the International Preliminary Examining Authority (IPEA) on the PCT application from which the European patent application is derived, the EPO will ask the Applicant to refer to the written opinion contained in the ISA or IPEA for details of the current objections and invite the Applicant to "respond" to the written opinion. Unlike now, the Applicant must respond to this invitation otherwise the application will be deemed to be withdrawn. Like the introduction of Rule 70a EPC, it is not clear to what extent the EPO requires an Applicant to "respond".

Again, this change seems to be forcing Applicants to deal with objections earlier in the prosecution cycle. However, as Applicants only get one month to respond to the Rule 161 EPC letter, it is important that Applicants look at the written opinion early, and preferably not wait for the Rule 161 EPC letter.

One other point to note is that in the change to Rule 137 EPC, the EPO has removed the opportunity for the Applicant to amend the application as of right in response to the "first communication" referred to in the previous Rule 137(3) EPC. After the Applicant has amended the application by "responding" to the written opinion in accordance with either new Rule 70a EPC or amended Rule 161 EPC, any other amendments are at the discretion of the Examining Division. This is of concern. In the future, if the EPO want Applicants to look at, and address, objections earlier during prosecution, Examiners may start to exercise discretion and not admit amendments (other than those as of right) into proceedings. Although it is currently unusual for Examiners to exercise their discretion, it is to be expected that this will become more common.

COMMENT

These changes will undoubtedly increase the speed at which the prosecution of European patent applications is concluded. However, it has to be questioned whether streamlining the prosecution procedure will automatically increase the "quality" of the patents issued by the EPO.

JONATHAN JACKSON

EDITORIAL

This newsletter contains information on important changes to the Implementing Regulations of the European Patent Convention to come into effect on 1 April 2010, which will require Applicants to review their pending European patent application portfolios and future filing practices. It also contains important articles on the patenting of antibodies in Europe and the practice of the UK Intellectual Property Office (UKIPO) in relation to patents for human embryonic stem cells.

There are signs of green shoots in the initiative of the UKIPO in a so-called "Green Channel" for UK patent applications that allows applicants to request accelerated processing of their application simply if the invention relates to a 'green' or environmentally-friendly technology.

We hope you enjoy the newsletter and find it informative.

IAN HARRIS, JUNE 2009

NEW EUROPEAN PATENT OFFICE PROPOSALS

RESTRICTED TIME LIMIT FOR FILING DIVISIONAL APPLICATIONS

The European Patent Office (EPO) has announced that the time limit for filing a divisional application from a European patent application is to be restricted. This change is likely to have a significant impact on prosecution strategies in Europe for many Applicants.

Currently a divisional application can be filed from any pending European patent application. In other words, any divisional application must be filed before the existing ("parent") application is granted, refused or withdrawn. This typically means that the Applicant can retain the option of pursuing protection for any invention disclosed in the parent application for many years after the initial filing date.

However when the new rule enters into force, any divisional application will normally need to be filed within 2 years from the first communication from the Examining Division on the parent application. The first communication from the Examining Division is usually the first substantive examination report, which sets out detailed objections raised against the application. The "search opinion", which may include possible substantive objections but is issued earlier together with the search report, does not appear to start the 2 years time limit.

The only exception to this is where the Examining Division issues an examination report which contains an objection of lack of unity. An objection of lack of unity is raised where the Examiner considers that the claims relate to multiple inventions which are not linked by a single inventive concept. In this case, the Applicant is allowed to file a divisional application within 2 years from the first communication raising that lack of unity objection. So this provision can only extend the period for filing a divisional application where a lack of unity objection is raised for the first time after the first communication from the Examining Division on the parent case.

It is important to note that the 2 years time limit for filing divisional applications starts from the first communication from the Examining Division on the earliest related application. Therefore, in the case of a series of divisional applications, where later divisional applications are divided from earlier divisional applications, all divisional applications must still be filed within 2 years from the first communication on the original parent case.

In addition to these new time limits, the previous requirement that the parent application must be pending at the time of filing the divisional application still stands. So any divisional applications must be filed before the parent application is granted, refused or withdrawn, even if this is less than 2 years from the first communication from the Examining Division on the parent.

The new rules apply to divisional applications filed on or after 1 April 2010. However the EPO has adopted transitional provisions which mean that a divisional application can still be filed on any pending European patent application until 1 October 2010. After that date, it will no longer be possible to file a divisional application on any application where more than 2 years have elapsed since both the first communication from the Examining Division and any later non-unity objection.

