

# D YOUNG & CO PATENT NEWSLETTER *no.17*

June 2010

In this issue:

<b>Patentability of Gene Sequences</b> US Courts Give the DNA Patentability Story a New Twist	<b>02</b>
<b>Enlarged Board of Appeal Decision in Case G 3/08</b> Patentability of Computer Programs	<b>04</b>
<b>New European Patent Office Divisional Application Rules</b> Review Your Portfolio Now!	<b>05</b>
<b>Supplementary Protection Certificates (SPCs)</b> Combination Products and First Marketing Authorisations	<b>06</b>

**Location Copenhagen:**  
**Your invitation to attend our**  
**Life Sciences Patent Seminar**  
**4-5 October 2010**  
**Registration opens 1 June 2010**

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## Life Sciences Seminar



4-5 October 2010

We are delighted to invite you to attend the D Young & Co Life Sciences Patent Seminar, to be held at the Radisson Blu (SAS) Royal Hotel, Copenhagen.

This two day seminar is ideally suited for European patent attorneys, trainee patent attorneys, patent managers, licensing executives and technology transfer managers with at least two years patent experience, working in the pharmaceutical, biotechnological or chemical field.

This is an event not to miss, providing interactive workshops addressing patent drafting strategies as well as in depth presentations covering a range of patent related topics. Speakers will include D Young & Co patent partners and representatives from European law firm Taylor Wessing and US law firm Brinks Hofer Gilson & Lione. Delegates are invited to join us for a drinks reception and dinner on the evening of 4 October 2010 at the seminar venue.

Registration opens 1 June 2010. We recommend that interested delegates book early to avoid disappointment as places are limited. Attendance will cost 700 Euro (+ VAT), 500 Euro early bird discount. To register, email [registrations@dyoung.co.uk](mailto:registrations@dyoung.co.uk), visit our website to download a pdf registration form, or telephone +44 (0)20 7269 8550.

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## More Events



14-18 June 2010

**Management Forum Patent Summer School**  
Kit Wong and Simon Davies will be speaking at this four day residential course.

12-14 July 2010

**UK National Stem Cell Network (UKNSCN) 3rd Annual Science Meeting 2010**  
Louise Holliday and Robert Dempster will be attending the 3rd Annual Science Meeting.

17 September 2010

**Patent Protection for Software-Related and Business-Related Inventions in Europe and the United States**  
Ian Harris will be presenting at this Management Forum seminar.

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## Article 01

# Patentability of Gene Sequences US Courts Give the DNA Patentability Story a New Twist

US district court hearing AMP v Myriad raises questions for future US patent practice



It has been some time since I assisted on the Human Genome Project while a post graduate student at the Sanger Genome Sequencing Centre ([www.sanger.ac.uk](http://www.sanger.ac.uk)), but before, and particularly after, the human genome was made publicly available in 2003, attempts have been made to patent individual naturally occurring genes. In some countries this has been considered controversial. Before the USPTO, long considered by some commentators to be a slightly more liberal jurisdiction than the EPO, the issue has not been particularly contentious. However, the situation in the US may be set for a change.

### AMP v Myriad

The US district court hearing AMP v Myriad recently handed down a judgement that could have wide reaching implications on US patent practice.

The US district court had to consider a series of patents in the name of Myriad. These patents concerned isolated BRCA1 and BRCA2 breast cancer related genes (DNA), and methods for analysing DNA to detect mutations in these genes which are known to increase the risk of breast or ovarian cancer. The discovery of these genes, and their use in cancer tests, has been



widely reported in the media:  
<http://news.bbc.co.uk/1/hi/health/3720939.stm>

A suit was filed against Myriad's BRCA gene patents by various individuals as well as political and charitable groups to invalidate the patents. The parties alleged that naturally occurring genes were not patentable on a number of grounds, including constitutional grounds.

Against this background, there is a long standing precedent in the US that "anything under the sun that is made by man" is patentable (see *Diamond v Chakrabarty*, 447 US 303 [1980]). Thus genes which have been isolated from their natural environment were often considered to fall within the scope of patentable subject matter. There is also case law in the US that says purification of a product of nature, without more, cannot transform it into patentable subject matter. Here, the US Courts said that a purified product must be seen to possess "markedly different characteristics" in order to satisfy the patentability requirements.

