D YOUNG & CO
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David Meldrum will be presenting at this PRG/Management Forum seminar.

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D Young & Co Life Sciences Patent Seminar
D Young & Co is hosting a Life Sciences patent seminar in Copenhagen. For more information and to register visit:
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Editorial

Doesn't time fly! Here we are already well into the second half of the year.

It's good to see the USPTO looking to find ways to introduce more flexibility for applicants. It will be interesting to see if the proposals discussed in our lead article will find favour with applicants.

We've also looked at a recent ECJ judgment regarding the scope of protection afforded by a claim directed to a DNA sequence, and have provided a case law round up in respect of SPCs.

We're sure that you don't need reminding of the need to review your patent applications in view of the new Rule 36(1) of the European Patent Convention to see whether any divisional applications need to be filed before 'D-day', namely 1 October 2010. See the article in our previous newsletter (no. 17) for more information.

Finally, some D Young & Co LLP news: we are pleased to announce that Darren Lewis and Simon O'Brien have been appointed partners.

Editor:
Ian Harris

Article 01

Making US Examination More Attractive?
USPTO Proposes Three Track Patent Examination Procedure

The United States Patent and Trademark Office (USPTO) has recently issued a press release outlining proposals for changing its patent examination procedures. The proposed initiative offers applicants a choice of three different examination "tracks":

- Track I
  Prioritised examination
- Track II
  Traditional examination under the current procedures
- Track III
  An applicant-controlled examination delay of up to 30 months

The aims of the "Three-Track" program include giving applicants greater control over the speed and timing of the examination of their applications, improving the efficiency of the examination process, reducing the prosecution time of patent applications, and enhancing work-sharing between intellectual property offices (IPOs).

Track I

Under Track I, an applicant would be able to request that an application enters a prioritised examination procedure, under which it would be examined more quickly than applications for which no request is made. A fee would be payable (to fund the additional examiners that will be required).

The goal is for a first office action on the merits to be issued within four months, and a final decision on allowance or refusal to be made within 12 months.

For an application first-filed at the USPTO, a request for Track I could be made at any time. For applications that claim priority from an application filed at a foreign IPO (convention filing), it would be necessary to provide the USPTO with the search report and first examination report from the IPO plus a reply to the examination report before Track I could be requested.

There is a suggestion that a prioritised application should be limited to a total of 30 claims, with a maximum of four independent claims. Early publication of prioritised applications is also under consideration.

> *USPTO Press Release* *http://www.uspto.gov/news/pr/2010/10_24.jsp*

> *Federal Register Article* *http://frwebgate3.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=hhVbFh/3/1/0&WAISaction=retrieve*

Track II

Track II would maintain the USPTO's existing examination procedure. However, a convention filing application would not be examined under Track II until the search and examination reports from the foreign IPO and a reply thereto are provided to the USPTO.

The new proposals suggest that the use of reports from foreign IPOs be limited to those from IPOs which are international searching authorities under the Patent Cooperation Treaty. The requirement to provide the reports to the USPTO may be limited to those applications that are already published. The USPTO is also considering negotiating with one or more foreign IPOs to offer applicants an optional supplemental search report drawn up by the foreign IPO. This would be used by the USPTO examiner, together with an additional USPTO search, in preparing the first office action for an application.

This use of the search and examination reports of foreign IPOs is intended to improve the efficiency of the USPTO's examination procedures and hence reduce the time taken to prosecute applications.

Track III

Track III would offer the applicant the opportunity of delaying the examination of an application for up to 30 months. This option could be selected at, or soon after, filing, but would be limited to applications first-filed at the USPTO or which claim the benefit of a US provisional application. The applicant could then choose to request examination and pay the examination fee at any time until 30 months from filing. Failure to do so by 30 months would result in the application being deemed abandoned. It is anticipated that this could be a useful abandonment mechanism for applications no longer of use to the applicant, thereby reducing the number of applications in examination and improving efficiency. Once examination is requested, the application would enter a queue for examination based on the date of the request. It would then be possible to transfer to prioritised examination under Track I by payment of the necessary fee. Track III applications would be published at 18 months, as usual.