This means that Applicants will need to review their portfolios to identify currently pending European applications where one or more divisional applications may be required at some stage. For many currently pending cases, any divisional applications will need to be filed by 1 October 2010, because the 2 year time limit will have already expired by this date.

In future, decisions concerning the filing of divisional applications will need to be taken at a much earlier stage in prosecution. The rule change is also expected to severely limit the opportunity to file a divisional application in order to maintain prosecution options in advance of a possible refusal or withdrawal of the parent application. This may lead to an increase in the number of Applicants choosing to take refusals of an application to appeal.

ROBERT DEMPSTER

PATENTING ANTIBODIES IN EUROPE

Antibodies are proteins found in the blood which are used by the immune system to identify and neutralise foreign entities, such as bacteria and viruses. Monoclonal antibodies (mAbs) are monospecific antibodies that are identical because they are produced by cells that are clones of a single parent cell. Monoclonal antibodies have great therapeutic potential: as they all have the same specificity, they exert a defined and reproducible effect *in vivo*.

Therapeutic monoclonal antibodies are big business: eight of the approved products currently have annual sales exceeding $1bn. It is therefore critical for companies developing such antibodies to have adequate patent protection. Although the patenting of antibodies is widespread, there are some "stumbling blocks" that are commonly encountered during prosecution of antibody patents. The two major hurdles for obtaining patent protection for antibodies in Europe are satisfying the inventiveness and sufficiency requirements.

INVENTIVENESS

This issue of inventiveness often arises in the patenting of antibodies because once a pioneering antibody technology is in the public domain, it is considered obvious to apply that technology to any other antibody. While an antibody that binds to a new and previously unidentified antigen is considered non-obvious because the antigen was unknown, it is considered obvious to generate an antibody to a known antigen using standard techniques such as immunisation or phage display.

If an antibody can be shown to have an *advantage* over known antibodies to the same target or antibodies produced by the same method, then this fact can often be used to establish that the antibody is inventive. An advantage can be any property that is useful, such as cross-reactivity, increased selectivity, increased affinity, new or improved downstream function or improved stability. To be useful in establishing an inventive step the advantage should be unpredictable considering the state of the art. So, if a known technique such as *in vitro* evolution is used to improve the affinity of an antibody, then the improved affinity of the resultant antibody is not "unexpected".

There are exceptions, but in general the bar is fairly low in Europe for a) the amount of "advantage"; b) its unexpectedness; and c) the amount of proof needed to show that the antibody has such an advantage. This is illustrated by a recent Decision of the Boards of Appeal of the European Patent Office (T 0601/05) that concerned a patent related to a pharmaceutical composition containing a human mAb that binds to tumour necrosis-factor α (TNFα). A murine anti-TNFα antibody was known and was in a Phase 1 clinical study but, according to the appellant, results had shown that it was not pharmaceutically effective.

In the Board's view, inventiveness of the human mAb hinged on whether the patent contained enough evidence that the human TNFα-binding mAbs would indeed have therapeutic value. The patent described an assay showing that one of the human antibodies was able to inhibit lipopolysaccharide (LPS)-stimulated

secretion of TNFα from a human monocyte cell line. According to the patent, TNFα is one of the factors secreted during septic shock and inflammatory diseases. This was held to be sufficient evidence to make the pharmaceutical usefulness of the antibody "plausible" and, accordingly, inventiveness was found.

There are two things to note from this decision. Firstly, the results obtained using the murine antibody were considered to prejudice against attempting to generate therapeutically useful human anti-TNFα antibodies. Secondly, *in vitro* data was considered sufficient to establish that human antibodies could be therapeutically useful. No data indicated that the human antibody actually inhibited TNFα secretion *in vivo*, let alone whether this would be therapeutically useful.

SUFFICIENCY

According to European patent law, a patent application must "disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art". This provision is sometimes referred to as "sufficiency" and is equivalent to the US "enablement" requirement.

The test commonly used for sufficiency in Europe is whether it would be an "undue burden" for a person skilled in the art to put the invention into effect, i.e., would it be an undue burden for a skilled person to fill in the gaps missing from the technical disclosure in order to carry out the invention?