Surprisingly to some observers, in the *AMP v Myriad* case, the Court ruled that the isolated DNA (gene) of the claims did not fulfil the requirement of being markedly different from natural DNA, and was thus not patentable.

For more information, we refer you to "Myriad Issues for Gene Patents", Life Sciences IP Review 2010, pages 6-9: [www.worldipreview.com/LSIPRAnnuals.asp](http://www.worldipreview.com/LSIPRAnnuals.asp)

#### Gene Patents in Europe

In Europe, after several years of discussion as to what constitutes a patentable biotechnological invention, the patentability of gene sequences isolated from their natural environment was clarified in statute by the EU Biotechnology Directive in 1998.

Article 3(2) of the Biotechnology Directive states:

*Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if it previously occurred in nature.*

Article 5(2) of the Biotechnology Directive states:

*An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*

This exact wording has been incorporated into Rule 27 and Rule 29(2) of the European Patent Convention (EPC).

For a number of years now, it has thus been possible to obtain grant of patents at the EPO for isolated naturally occurring gene sequences, provided that those sequences fulfil all of the other patentability requirements of novelty, inventive step, industrial applicability etc. The EPO has in fact already ruled in favour of Myriad's European BRCA gene patents, affirming that the EPC is to be interpreted in accordance with the implementing rules, which state that an element isolated from the human body or otherwise produced by

means of a technical process may constitute a patentable invention. This finding applies to claims relating to products, here genes, and is for still stronger reasons applicable to related method claims (see EPO Board of Appeal Decisions T1213/05, T666/05 and T0080/05).

Therefore the patentability as such of gene sequences isolated from their natural environment does not appear at present to be a debatable issue in Europe. But, in some European countries, patents directed towards isolated genes have recently been opposed on the grounds of lack of industrial application. Therefore it may be more important in the future to specify the intended final use of an isolated gene sequence when filing a patent application. This topic was discussed by Catherine Mallalieu in the April 2010 edition of this newsletter (issue 16).

The gene world now awaits the expected appeal on the *AMP v Myriad* case with interest.

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#### Useful links:

<http://news.bbc.co.uk/1/hi/health/3720939.stm>

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# Enlarged Board of Appeal Decision in Case G 3/08 Patentability of Computer Programs

The Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) has released its opinion in the case of G 3/08 concerning the patentability of programs for computers.

The case arose from a referral under Article 112(1)(b) EPC, which allows the President of the EPO to “refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that question”.

The origin of the referral can be traced to a judgement by the UK Court of Appeal in *Aerotel*. The judgement in this case reviewed (and rather criticised) EPO case law in this area, and proposed some questions that the EPO President might consider submitting to the EBA (national courts have no formal ability to submit questions themselves to the EBA). The then President of the EPO, Alain Pompidou, declined to follow this suggestion on the grounds that he did not think there was any inconsistency in the decisions from the Boards of Appeal, and hence no basis for a referral under Article 112(1)(b) EPC.

It was slightly surprising that less than two years later, Mr Pompidou's successor as EPO President, Alison Brimelow, decided that there was basis for a referral, and that forms the basis for G 3/08. Note that the referral only cites decisions that were already available when Mr Pompidou decided not to make a referral, so the difference in position was not triggered by any new case law.

In the event, the EBA has decided that the referral was indeed *inadmissible* because the referral failed to identify the required differences in case law. In particular, the EBA held that although the decisions cited in the referral did demonstrate some differences in approach, these could be considered as part of the standard development of law in an area. Newer decisions have all followed the same line of legal development, and hence there are no different (conflicting) decisions within the

sense of Article 112(1)(b) EPC.

Although a finding of inadmissibility already implies maintaining the current legal position, the opinion generally goes further and does contain some discussion of the four questions contained in the referral. The arguments presented by the EBA in this analysis appear to offer explicit support for recent decisions.

In particular, the EBA comments as follows on the 4 questions included in the referral (shown here slightly simplified and shortened):

1. Can a computer program only be excluded as a computer program as such if it is explicitly claimed as a computer program?  
*Despite the finding of inadmissibility, the EBA discusses this question at some length, especially in relation to T1173/97 and T424/03. Although the “contribution” approach of T1173/97 is no longer followed, the EBA regards this as a normal development of case law. In addition, the EBA goes some way towards reconciling more modern decisions with the reasoning provided in T1173/97.*
2. Can a claim in the area of computer programs avoid exclusion merely by explicitly mentioning the use of a computer or a storage medium? If not, is a further technical effect necessary to avoid the exclusion?  
*The EBA mainly decides that the decisions cited in the referral do not diverge on this point (hence the question is not admissible). It is clear from the discussion of Question 1 that the EBA would regard the answer to this question as “Yes”.*
3. Must a claimed feature cause a technical effect on a physical entity in the real world in order to contribute to the technical character of the claim? If so, can the physical entity be an unspecified computer? If not, can features contribute to the technical character of the claim if the only effects to which they contribute

are independent of any particular hardware?

