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Events

11 October 2011
Innovate '11 Conference, London, UK
Attended by Garreth Duncan and Simon Davies.

20-22 October 2011
AIPLA Annual Meeting, Washington, DC, USA
Attended by Jo Bradley and David Alcock.

27-28 October 2011
Advanced Patent Law Institute, Austin, Texas, USA
Attended by Nigel Robinson.

More information: www.dyoung.com/events

D Young & Co Event

19 October 2011
Biotechnology European Patent Case Law Webinar
Robert Dempster and Simon O'Brien of D Young & Co will be giving a 45 minute webinar update on significant recent EPO case law. For more info and to register visit: www.dyoung.com/event-webinar1011

Editorial

Welcome to the October edition of our patent newsletter. In this edition we include a summary of the eagerly awaited decision of the EPO Enlarged Board of Appeal on disclaimers.

We are also pleased to introduce our new partners, Garreth Duncan, Nicholas Malden and Helen Cawley (see page seven). The firm continues to grow with the number of partners now at 33.

Just as we go to press, the Legal 500 2011 results have been published and we are delighted with our top tier ranking. We would like to thank our clients and associates for their support and contributions to the review, in particular for their positive comments.

Editor:
Simon O'Brien

Article 01

G 2/10 Disclaimers
A Direct and Unambiguous Decision?

The EPO's Enlarged Board of Appeal has handed down its decision concerning the use of so-called positive disclaimers. The decision concerns whether or not it is allowable under Article 123(2) EPC to amend a claim to exclude subject matter that was disclosed as an optional or preferred embodiment in a positive sense in the application as filed.

The decision does not give a 'hard and fast' rule about when such disclaimers would be allowable. Instead, the Enlarged Board has reverted back to what it refers to as the 'gold standard' of added subject matter assessment: the 'directly and unambiguously derivable' test.

Background

The decision came from a referral from T 1068/07 and concerned claims relating to a catalytic DNA molecule, which had been initially refused by an EPO Examining Division. On appeal, in order to account for an item of prior art, the applicant attempted to amend the claims using a 'positive disclaimer', ie, a disclaimer directed to subject matter disclosed in the application as filed. Consequently, the following question was referred to the Enlarged Board:

"Does a disclaimer infringe Article 123(2) EPC if its subject matter was disclosed as an embodiment of the invention in the application as filed?"

The Decision

The Board held that G 1/03 concerned the allowability of 'undisclosed disclaimers' where both the negative limitation (ie, the 'disclaimer') and the excluded subject-matter were not disclosed in the application as filed, and therefore does not relate to disclaimers of the type discussed in this referral.

In the present case, the Board held that an amendment which includes the introduction of a positive disclaimer will only comply with Article 123(2) EPC where the subject matter remaining in the claim after the introduction of the disclaimer can be directly and unambiguously derived from the application as filed. More specifically, the Enlarged Board concluded:

"1a. An amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123 (2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.

1b. Determining whether or not that is the case requires a technical assessment of the overall technical circumstances of the individual case under consideration, taking into account the nature and extent of the disclosure in the application as filed, the nature and extent of the disclaimed subject-matter and its relationship with the subject-matter remaining in the claim after the amendment."

Thus, there are circumstances when the introduction of a positive disclaimer will not infringe Article 123(2) EPC, but equally so, there may be other circumstances where Article 123(2) EPC is infringed.

The use of the 'logical compliment' argument was put forward by the appellant in their submissions as a means for assessing whether the claim as amended complies with Article 123(2) EPC. The logical compliment method of analysing the amended claim provides that the subject matter of a claim including a positive disclaimer must always be directly and unambiguously derivable from the application as filed as it is the implicit result of subtracting the disclaimed embodiment from the original disclosure.

Thus, where the original disclosure can be identified as A, and the disclaimed subject matter as B, according to the logical compliment argument the subject matter remaining in the claim following the introduction of the disclaimer is simply A-B. By disclosing A and disclosing B in the application as filed, the argument is that A-B must be implicitly disclosed.

> *Knowledge Bank*
Scan the QR code below using your internet enabled smart phone to access our knowledge bank

> *Missed anything?*
In between issues of this newsletter we posted news about the US Federal Circuit's decision on the 'Myriad' case and the EPO's Legal Board of Appeal's referral to the Enlarged Board of Appeal (G 1/11) Visit our website for up to the minute IP related articles and news.