The USPTO recognises that these proposals have potentially wide-reaching effects on existing aspects of patent prosecution, and has identified a number of issues in particular. It is possible that the number of applications which are first-filed at the USPTO will increase. It would be necessary to adapt the patent term adjustment system (under which the term for which a granted patent can remain in force is adjusted to take account of delays during prosecution) to accommodate Track I and Track III applications. A range of USPTO procedures that already offer accelerated examination would need to be harmonised with the prioritisation of applications under Track I. Given the different treatments proposed for first-filed applications and convention-filed applications, PCT applications entering the US national phase would need to be designated accordingly. It might be appropriate to charge an additional Track I fee if a request for continued examination was filed for a Track I application.

Consequently, the proposals have been put up for public consultation. A public meeting at the USPTO was scheduled for 20 July 2010, and written comments can be submitted until 20 August 2010.

Further details of the proposals can be found in the press release dated 3 June 2010 on the USPTO's website, and also in an article in the 4 June 2010 edition of the Federal Register (see links, above right).

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DNA Patent Protection in the EU

ECJ 'Rounds Up' Facts to Pass Judgment in Monsanto v Cefetra

The patenting of DNA has always been a controversial subject. A new decision from the European Court of Justice (ECJ) re-enforces the perception that the courts tend to treat DNA inventions differently from other chemical inventions. It has been long established that the function of a gene must be known in order to satisfy the industrial applicability requirement of patentability for that gene. However, it has now been decided by the ECJ that a claim directed to a DNA sequence may only cover that sequence when it is performing its stated function.

The case in issue originates from a dispute surrounding Monsanto's patent, the claims of which are directed towards specific DNA sequences. The particular DNA sequences encode an enzyme which is resistant to Monsanto's herbicide RoundUp. When the sequences are incorporated into plants they become resistant to the herbicide RoundUp. Hence, spraying RoundUp onto a crop results in killing weeds but the RoundUp resistant crop survives.

Monsanto was unable to obtain a patent to this invention in Argentina, where the (so-called) "RoundUp Ready" soya plants have been grown with success. Cefetra imported soya meal made from these Argentinean plants into the EU. Monsanto attempted to enforce its European patents against Cefetra in several countries in order to prevent importation of soya meal containing traces of the patented DNA sequences in question.

> Argentine growers planted approximately 43 million acres of soybeans containing Monsanto's Roundup Ready trait last year.

The Dutch Court referred four questions to the ECJ seeking interpretation of some sections of the 1998 Biotechnology Directive (Biotech Directive). The Biotech Directive was implemented to try to achieve harmonisation of national laws on the legal protection of biotechnological inventions.

This ECJ judgment agrees with the earlier opinion of the Advocate General issued in March 2010 (see the legal update of 2 June 2010 on our website).

Question 1: Article 9 of the Biotech Directive

The first question posed asked how Article 9 of the Biotech Directive should be interpreted for the importation into the EU of a patented DNA sequence in a product where the DNA was no longer performing its function.

Article 9 of the Biotech Directive reads as follows:

> *'The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.'*

In answer to this question, the ECJ ruled that **there is no protection for a DNA sequence as such**. In order to obtain a patent over a DNA sequence, its function must be disclosed, and it must be performing its function. In other words, the word 'performs' in Article 9 is used in its present tense.

> *Related Articles*
D Young & Co knowledge bank legal update: www.dyoung.com/legalupdate-monsanto

> *Information on TRIPS*
http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.html

It was already established in the case law that the function of a gene must be known in order to satisfy the industrial applicability requirement of patentability for that gene. Thus, the ECJ decision appears to restrict further the scope of DNA patents - in that it appears that coverage of a DNA patent claim is now limited to the field in which the DNA is functioning. In this case, Monsanto's patent for a gene in a soya plant which confers herbicide resistance does not, therefore, extend to soya meal containing this gene where the gene is no longer performing its herbicide function. It was further decided that it was immaterial whether the DNA could possibly again perform its herbicide resistance function if was extracted from the soya meal and inserted into living cells.

This decision appears to separate DNA from other chemicals, as in many cases chemical per se protection is not limited to a specific function.

Question 2: National Laws

In answer to further questions referred by the Dutch Court, the ECJ went on to state that there is no discretion for individual EU states to offer wider protection to DNA sequences under national law.

Potentially this does not apply to non-EU states which are part of the European Patent Convention, such as Norway and Switzerland. However, in general, the laws of these states are mostly in line with the EU.

Question 3: Retroactive Effect

The ECJ also considered that the Biotech Directive applies to all patents, including patents such as that in dispute which were issued prior to the adoption of the Biotech Directive.