*The EBA complains that this question is based on features of a claim, rather than the claim as a whole. The EBA concludes strongly that this question is inadmissible and provides no substantive discussion of the question itself.*

4. Does programming a computer necessarily involve technical considerations? If so, do all features resulting from programming contribute to the technical character of a claim? If not, do they only contribute to the technical character of a claim if they contribute to a further technical effect?  
*Again the EBA regards this question as inadmissible. However, the EBA does indicate that a computer program per se does not necessarily involve technical considerations. This perhaps opens the door to rejecting computer program claims (but not physical medium claims) under Article 52(2) EPC depending upon the purpose of the computer program, i.e. if the computer program serves no technical purpose.*

In summary, the opinion represents a significant endorsement of current EPO procedures for handling the patentability of programs for computers. Consequently, it is expected that the opinion will cause little if any change regarding which applications are, or are not, allowed by the EPO. In particular, the EPO will continue to allow patents for inventions which represent a technical problem to a technical solution (irrespective of whether or not they are implemented using a computer program). However, the opinion may be more significant for harmonising national courts across Europe, which have not necessarily always followed the EPO approach.

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# New European Patent Office Divisional Application Rules Review Your Portfolio Now!

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D Young & Co knowledge bank article "Filing European Divisional Applications" by Kit Wong [www.dyoung.com/article-divisionalapplications](http://www.dyoung.com/article-divisionalapplications)

## > Related Articles

D Young & Co June 2009 patent newsletter (issue 11) article 2 "New European Patent Office Proposals - Restricted Time Limit for Filing Divisional Applications" by Robert Dempster [www.dyoung.com/patentnewsletter-jun09](http://www.dyoung.com/patentnewsletter-jun09)

**O**ur June 2009 newsletter (issue 11) contained an article about the European Patent Office's new time limit for filing divisional applications. For many currently pending applications, the final due date for filing divisional applications will be 1 October 2010. Therefore we strongly recommend that applicants review their portfolios now for cases where divisional applications may be required.

According to the new rule (Rule 36(1) EPC), a divisional application filed from a pending European patent application generally has to be filed within two years from the date of notification of the first communication issued by the Examining Division on the pending application. In the case of a series of divisional applications, the two year period runs from the date of notification of the earliest communication issued on any of the applications in the series, which will usually be the original parent application. The only exception to the rule occurs if a later communication from the Examining Division raises a new objection that there is a lack of unity of invention. In this case, a new two year period starting from the date of notification of the later communication is given. No extensions of time are available for these time periods, and further processing is not allowed.

According to the EPO's Guidelines for Examination, the first communication from the Examining Division is the first examination report (office action), or the communication under Rule 71(3) EPC of intention to grant a patent (notice of allowance) if this comes first. However, the Examining Division may send other types of communication before the first examination report, for instance inviting a reply to the Written Opinion of the International Searching Authority (in the case of a Euro-PCT application). Rule 36(1) EPC does not explicitly define whether such communications trigger the start of the two year divisional filing period. Since it is possible that a future EPO Board of Appeal could overrule the Examination Guidelines, the cautious approach would be to file any necessary divisional applications within two years from the earliest communication from the Examining Division, even if this communication is not an examination report or notice of intention to grant.

**For many currently pending applications, the final due date for filing divisional applications will be 1 October 2010**



The EPO has adopted transitional provisions for pending European applications for which the time limit set by the new rule has already expired or will expire soon. The effect of these provisions is that a divisional application can be filed from any pending European application until 1 October 2010. Extensions of time and further processing are not available. After this date the two year time limit will apply, so that (for example) on 2 October 2010 it will no longer be possible to file a divisional application from an application where the first communication from the Examining Division was notified on 1 October 2008 or earlier.

If you are responsible for any European patent applications, we recommend that you now check them carefully to see if the 1 October 2010 deadline applies. You may have already received reminders from us about any such applications in your portfolio. If any divisional applications are required, please send filing instructions to your representative well before 1 October 2010.