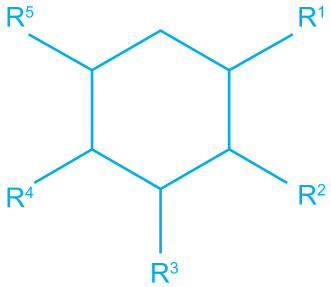
The Board did not agree that such a 'schematic' assessment could apply to all situations and suggested that the extent of analysis required for an amended claim which includes a positive disclaimer will differ depending on the subject matter actually disclaimed. However, the Board appeared to suggest that where only a single embodiment or example is disclaimed, the logical compliment analysis may hold stating that:

"The main problem of the compatibility of disclosed disclaimers with Article 123(2) EPC does not lie in one specific 'embodiment' of an invention being disclaimed from a broad generic claim. Rather, it arises in those cases in which a whole area or subclass is disclaimed".

and

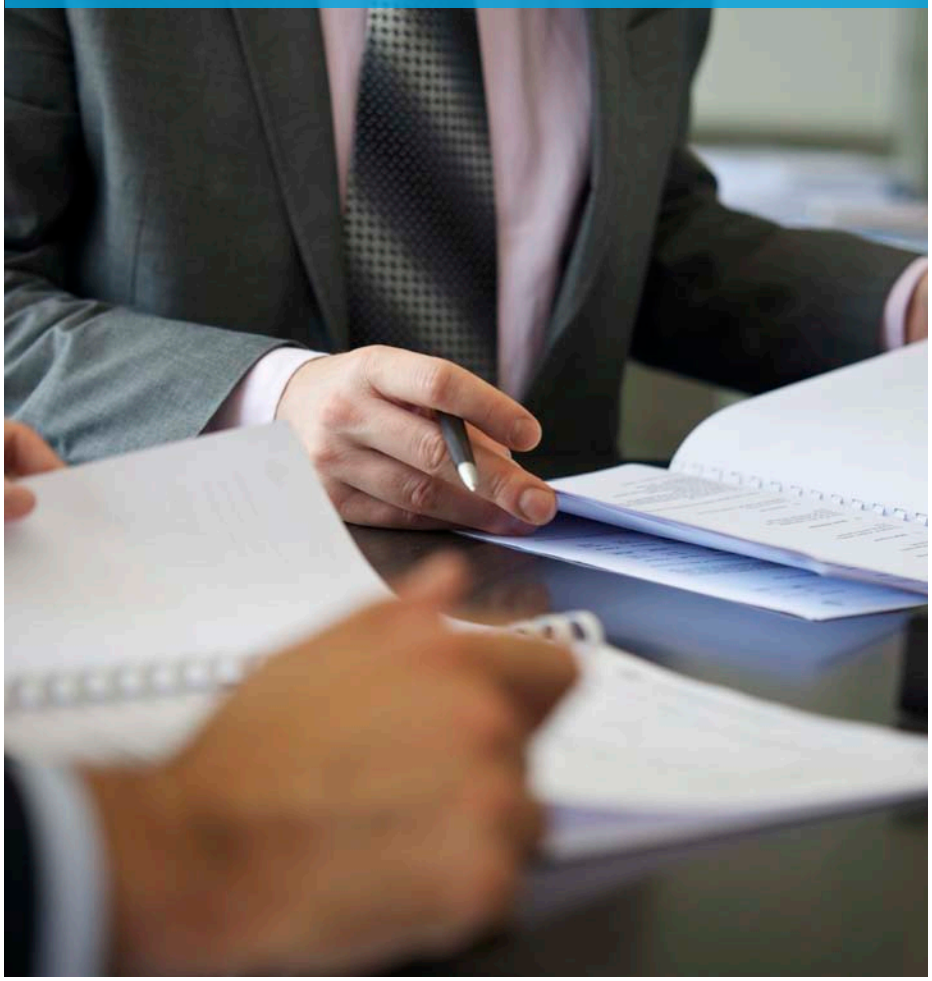
"It appears immediately evident that the nature of the question differs according to whether only one specific embodiment is disclaimed from a generally drafted claim or whether, on the other hand, a whole subgroup or area is disclaimed".