Where an antibody is defined by the target and the target is a new antigen, the antibody is generally considered to fulfil the sufficiency requirement, even if the patent application does not describe the actual generation of such an antibody, because it is possible to generate an antibody to a given antigen using standard techniques.

However, difficulties can arise where an antibody is defined in terms of its activity. The sufficiency requirement requires the patent application to provide sufficient information for the invention to be practiced over the whole claim breadth. Often, the requirement is satisfied when an antibody is defined by its function and at least one example is provided of an antibody having such a function. It is important that the example(s) provided are described in sufficient detail so that further embodiments could be generated within the scope of the claim.

This point is illustrated by a Decision of the Boards of Appeal (T1466/05) which related to a patent application in which the definition of the antibody included the following: "An antibody reactive with pyridinoline in peptide-linked pyridoline and not free pyridoline".

The application described one specific monoclonal antibody produced by a deposited hybridoma that was stated to have the claimed activity. However, the application did not provide any technical details on how the specific monoclonal antibody was prepared and did not provide any guidance on the preparation of further antibodies having the desired activity. In particular, the application provided no guidance with respect to an antigen suitable for raising antibodies with the desired specificity, or screening antibody-producing clones or antibody libraries.

The application was therefore considered to provide insufficient information for the invention to be put into effect over the whole scope of the claim. It was considered an "undue burden" for a person skilled in the art to make other antibodies within the scope of the claim, given the lack of detail of a) the antigen required to raise the antibodies; and b) the screening process for the specific selection of such antibodies.

In order to avoid provoking an objection of lack of sufficiency, the patent application should provide detailed technical information on the preparation of each antibody, together with all known details of structure-function relationships, in order to provide support for the broadest possible antibody claim.