When reviewing your applications, it will sometimes be clear that a divisional application is potentially of interest. For example, claims may have been withdrawn to address a non-unity objection, so that there is subject matter which is not currently claimed in a pending application. This subject matter may be lost after 1 October 2010 if divisional applications are not filed before that date. Remember also the situation for a series of

divisional applications. If you have an existing divisional application from which you might want to file a further divisional application, check the date of the earliest Examining Division communication issued on any of the series. If it is on or before 1 October 2008, the 1 October 2010 deadline applies to your existing divisional application. If the parent application contains multiple inventions, all necessary divisional applications should be filed within the deadline under Rule 36(1) EPC, rather than filing a single divisional application to be further divided later.

You should also consider any applications for which a Rule 71(3) communication has been issued, or which may soon be refused or withdrawn. Under the new rules, any divisional application will still need to be filed whilst the parent application is pending, i.e. before the parent application is granted, withdrawn or refused, in addition to the new two year restriction. If it looks possible that an important application will be refused at a later date, a divisional application would need to be filed both before the end of the two year period under Rule 36(1) EPC (or 1 October 2010 where appropriate) and before the date of refusal, whichever comes first, if it is desirable to ensure that a pending application covering the invention is maintained.

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# Supplementary Protection Certificates (SPCs) Combination Products and First Marketing Authorisations

In European Economic Area (EEA) member states<sup>1</sup> the duration of protection for certain patented subject matter (i.e. medicinal products and plant protection products) may be increased by a Supplementary Protection Certificate (SPC). SPCs were introduced to partly compensate for the reduced effective term of patent protection for inventions that require approval by regulatory authorities.

The SPC comes into force after the national patent has expired (i.e. exceeded the full twenty year term). The term of the SPC is calculated as the period between the filing of the patent and the date of first marketing authorisation in the EEA minus five years, subject to a five year cap. Hence, SPCs, in combination with the patent, aim to provide fifteen years of marketing exclusivity.

**An SPC shall be granted if the following criteria are met:**

1. the product is protected by a basic patent in force;
2. a valid authorisation to place the product on the market as a medicament has been granted pursuant to Directive 2001/83/EC or Directive 2001/82/EC;
3. the product has not already been the subject of an SPC; and
4. the marketing authorisation (MA) is the first authorisation to place the product on the market as a medicament.

The subject matter capable of protection is limited to the product covered by the authorisation to place the corresponding medicinal product on the market and for any therapeutic use of the product authorised before the expiry of the SPC. Product is defined as the active ingredient or combination of active ingredients of the medicinal product.

Although created by European legislation, the grant of SPCs is handled by national authorities. As such, interpretation of the regulations has varied across Europe, leading to a number of court cases and referrals to the European Court of Justice (ECJ). Set forth below is a summary of the main decisions over the past twelve months relating to combination products and first marketing authorisations.

## Combination Products and First Marketing Authorisations

There have been several cases, spanning jurisdictions, in respect of the conditions that must be met for a combination of active ingredients to be protected by an SPC.

In the Astellas case<sup>2</sup> the Appellant's application for the grant of an SPC directed to a combination of emodepside/praziquantel based on European Patent (UK) No. 0634408 was deemed to have been correctly refused. Although claim nine of the patent was directed to emodepside, there was no disclosure of praziquantel in the claims or description, let alone in combination with emodepside. In view of this, it was found that the combination was not "protected" by the basic patent in line with requirement (1) mentioned above. It was held that "protected" means that the patent must include a claim expressly directed to a combination of all of the active ingredients present in the product. It is not sufficient that the combination is merely encompassed by the patent by virtue of claiming one of the components of the combination.

A similar issue, but involving vaccines, was considered in the Medeva BV case<sup>3</sup>. A total of five SPCs were applied for in respect of various combinations of active ingredients, with the combinations containing between two and nine active components. The applications were supported by four MAs in respect of

## Recent SPC decisions reviewed



combinations of between eight and eleven active ingredients. The basic patent (European Patent (UK) No. 1666057) claimed a combination of two of the active agents. The same combination was the subject of one of the SPC applications but was not the subject of an MA. It was held that four of the SPC applications were for combinations containing more active agents than the claims of the basic patent and, therefore, did not meet requirement (1) above. The SPC application that did meet requirement (1), i.e. basic patent protection for the combination of the two active agents, did not meet requirement (2) as these two agents were not the subject of an MA. Hence, all five applications were rejected.