Thus, the Board appears to be indicating that while it may be allowable in certain circumstances to disclaim one specific embodiment, problems in respect of Article 123(2) EPC may arise when disclaiming a whole subgroup. Although the Enlarged Board did not give any specific examples of such situations, the following Markush claim may help to illustrate this issue. For example, if an original disclosure is directed to a group of compounds:



where each of R1- R5 has 10 possible definitions, what would be the situation

The Enlarged Board has reverted back to the 'directly and unambiguously derivable' test



where five of the ten options for each R group are disclaimed? Such a disclaimer could be viewed as constituting a 'selection' of subject matter. The EPO is very strict on amendments which result in the selection of subject matter not implicitly disclosed in the application as filed. Situations such as this may have encouraged the Board to move away from the logical compliment approach, and to retreat to the 'gold standard' of assessing added subject matter (the 'directly and unambiguously' derivable test).

In summary, while the Board appears to be indicating that it may be permissible to disclaim one specific embodiment that is disclosed in the application as filed, problems in respect of Article 123(2) EPC may arise when disclaiming a a subgroup or an intermediate generalization which cannot be regarded as disclosed in the application as filed.

Authors:
Connor McConchie
Simon O'Brien

Useful links
Full text of decision G 2/10:

http://bit.ly/epog210

Indirect Infringement Issues for Second Medical Use Claims

Recent decisions highlight how indirect infringement affects second medical use claims

In the last year the UK Court of Appeal has issued two important decisions *(Grimme v Scott and KCI v Smith & Nephew)* relating to indirect infringement. The relevant provision of the UK Patents Act is section 60(2) which states that:

"60(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he ***knows****, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are* ***intended*** *to put, the invention into effect in the United Kingdom."*

The decisions in *Grimme v Scott* and *KCI v Smith & Nephew* have clarified how the knowledge and intention requirements are to be applied. This clarification was summarized in paragraph 53 of KCI v Smith & Nephew which stated:

"53…i) The required intention is to put the invention into effect. The question is what the supplier knows or ought to know about the intention of the person who is in a position to put the invention into effect – the person at the end of the supply chain.

ii) It is enough if the supplier knows (or it is obvious to a reasonable person in the circumstances) that some ultimate users will intend to use or adapt the "means" so as to infringe.

iii) There is no requirement that the intention of the individual ultimate user must be known to the defendant at the moment of the alleged infringement.

iv) Whilst it is the intention of the ultimate user which matters, a future intention of a future ultimate user is enough if that is what one would expect in all the circumstances.

v) The knowledge and intention requirements are satisfied if, at the time of supply or offer to supply, the supplier knows, or it is obvious to a reasonable person in the circumstances, that ultimate users will intend to put the invention into effect. This has to be proved on the usual standard of the balance of probabilities. It is not enough merely that the means are suitable for putting the invention into effect (for that is a separate requirement), but it is likely to be the case where the supplier proposes or recommends or even indicates the possibility of such use in his promotional material."

The fact that the relevant intention is that of the ultimate users means that a supplier cannot avoid the effects of this section by only offering or supplying the essential means for carrying out the invention to middlemen. Moreover, a potential difficulty for any supplier whose only intention is to supply for legitimate purposes is that they may be considered an indirect infringer because of what is considered obvious about the intention of ultimate users over whom the supplier may have no control.

Furthermore, in *Grimme v Scott* the judge stated in paragraph 88 that action under s.60(2) may be taken:

"88…(1) even though what is supplied is capable of perfectly lawful, non-infringing use, (2) even though what is supplied never has been and may never in fact be used in a way directly infringing the patent in suit, (3) without any damage being suffered by the patentee, and (4) at the moment of supply, irrespective of anything that may or may not occur afterwards.

90…If and to the extent that Mr Scott's case is that there can be no infringement under s.60(2) unless there is actual direct infringement, it is plainly wrong. In this connection it is particularly important to observe that there can even be infringement

Notes

1 See "CIPA Guide to the Patents Act", 6th Edition, Ed. Jones, S. F., et al. (2009), section 60.09, page 639, paragraph 4

by 'offering' to sell an essential means – at the time of the offer there is unlikely to be any particular end user in mind."

