D YOUNG & CO PATENT NEWSLETTER no. 24

August 2011

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Events

8-10 September 2011
Oligonucleotide Therapeutic Society 7th Annual Meeting, Copenhagen
Charles Harding and Zöe Clyde-Watson will be attending the Oligonucleotide Therapeutics Society's 7th Annual Meeting in Copenhagen, Denmark.

For more information and event listings see www.dyoung.com/events

Editorial

It's the holiday season for many. If you are off on your vacation soon then we hope you have a nice time. Hopefully you will find the newsletter interesting whether you are in the office, on the train or on the beach, so why not download an audio version and take life at a slower pace while you listen to our latest update? If you have already been on your vacation, then welcome back!

D Young & Co's first biotechnology webinar reviewing biotechnology specific European case law was well received with many more joining us than we imagined. If you joined in then I hope you found the webinar useful and topical. Thank you for taking the time to join us. Feedback is always welcome - please email rjd@dyoung.co.uk.

The feedback from delegates that attended the D Young & Co seminar designed to give IP advice to SMEs and university start-ups in the chemistry and life sciences technologies was very positive and encourages more events like this in the future, including in other technical areas. We welcome suggestions for other events that might be of interest to you - again, please email rjd@dyoung.co.uk with any suggestions.

Editor:
Aylsa Williams

Article 01

How Late Can Claim Requests be Filed? How Long is a Piece of String?

We filed our opposition years ago. They surely can't file claim amendments now?" Is this true? "I need to file claim amendments at the latest possible moment to judge commercial importance of the invention." Is this risky?

Some recent Board of Appeal decisions may point us in the right direction.

T0878/09 – 3.3.04 related to a method for the detection of prion proteins. A new Main Request claim 1 was filed less than a month before the oral proceedings. The claim was identical with claim 1 submitted with the statement of the grounds of appeal, except that the feature "wherein said sample has been pretreated by predigestion with enzymes and by denaturation with strong alkali" had been introduced into the claim. Crucially, however, the absence of the added feature from the claim had been objected to throughout the opposition and appeal proceedings.

The Board remarked that although it agreed with the opponent's view that the patentee could have filed the claims earlier, the Board considered that it could be safely assumed that the opponent had no difficulties in preparing arguments in relation to the amended claim. Therefore an amended claim filed only a month before the oral proceedings was admitted into the proceedings.

T0495/09 – 3.3.04 related to the treatment of rheumatoid arthritis. The Opposition Division had decided that claim 1 contained added matter.

The statement of grounds of appeal also contained the request: "In the event that the Board does not find the Main Request to be allowable, we request the opportunity to make further amendments where such amendments address any concerns the Board has", which in retrospect was not helpful to the patentee.

During the appeal, the Board indicated to the parties that it did not expect any further written submissions following the formal round of briefs, and referred to Article 13 Rules Procedure of the Boards of Appeal (RPBA):

Article 13 RPBA - Amendment to a party's case

A13(1) Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of *inter alia* the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy.

A13(2) Other parties shall be entitled to submit their observations on any amendment not held inadmissible by the Board *ex officio*.

A13(3) Amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings.

Nevertheless after the summons to oral proceedings issued, and two months before the oral proceedings, the patentee filed a new request combining previous claims 1 and 2, and requesting remittal of the case back to the Opposition Division as the amendment overcame the added matter problem.

The Board responded:

"If the appellants wished the board to consider two attempts to overcome the decision under appeal, they should have set out both in their statement of grounds of appeal, and by not doing so they failed to meet the complete case requirement of Article 12(2) RPBA... Even if, as the appellants also argued, the respondents could have expected such a fall-back position, that possibility cannot justify non-compliance with the rules of procedure – patent proceedings are not guessing games."

Article 12(2) RPBA – Basis of proceedings

A12(2) The statement of grounds of appeal and the reply shall contain a party's complete case. They shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld,

> *Useful links*

Full text of decisions:
T0878/09:
http://bit.ly/t087809

T0495/09:
http://bit.ly/t049509

T0023/10:
http://bit.ly/t002310

T1067/08:
http://bit.ly/t106708

and should specify expressly all the facts, arguments and evidence relied on. All documents referred to shall be:

(a) attached as annexes insofar as they have not already been filed in the course of the grant, opposition or appeal proceedings or produced by the Office in said proceedings;

(b) filed in any event to the extent that the Board so directs in a particular case.

The Board did however enter the new request and eventually remitted the case back to the Opposition Division. They commented that it was "fortunate" for the patentee that the opponent had not objected to the entry of the new request. Therefore, if you are the opponent, object to the filing of new requests by the patentee.