Both of these decisions follow the reasoning in Gilead Sciences' SPC application<sup>4</sup>, which stated that for an SPC application for a combination of active ingredients to be allowed, the patent must explicitly claim the combination. This claim may however take the form of a claim where one of the active ingredients is only described generically, e.g. as a further active agent.

The above interpretations of the requirements for granting an SPC appear to be consistent with those in other European jurisdictions. In Daiichi Sankyo Company Limited v Monsieur le Directeur de l'INPI (Paris Court of Appeals) an SPC application for a combination of olmesartan medoxomil and hydrochlorothiazide was rejected. The

## > Notes Page 6

- 1) *EEA member states are the EU member states plus Norway, Liechtenstein & Iceland*
- 2) *Astellas Pharma Inc v Comptroller-General of Patents (High Court) [(2009) EWHC 1916 (Pat)]*
- 3) *Medeva BV v Comptroller-General of Patents (High Court) [(2010) EWHC 68 (Pat)]*
- 4) *[2008] EWHC 1902 (Pat)*

## > Notes Page 7

- 5) *Generics (UK) Limited v Daiichi Pharmaceutical Co Ltd and Daiichi Sankyo Co Ltd (High Court) [(2008) EWHC 2413 (Pat)]*
- 6) *BL O/066/10*
- 7) *BL O/384/09*
- 8) *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents (Case C-202/05)*
- 9) *Pharmacia Italia v Deutsches Patentamt (Case C-31/03)*

application was based on European Patent (FR) No. 503785, which did not expressly claim the combination of active agents. It was held that a patent encompassing the combination by claiming one of the components of the combination is not sufficient as basis for an SPC application to the combination.

As noted above, it is necessary that for an SPC application to be successful the MA relied on must be the first MA for that product. In the *Generics/Daiichi* case<sup>5</sup> the question considered was whether an MA for a racemic product also constituted the first MA for one of the enantiomers. Specifically, this case related to the anti-microbial agent levofloxacin, which is an enantiomer of ofloxacin. An MA for ofloxacin issued in 1985 and in 1997 an MA for levofloxacin also issued. It was held that levofloxacin and ofloxacin were different products with differing medicinal properties. Therefore, the authorisation to place ofloxacin on the market cannot be considered to be an authorisation to place levofloxacin on the market. Hence, the SPC for levofloxacin had been validly granted.

This line of reasoning was also used by the Federal Court of Justice of Germany in respect of the validity of the SPC granted on European Patent (DE) No. 0347066 directed to escitalopram. Escitalopram is the (s)-enantiomer of citalopram. It was decided that the therapeutic activity of citalopram was the result of contributions from both enantiomers and, hence, citalopram was considered to be a different active ingredient from each of the individual enantiomers. Thus, the earlier MA to citalopram did not prove a bar to the grant of an SPC for escitalopram.

The importance of selecting which MA to support an SPC application was highlighted by a decision of the UK Intellectual Property Office. Imclone Systems Inc and Aventis Holdings Inc jointly filed SPC applications for 'cetuximab in combination with Irinotecan' and for cetuximab<sup>6</sup>. These were based on European Patent (UK) No. 0667165, which claimed a combination encompassing cetuximab and Irinotecan. Two MAs relating to cetuximab had issued, one for Erbitux® (the product containing cetuximab

alone), granted by the European Medicines Agency (EMA), and one entitled "*Combination therapies with cetuximab and Irinotecan*", granted by the Swiss national authorities. However, only the European MA could be relied on to support the SPC applications in the UK. The European MA was unable to support the SPC application for the combination as it was directed to Erbitux® alone. It was also found that, as the patent relied on related to the combination of cetuximab and Irinotecan, it could not support the application for cetuximab alone. Thus, both applications were rejected.

Combinations of active ingredients and inactive ingredients have also led to court proceedings across Europe. The UK High Court rejected an application of Neurim<sup>7</sup> in respect of the medicinal product Circadin®, which contains melatonin. The basic patent for this SPC application was European Patent (UK) No. 0518468 relating to the use of melatonin to correct the plasma melatonin profile in a human. An MA for this use was granted in June 2007. However, an MA for melatonin as a veterinary product had already been issued. In line with the ECJ decisions in the *Yissum*<sup>8</sup> case and the *Pharmacia*<sup>9</sup> case, the court held that the decisive issue was whether an earlier MA for the same product existed regardless of its intended therapeutic use (veterinary or human). Thus, the SPC application was rejected as the MA for Circadin® did not constitute the first authorisation to market melatonin as a medicinal product.