Thus, a supplier may indirectly infringe a patent by supplying an essential means to put the patent into effect even though no actual direct infringement by an ultimate user has been proven, provided the knowledge or intention requirements are met. This reduces a patentee's burden in proving indirect infringement but makes matters more difficult for the supplier.

This reasoning appears to create particular difficulties for second medical use claims.

Second medical use claims are directed to a known substance or composition for a further medical use. The patentability of such claims relies on this further medical use for the substance or composition being considered novel and inventive.

The difficulties are best illustrated with an example. If we first consider the common situation where there is no longer any patent protection for a drug *per se* or for its use for the treatment of a first disease, a generic manufacturer may legitimately proceed to obtain approval for a generic version of the drug and to offer and supply it in the UK for the treatment of the first disease. However, this situation becomes more complicated if there exists a granted patent, in force in the UK, with claims to a second medical use of the drug for treating a second disease.

There has been some speculation that such second medical use claims should only be held as an indirect infringement where the essential means is made available in the UK specifically for the stated purpose[1]. As yet no judgment considering this point has issued from the UK Courts. However, the reasoning in *KCI v Smith & Nephew* (see points i to iii above) that the required intention is that of the ultimate user appears to suggest that there will be indirect infringement by the generic manufacturer if a generic version of the drug is offered or supplied for any purpose, provided the generic manufacturer knows, or it is obvious, that ultimate users intend to use the generic drug for the second medical use.

The intention of ultimate users can be particularly problematic in pharmaceutical situations because physicians are known to prescribe generic versions of drugs off-label. That is to prescribe generic drugs for diseases for which they have not been specifically offered, supplied or approved in the label if the physicians are aware that the specific drug can be used to treat the particular disease.

A further difficulty is that it appears that the question of whether supply of a generic drug is an indirect infringement of a second medical use patent may change over time (see point iv above). For example, initial supply of the generic drug may not be considered an indirect infringement because at that time it would not be obvious to a reasonable person that some ultimate users intend to use the generic drug for the claimed second medical use. However, over time the efficacy of using the drug for the claimed second medical use may become widely known to physicians and, as a consequence, this could alter whether it would be considered obvious that some off-label prescription of the generic drug for the second medical use would occur.

Thus, where a second medical use patent for a drug is in force in the UK it may prove difficult for a generic manufacturer to avoid a risk of being considered an indirect infringer if they offer or supply a generic version of the drug in the UK. In theory, the generic manufacturer's position may be improved if ultimate users were convinced that the generic drug is not suitable for any off-label applications, for example because of the way it is formulated. However, in practice such an aim may be difficult to achieve. One aspect that has been reiterated in *Grimme v Scott* is that any mention of the second medical use in connection with a generic version of the drug or with its promotional material is likely to be considered as satisfying the knowledge and intention requirements.

Suppliers of generic drugs could also be affected

Given the above issues, it appears that uncertainty regarding the application of indirect infringement to second medical use patents will remain until a suitable case is considered by the courts.

Author:
Michael Simcox

Useful links

Full text of decisions:

Grimme Maschinenfabrik GmbH &Co KG v Derek Scott [2010] EWCA Civ 1110:

http://bit.ly/oQMzoF

KCI Licensing Inc. and others v Smith & Nephew plc and others [2010] EWCA Civ 1260:

http://bit.ly/riJYvn

What's In a Number?
A Brief History of Patent Numbers

In August the United States Patent and Trademark Office (USPTO) celebrated the 100th anniversary of its one-millionth granted patent. Patent number US 1,000,000 was issued on 8 August 1911, to Francis H Holton from Ohio, for an invention relating to vehicle tyres.

Under this patent numbering system, which is still in use by the USPTO today, patent number 1 was issued in 1836. The first million patents were therefore issued over a period of 75 years, but only 24 more years took the country to its two-millionth patent. Patent number US 2,000,000 was issued on 30 April 1935 to J Ledwinka for, coincidentally, another vehicular invention: a vehicle wheel construction.

Since then, the USPTO has continued to issue patents at an ever-increasing rate, as can be seen from the accompanying graph, above, right. Patent number US 8,000,000 will be issued later this year, a mere five years after patent number US 7,000,000 was issued on 14 February 2006 to DuPont. This patent relates to polysaccharide fibres, for use in textiles rather than the sweet and sugary purposes suggested by the title and befitting the St Valentine's Day issue date.