Question 4: TRIPS

The final question referred to the international agreement known as TRIPS (Trade-Related Aspects of Intellectual Property Rights), and it was decided that the specified articles of TRIPS do not affect the interpretation of the Biotech Directive.

In particular, Article 27(1) of TRIPS states that (**emphasis added**):

> *Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the **field of technology** and whether products are imported or locally produced.*

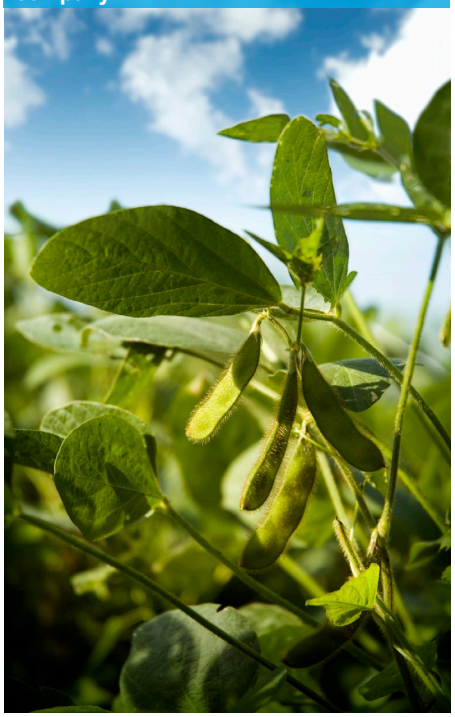
It is interesting to note that the current judgment was not interpreted as discrimination against any particular field of technology.

For further information on TRIPS, see the World Trade Organization website (see link, above right).

Conclusion

This judgment from the ECJ may have dramatic consequences on the scope of DNA patents. For example, it may be difficult to enforce a patent against importation and/or use of products containing a patented DNA sequence which is no longer performing its stated function.

Monsanto is the world's biggest seed company



It is also unclear how exactly the function of a DNA sequence will be interpreted. The function of DNA could merely be to produce a specified protein, or it could be interpreted to be limited to the specific use of that protein. We await further developments on this issue.

Important caveat

It is important to note that Monsanto's patent did not contain any claims to soya meal itself or to the process of producing soya meal. If it had, then perhaps the outcome could have been different.

If you have any questions about patenting in the biotechnology arena, please contact your usual D Young & Co advisor.

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Supplementary Protection Certificates
Case Law Round Up

Following the round up of cases in the field of Supplementary Protection Certificates (SPCs) involving combination products and marketing authorisations in the previous edition of this newsletter, this article provides a summary of the recent main decisions in respect of other areas of interest.

Referrals to the European Court of Justice

Grant of SPCs is a matter for the national authorities to decide. This has lead to differing interpretations across Europe and, hence, several referrals to the European Court of Justice (ECJ).

Two of these[1] relate to the interplay between Marketing Authorisations (MAs) based on national law and MAs based on EU medicinal product legislation (Directive 2001/83/EC or Directive 2001/82/EC).

In the appeal on the Medeva case[2], the English courts referred several questions with regards to whether or not different interpretations of the SPC regulations should be applied in respect of vaccines that comprise a combination of active ingredients.

The Merck & Co Inc referral[3] queries whether an SPC may be granted if the period of time between filing the basic patent and the first marketing authorisation in the European Community is less than five years. Presently, in respect of this application, in the UK and the Netherlands so-called "negative term" SPCs have been allowed. In Greece a 'zero term' SPC has been granted. In Portugal, Slovenia and Germany the SPC application has been refused. The grant of a negative or zero term SPC may be important as a granted SPC is necessary to obtain the paediatric extension.

The Lovells referral[4] relates to whether a national provisional authorisation to place on the market constitutes a full MA in respect of an SPC application for a plant protection product, e.g. a herbicide.

The Opinion of the Advocate General has recently issued, wherein it is stated that a provisional authorisation is not sufficient to base an SPC on. However, it was also stated that this finding could not be used to challenge the validity of an SPC filed prior to this decision.

Infringement

Given the expiry over the next five years of a number of significant pharmaceutical patents, the question of infringement of an SPC will become increasingly important. However, there is little case law in this regard and, unfortunately, what there has been over the last year is contradictory.

In the losartan case[5] there have been three recent decisions, two in Belgium and one in France[6], regarding infringement of an SPC.