T0023/10 – 3.3.02 related to a powder for an inhaler. This patent was revoked at the opposition stage because dependent claim 11 contained added matter. The opposition minutes noted that the patentee, after the chairman had announced that the subject-matter of claim 11 added matter, was asked whether he had any further requests. After an interruption, the patentee announced that he had no further requests. Note - if as opponent you are faced with this situation, ask that non-submission of further requests be minuted.

With the statement of grounds of appeal the patentee filed a Main Request and Auxiliary Requests 1 to 7 all containing the problematic claim 11, together with Auxiliary Requests 8 to 15 from which the claim had been deleted. Just one month before oral proceedings, the patentee withdrew the Main Request and Auxiliary Requests 1 to 7 and asked for the case to be remitted back to the Opposition Division given that the added matter problem had now gone away.

In its decision the Board started by seeing whether in the circumstances the appeal was formally admissible, but they could find no grounds for denying the appeal *ab initio*. The Board then went on to look at the formal admissibility of Auxiliary Requests 8 to 15 into the appeal. Now, although some requests had been cancelled and others re-ordered just one month before the oral proceedings, the claims had been filed with the statement of grounds of appeal. Following the earlier cases, it would be a reasonable bet that they would be admitted. However, the Board referenced Article 12(4) RPBA.

According to Article 12(4) RPBA, a Board can hold inadmissible facts, evidence or requests that could have been presented in the opposition proceedings.

The Board thought that admission of the requests into the appeal would be contrary to a reliable and fair conduct of proceedings. The Board decided that a patentee withholding claim requests in opposition proceedings should be precluded from having those requests admitted on appeal. Our cautionary tale ends with Auxiliary Requests 8 to 15 being deemed inadmissible and the patent revoked due to simple added matter in a dependent claim. In its decision the Board referenced the principle: *"nemo auditor propriam turpitudinem allegans"*

> ***Note from author:*** *Send your translations to me at clm@dyoung.co.uk!*

This principle was followed in T1067/08 - 3309, a case in which D Young & Co was successfully involved. The opposed patent concerned a granulate product and had been objected to under Article 123(2) EPC as adding matter throughout the opposition. The patentee filed various replacement claims sets during the written procedure, but the Article 123(2) EPC issue was not resolved.

During oral proceedings the Opposition Division decided that the granulate claim did add matter. In response, the patentee submitted a new set of amended claims to become the **sole** request. The patentee withdrew the previous Main Request. D Young & Co and the other opponents objected to the new set of amended claims as being late filed. These claims were broader than those on file. The late filing was in breach of good faith, and a substantial break would be needed to respond with due care.

The patentee made the error of confirming to the Opposition Division that they did not want to file a further request.

Recent Board of Appeal decisions may provide guidance to filing late claim requests

The Opposition Division decided that this new set of amended claims was unallowable as its late filing constituted an abuse of procedure.

The patentee appealed the decision of the Opposition Division not to enter the new set of amended claims during oral proceedings. Additional claim set requests were also filed.

The Board reviewed the conduct of the patentee during the opposition and concluded that the Opposition Division had correctly exercised its judgment not to admit the claim set into the proceedings. They agreed that there had been an abuse of procedure.

The Board then went on to look at the admissibility of the requests filed with the appeal. They refused to exercise their discretion to enter them into the proceedings. Their view was essentially that if such requests were entered then there would be no adverse consequence for the patentee, who in their view had abused the opposition procedure.

Given that there were no requests in the proceedings, the patent was revoked.