In France, Liposome Company Inc applied for an SPC based on European Patent (FR) No. 0282405 in respect of a combination of amphotericin B and two phospholipids. An MA was granted for this combination in June 1997. However, amphotericin B alone had already been the subject of an MA granted in 1973. It was held that the two phospholipids were merely toxicity reducing excipients and, therefore, the later MA was not for a combination of active ingredients. In view of this it was found that requirement (4) mentioned above was not met, i.e. the MA granted in June 1997 was not the first MA for the product amphotericin B. This finding follows the reasoning of an earlier ECJ decision, i.e. Case C-431/04 (MIT).

Similar conclusions were reached in both France and the Netherlands in respect of Gravax®. It was argued that an earlier MA relating to the same active ingredient as present in Gravax® was for a combination of active ingredients including the adjuvant aluminium hydroxide and, therefore, this MA did not bar the granting of an SPC for the active ingredient alone. However, the court held that as aluminium hydroxide had no therapeutic effect of its own, the earlier MA was not for a combination of active ingredients and that this earlier MA did represent the first authorisation to place that active ingredient on the market as a medicinal product. Hence, the SPC application for Gravax® was refused.

Recently, in Italy and Slovenia, SPCs have reportedly been granted in respect of a combination of an antigen and an adjuvant and to the adjuvant alone. However, these decisions appear to differ from the above cases in that the adjuvant alone is capable of being the subject of an SPC, i.e. is an active agent in its own right. Thus, in these cases the SPC applications may be viewed as for combinations of active ingredients.

## Summary

In order for a combination product to be the subject of SPC protection, the application should be based on a patent that contains a claim to that combination, even if the individual components of the combination are only described generically. Therefore, when drafting patent specifications basis should be provided for claims to future possible combinations of active ingredients.

An earlier MA to an active agent provides a bar to an SPC application supported by an MA to a specific use of the active agent as both MAs relate to the same product

An MA for a combination of active agents does not provide a bar to an SPC application to one of the active agents, as the MAs relate to different products.

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# D YOUNG & CO INTELLECTUAL PROPERTY

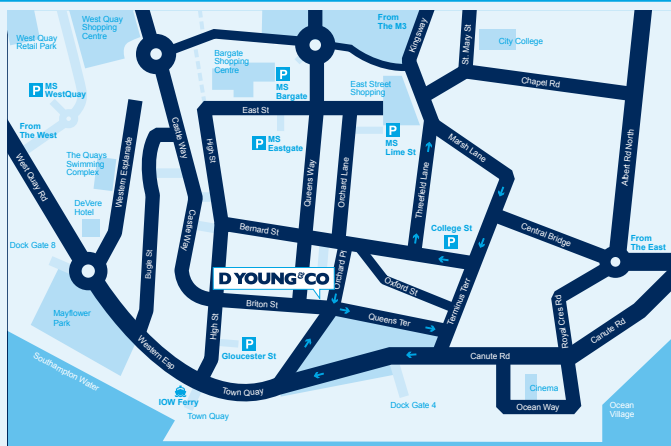
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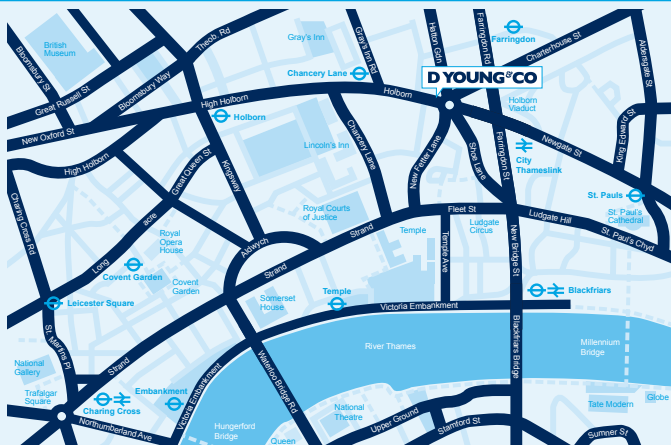


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