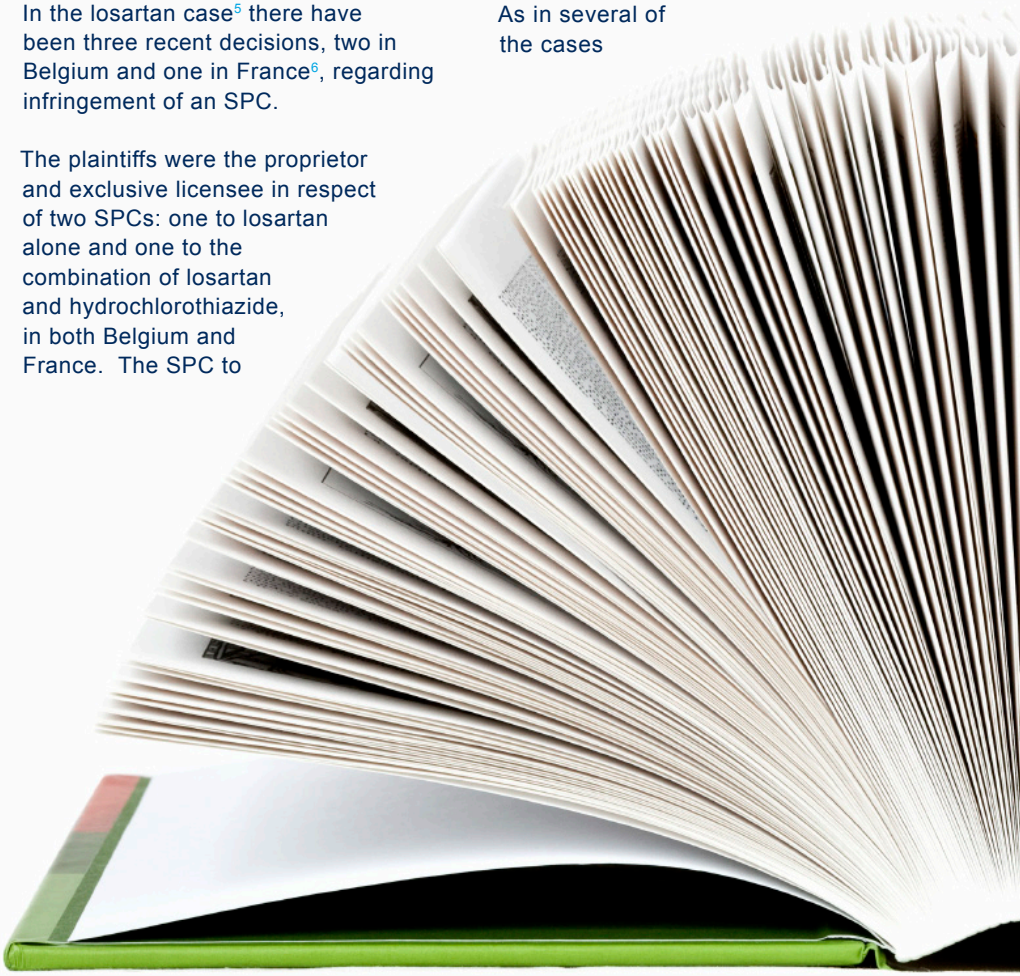
The plaintiffs were the proprietor and exclusive licensee in respect of two SPCs: one to losartan alone and one to the combination of losartan and hydrochlorothiazide, in both Belgium and France. The SPC to the combination expired prior to the SPC directed to losartan alone.

The defendant planned to market a combination of losartan and hydrochlorothiazide as soon as the combination SPC expired, but prior to the expiry of the other SPC.

Therefore, the question of whether a combination of active agents could infringe an SPC to one of the active agents was considered.

In France it was decided that the combination did infringe the SPC, whereas in both cases in Belgium it was decided that the combination did not infringe.