Patents are often seen as an indicator of creativity and of economic and technological development, so the graph provides a snapshot of an aspect of the United States's growth over the past two centuries. It would be interesting to compare graphs for other nations and regions. However, many other patent numbering systems are not as obliging as that used by the USPTO when it comes to revealing the actual quantity of patents.

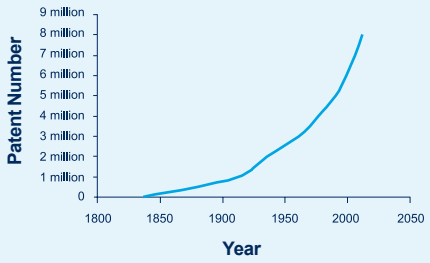
Beginning with patent number 1 in 1836, the USPTO uses a consecutive numbering system to allocate numbers to patents as they are issued, or granted, from patent applications. The original applications are numbered according to a different system. Thus, the number of a granted US patent directly tells us how many patents have been granted since 1836 up to the date of that patent.

The European Patent Office (EPO) uses a different arrangement. Under its system, consecutive numbers are allocated to patent applications as they are published, and these numbers are retained as the patent number upon grant. However, not every published application matures into a granted patent, so the number of a European patent does not indicate how many granted patents have preceded it. For example, European publication number EP 1,000,000 was granted as patent number EP 1,000,000 on 12 February 2003 (25 years after the EPO opened for business in 1978), but European publication number EP 2,000,000 was withdrawn before grant. Being many years younger than the USPTO, the EPO is currently allocating far lower numbers than its transatlantic counterpart, and has not yet reached 2,400,000.

The situation in the United Kingdom is more complicated still. Like the EPO, the UK Intellectual Property Office (UK IPO) currently allocates consecutive numbers to published applications, the numbers being retained on grant. However, since the birth of the UKIPO in its modern form in 1852, several different numbering systems have been employed, so the patent numbers do not offer a clear picture of the growth of the patent system. Up until 1915, application numbers were restarted at 1 each year, with granted patents keeping the same number. In 1916 a system using separate numbers for applications and for publication/grant was introduced, starting at 100,001. Patent number GB 1,000,000 appeared in 1965. Then the Patents Act of 1977 created the need for a new series of numbers (allocated from 1979 onwards), to distinguish between patents published and granted under the old and new legislations. However, this series was started at 2,000,001, so the number 2,000,000 has never been used for a United Kingdom patent or application.

Of course, one can obtain the data necessary to chart the growth rate of issued patents in different countries without difficulty, and figures for the amount of filed applications and published applications can be similarly studied. However, the actual application and patent numbers typically lack the useful transparency of the USPTO's longstanding and consistent approach. Given humankind's affection for round numbers, no doubt the future lucky recipient of patent number US 8,000,000 will experience a certain satisfaction and pride in owning the country's eight-millionth granted patent.

US Patent Numbers by Year of Issue



The USPTO numbering system differs greatly to that of the UK IPO and EPO

Author:
Cathrine McGowan

Article 04

Human Genetics Commission Report Leading the Way for DNA Patents

Regular visitors to our website will have been alerted to the publication of the UK's Human Genetics Commission's (HGC) report on the impact of DNA patents on diagnostic innovation. The HGC is the Government's advisory body on new developments in human genetics with a particular focus on social, ethical and legal issues.

The HGC believed that empirical research has shown that the enforcement of DNA patents has led clinical genetics labs to withdraw some tests, although more commonly in the USA than Europe. Moreover it appeared to the HGC that at the moment UK labs are largely unaffected in practice by DNA patents, or have not negotiated IP arrangements. Nevertheless the HGC recognised a profound tension between the industry's need to sustain their R&D activities and the 'routine infringements of such IP in NHS laboratories'.

To begin to address these tensions they made the following four recommendations:

1. UK research councils should review their guidelines on licensing patents;
2. to establish a biomarker IP monitoring function;
3. to develop and support national implementation of ways to manage biomarker IP issues; and
4. to establish a forum to gather independent evidence on the impact of biomarker IP on diagnostic innovation.