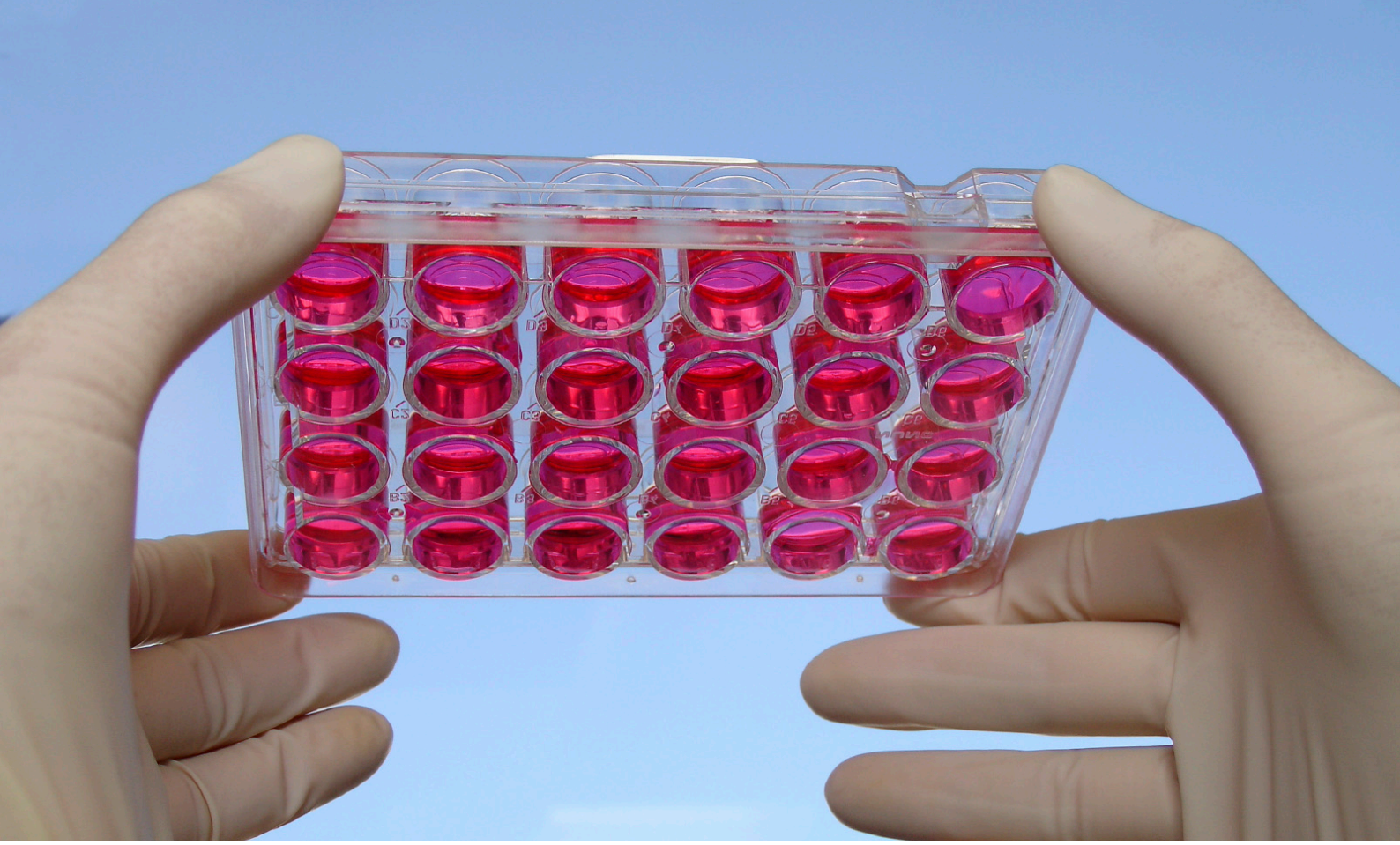
LOUISE HOLLIDAY

NEW D YOUNG & CO ASSOCIATE

D Young & Co have appointed Dr Stephen Blance to join the firm as an Associate in the Pharmaceutical, Biotechnology and Chemicals group at our Southampton Office.

Steve is a qualified European Patent Attorney and Chartered Patent Attorney with eight years experience in private practice and specialises in biotechnology, molecular biology and genetics, including "on chip" technology, sequencing techniques, diagnostic agents, vaccines, transgenics, gene therapies, pesticide formulations and medical devices.

A more detailed profile of Steve can be found at: www.dyoung.com/people/staff/stephenblance.htm



HUMAN EMBRYONIC STEM CELLS PATENTS

UKIPO CLARIFIES PRACTICE

The UK Intellectual Property Office (UKIPO) has updated its practice in relation to patenting human embryonic stem (hES) cells. Whilst it will follow a recent decision of the European Patent Office (EPO), the UKIPO has maintained its positive stance in relation to the patentability of certain types of hES cells.

In our last newsletter we reported on the decision of the Enlarged Board of Appeal of the EPO in relation to the Wisconsin Alumni Research Foundation (WARF) stem cell application. In that case, the EPO decided that patents could not be granted for inventions which would have necessitated the destruction of human embryos in order to be performed at the filing (or priority) date of the patent application.

The UKIPO has now confirmed that it too will only grant patents relating to hES cells if "at the filing or priority date, the invention could be obtained by means other than the destruction of human embryos." So, patent applications containing claims relating to hES cell technology which do not describe alternative sources of human stem cells (such as established hES cell lines or induced pluripotent stem (iPS) cells), and which were filed at a time when such alternative sources were not publicly available, are unlikely to be granted either by the EPO or UKIPO.

However, the UKIPO has affirmed that it will continue to grant patents covering pluripotent hES cells, subject to the above proviso. Since pluripotent hES cells do not have the potential to develop into the entire human body, the UKIPO maintains its previous view that patenting pluripotent hES cells is not contrary to morality in the UK. Totipotent hES, which do have the potential to develop into an entire human body, will continue to be excluded from patentability in the UK.

The statement from the UKIPO that pluripotent hES cells are, in principle, neither immoral nor excluded from patentability provides welcome clarity for developers of stem cell technologies. In contrast, the position at the EPO is still far from clear despite the recent WARF decision. As we reported last time, the Board in the WARF decision stressed that it was not ruling on the general question of the patentability of hES cells. In some cases, applicants working in this area may wish to consider filing a UK patent application, or entering the UK national phase of a PCT application. Any patent granted by the UKIPO will only cover the UK, so for pan-European protection an application via the EPO could be filed in parallel, if required. However the continuing uncertainty in relation to patenting hES cells in the rest of Europe makes a UK national application a more attractive possibility for obtaining some valuable protection, in the short term at least.