As in several of the cases



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1) Synthon BV v Merz Pharma Gmbh & Co KG (Case C-195/09) and Generics (UK) Ltd v Synaptech Inc (Case C-427/09)
2) Appeal No. A3/2010/0295. See D Young & Co patent newsletter, issue 17, for case history
3) Case C-125/10

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4) Lovells, Dusseldorf v Bayer Cropscience AG (Case C-229/09)
5) E.I DuPont de Nemours & Co and Merck Sharp & Dohme (the plaintiffs) v Mylan (the defendant)
6) R.K 00014/2010 and A.R nr. 2010/KR/53 in Belgium and 10/51453 in France
7) D Young & Co patent newsletter, issue 17

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8) 14W (pat) 12/07
9) Pursuant to Directive 2001/82 EC or Directive 2001/83 EC
10) E.I DuPont de Nemours & Co v UKIPO, [2009] EWHC 1112 (Ch)
11) D Young & Co patent newsletter, issue 13
12) AHP Manufacturing BV v Bureau voor de Industriële Eigendom
13) Chiron Corp's and Novo Nordisk A/S's SPC application ([2005] RPC 24)

previously discussed in respect of combinations[7], the decisions may be separated on the grounds of a 'regulatory' approach (ie, limited to the subject matter of the MA: Belgium) versus a 'patent' approach (ie, an 'infringement'-type test: France).

Given the national contradictions in the granting of SPCs, these decisions are likely to be a taster of what is to come with regard to infringement, and it can be expected that there will be at least one referral to the ECJ.

Implantable Medical Devices

The Federal Patent Court of Germany granted an SPC for yttrium-90 glass microspheres[8], which are used as implantable medical devices. The case centred on the issue of whether an MA granted pursuant to Directive 90/385/EC (for implantable medical devices) is sufficient to meet the SPC requirement that a valid authorisation to place the product on the market has been granted[9].

The court found that the MA obtained for the microspheres was analogous to an MA obtained under Directive 2001/83/EC and met the necessary requirements. Similar SPCs were granted in the Netherlands and France (subsequently surrendered).

However, there has not been a consistent approach to this matter across Europe. The corresponding SPC applications in Belgium, Denmark, Italy and Sweden have been refused. In view of the conflicting national decisions, a reference to the ECJ may be required to decide the issue.

Paediatric Investigation Plan (PIP)

It is possible, under certain circumstances, to extend the duration of an SPC by six months by applying for a 'paediatric extension'. This extension aims to compensate the patentee for the substantial cost of conducting clinical trials in children.

In the E. I. du Pont case[10] the requirements for filing a valid extension application were considered. The case was concerned with whether the appellant had filed an MA statement indicating compliance with the PIP.

The application merely contained an email from the Dutch reference authority that stated that the product would be eligible for the extension. However, the amended MA did not issue until after the application had been filed. It was held that this was not sufficient.

However, the court was more liberal in its interpretation of the provisions for overcoming such 'irregularities' in an application. Although it is still necessary to attempt to fulfil all requirements for extending an SPC by the relevant deadline, for unavoidable delays (eg, a member state taking too long to grant an MA), the applicant will not be unduly punished and may have the possibility to rectify any omissions.

SPCs to the Same 'Product'

As discussed in a previous patent newsletter[11], in response to a referral by the Dutch courts, in Case C-482/07[12] the ECJ clarified the scope of the requirement for the grant of an SPC application that the product must not have been the subject of a previous SPC. The ECJ confirmed that this requirement was actually intended to prevent a single patentee holding several patents encompassing the same product from being granted a series of SPCs for that product.

Therefore, this requirement must not be intended to prevent a holder of a basic patent from obtaining SPC protection even if SPCs have been granted to one or more holders of one or more basic patents to that product. This mirrors the earlier decision in the UK in the Chiron case[13].