The HGC report comes at the same time as the US Federal Circuit's acknowledgement that the patenting of genes has become the basis for a valuable industry[1]. Nevertheless concern remains in Europe over how the European courts will now interpret the extent of 'gene patents' following the Monsanto decision from the Court of Justice of the European Union. In this Monsanto decision they ruled that there is no protection for a DNA sequence "as such" and that a patent directed to a DNA sequence may only cover that sequence when performing the function for which it is patented.

DNA diagnostics are a valuable medical tool

The risk of breast cancer in the general population of women is one in nine. Those with one of the BRCA mutations can have a four in five chance of developing breast cancer and often choose preventive surgery. DNA diagnostics will therefore continue to present an extremely valuable medical tool where preventative or treatment options are available. It is vital that industry and the medical profession are supported in bringing such tools to patients, and the work of the HGC in this arena is to be welcomed.

Author:
Catherine Mallalieu

Useful links:

C-428/08 (Monsanto decision):

http://bit.ly/oLSP9X

D Young & Co article – Myriad Case – US Federal Circuit's Decision in Association for Molecular Pathology v USPTO:

http://bit.ly/n3dbfC

Notes

1 Association for Molecular Pathology et al v US Patent & Trademark Office et al ('Myriad' or 'BRCA' decision)

Article 05

D Young & Co Appoints Three New Partners

We are delighted to announce the appointment of two new patent partners, Garreth Duncan and Nicholas Malden, and the appointment of trade mark partner Helen Cawley.

Prior to joining D Young & Co in 2007 Garreth worked both in private practice and in Pfizer's European Patent Department. Garreth has been appointed as a partner in our Biotechnology, Chemistry & Pharmaceuticals Group and specialises in all types of chemical subject matter, including pharmaceuticals, food chemistry, petrochemicals, agricultural chemistry, polymer chemistry and chemical synthesis and processes. He has particular experience in obtaining Supplementary Protection Certificates and other forms of patent term extension.

Nicholas joined D Young & Co in 2005 and qualified as a Chartered Patent Attorney and European Patent Attorney in 2009. Nicholas has been appointed a partner in our Electronics, Engineering & IT Group and is based at our Southampton office. Nicholas specialises in the fields of physics and electronics, including various computer-implemented technologies. Digital electronics, consumer devices and microprocessor technologies also feature strongly in Nick's portfolio.

Helen joined D Young & Co in 2004 as a trainee trade mark attorney, and we are proud to see her career develop over the years and to announce her appointment as a partner within our Trade Mark Group. Helen strengthens a team recently acclaimed by Legal 500 to be 'top of its field' and deals with all aspects of trade mark work from clearance searches to enforcement issues. In particular Helen focuses on contentious matters and has handled numerous oppositions and cancellation actions before the IPO and OHIM.

Useful links:

People:

www.dyoung.com/garrethduncan

www.dyoung.com/nicholasmalden

www.dyoung.com/helencawley

D YOUNG & CO INTELLECTUAL PROPERTY

And finally…

Legal 500 Results
D Young & Co Ranked as Top Tier for Patents and Trade Marks 2011

We are delighted to announce that Legal 500 has once again rated D Young & Co as a leading UK IP firm, ranking us as top tier in all three PATMA (patent & trade mark attorney) categories. Legal 500 recommendations are largely based upon client assessment and comments, so we are particularly grateful to our clients for their invaluable contribution to the research process.

In this year's Legal 500 report, clients say that D Young & Co has *"strong acumen in defending patents"* and *"deep knowledge and understanding of the science behind patented inventions"*. Our Trade Mark Group is *"top of its field"* with *"extensive knowledge"*.

Legal 500 also notes that we are the first firm of patent and trade mark attorneys to establish a Legal Disciplinary Practice (LDP) and highlight our recently established Dispute Resolution & Litigation Group, headed up by *"great litigator"* partner Ian Starr.

The full report can be viewed online at www.dyoung.com/news-legal5002011

Patent Group

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Nigel Robinson
Ian Harris
Charles Harding
James Turner
Catherine Mallalieu
David Horner
Neil Nachshen
Miles Haines
Jonathan DeVile
David Alcock
Aylsa Williams
Simon Davies
Zöe Clyde-Watson
Kirk Gallagher
Louise Holliday
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