ROBERT DEMPSTER

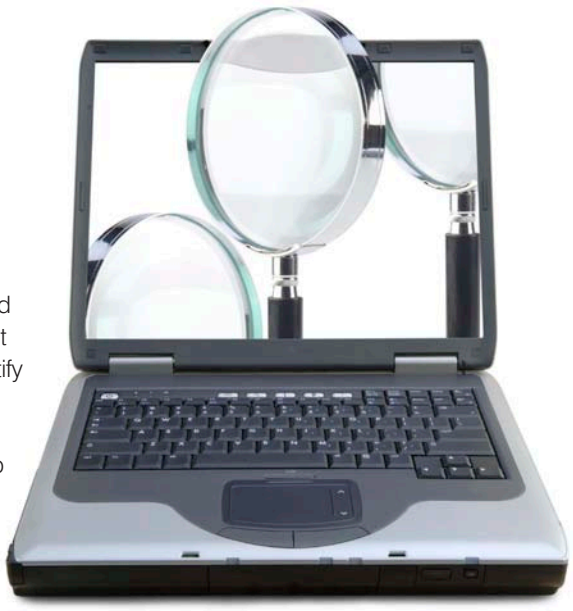
IPSCORE
FREE PATENT EVALUATION SOFTWARE FROM THE EPO

Patent departments and universities may be interested in a software tool called IPscore that the EPO are making freely available on their website.

Individual patents and portfolios of patents, and even ideas that are at an early stage and have not yet generated a patent application, may be evaluated using 40 input variables to produce a forecast of net present value and various types of graphical output, such as a risk-versus-opportunity matrix that depicts the patents in a portfolio with the intention of helping management to weed out of the portfolio the so-called "weak" patents having high risk and low opportunity.

The software can be customised to suit particular user requirements and is a Microsoft Access based application. The EPO provides a user manual that can be downloaded and training courses for users who want to become experts in using IPscore, which originated in Denmark and has been purchased by the EPO from the Danish Patent and Trademark Office, before being improved and made available free of charge to users.

The EPO particularly hopes to encourage its use by small and medium size companies and suggests that it may help identify "forgotten treasure" in a patent portfolio that could be turned to financial advantage by developing new products or granting a licence to a company that is not a competitor. Also, strong patents in a portfolio may be identified and used to guide the future development direction of the patent portfolio.



For further details please visit the EPO website at: www.epo.org/patents/patent-information/business/valuation/ipscore.html

PAUL PRICE

PATENT APPLICATION "GREEN CHANNEL"
THE GRASS IS ALWAYS GREENER

On 12 May 2009 the UK Intellectual Property Office (UKIPO) introduced a fast-track system for UK applications relating to a "green" or environmentally-friendly technology, which means they could be granted within 9-months from filing.

The so-called "Green Channel" for UK patent applications allows applicants to request accelerated processing of their application simply if the invention relates to a 'green' or environmentally-friendly technology.

To enter the Green Channel, an applicant's representative simply needs to make a request in writing, indicating:

- That the application relates to a 'green' or environmentally-friendly technology; and
- Which actions they wish to accelerate, e.g. search, combined search and examination, publication and/or examination.

The UKIPO will require no further reasons for accelerated processing.

This service will apply to existing UK applications as well as to UK applications filed after 12 May 2009.

For more information please contact your usual D Young & Co adviser.

AYLSA WILLIAMS

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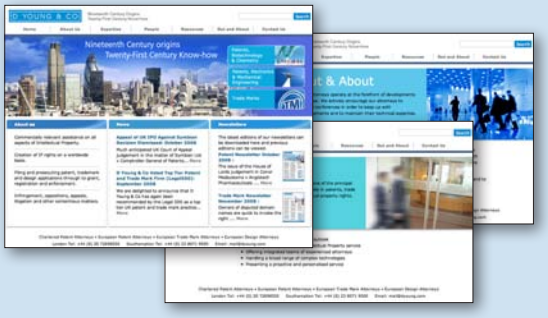
OUT AND ABOUT

PATENT SUMMER SCHOOL
15-19 June 2009

Kit Wong and Simon Davies will be speaking at Management Forum's Patent Summer School at the Rembrandt Hotel, London. Kit and Simon will be discussing patent litigation during this course, which will provide delegates with a comprehensive introduction to patents by outlining the basic concepts of intellectual property and explain the roles and responsibilities of those directly involved.

For further information of this and other events attended by D Young & Co attorneys, please visit the Events section of our website: www.dyoung.com/out_and_about/events.htm



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