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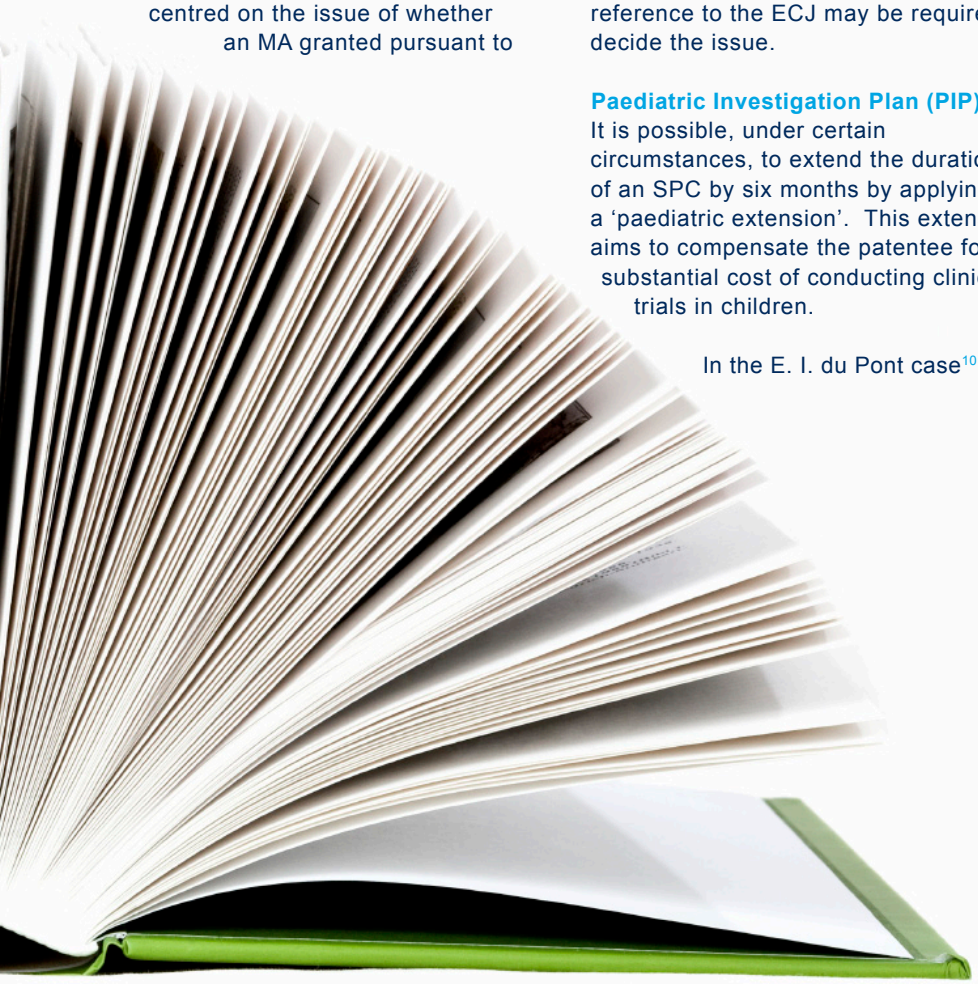

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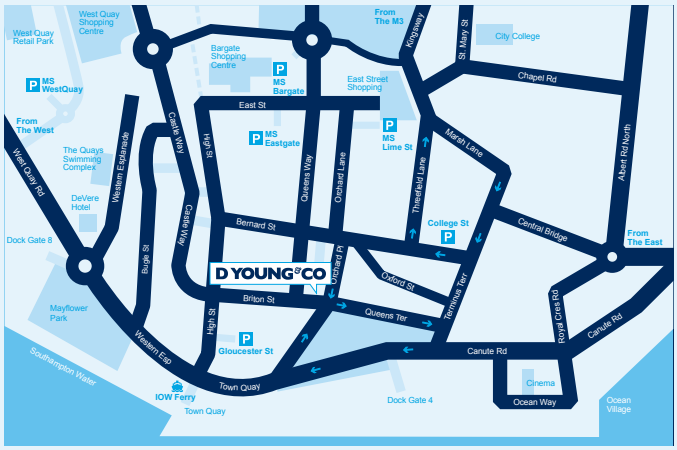

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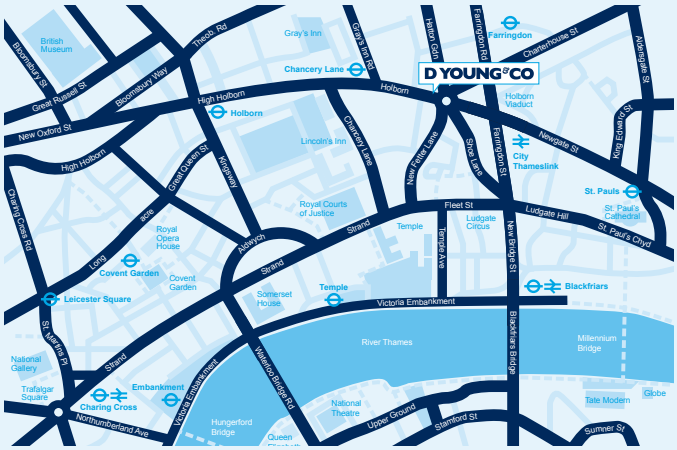

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