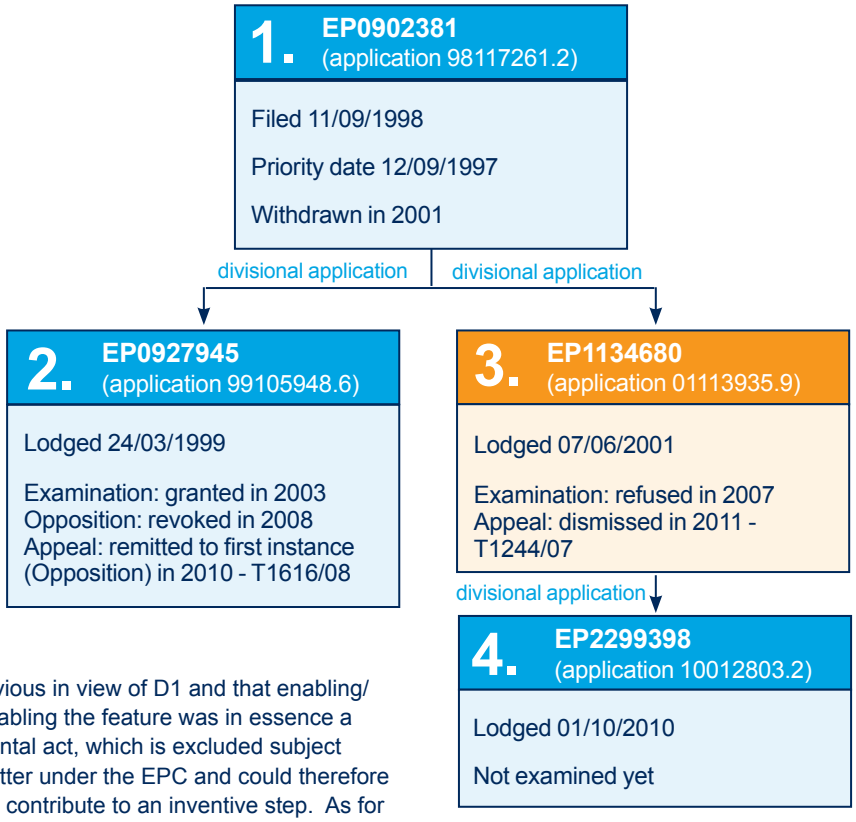
So, when is the latest new claim requests can be filed? Your patent attorney sighs, "Well, it all depends …"

Author:
Catherine Mallalieu

Amazon's 'One-Click' Patents
EPO Issues New Decision in Ongoing Saga

The European Patent Office (EPO) has recently issued a new decision, T1244/07, in the Amazon 'one-click' saga. Amazon is the applicant and owner of patent applications and patents relating to the one-click feature in a number of jurisdictions. This one-click feature relates to the purchasing of an item in a single action. The events regarding members of this family have been followed not only by IP professionals but also by many people with an interest in computer sciences and/or in software patentability. The interest generated by these cases tends to put any one-click decision in the spotlight.

The structure of the main one-click family at the EPO is illustrated in the figure, right. Even though patent 2 is a divisional application from the original one-click case, some consider it to be rather aside from the other cases on the grounds that it relates to gift giving. T1244/07 (decided 27 January 2011, published in June 2011) corresponds to an appeal filed by the applicant against a decision of the Examining Division to refuse patent application 3 (shaded orange in the figure). Interestingly, although most Boards of Appeal usually have three members, the Board of Appeal for T1244/07 was expanded to five members, which may show that the EPO was well aware of the sensitivity of this decision, which was likely to be scrutinised by many.



Claim 1 of the main request at oral proceedings was found to be novel over D1[1], a document relating to the use of cookies for a web shopping cart. Thus the discussion focussed on inventive step. The Board of Appeal recognised that claim 1 could be considered as addressing the problems of reducing the number of actions necessary for purchasing an item and of reducing the risk of sensitive information being intercepted. It considered the main differences between claim 1 and D1 to be the use of cookies storing a customer identifier and the feature that the single action ('one-click') feature could be enabled or disabled. The Board, however, considered that the use of cookies was obvious in view of D1 and that enabling/disabling the feature was in essence a mental act, which is excluded subject matter under the EPC and could therefore not contribute to an inventive step. As for other factors that could show an inventive step, the Board took the view that, because cookies technologies were a new field at the time of the invention, the invention was not in response to a long-felt want and that this outweighed the fact that the invention then went on to be very successful. The Board then considered that the additional features of the first and second auxiliary requests related to an administrative rule and to presentation of administrative information, ie, to excluded subject matter, and that the technical means for implementation of these features were well known in the art.

The Board therefore agreed with the Examining Division's decision to revoke the patent and dismissed the appeal.

The various examinations, re-examinations or other challenges to the one-click patents and patent applications have previously resulted in different outcomes in different jurisdictions. For example, Amazon achieved grant in the US, in Canada, and is likely to achieve grant in Australia soon for application 3, while application 3 has now been refused in Europe. Different factors account for these differences, for example different national laws (eg, business methods are typically allowable in the US), different approaches to or tests for inventive step or non-obviousness, different rules of interpretation of a document's disclosure, etc. This one-click family is therefore a good illustration of how difficult it can be for an applicant to achieve similar protection in different jurisdictions.

Returning to the European one-click family, the opposition of patent 2 is still pending while the examination of application 4 has not yet started, so we are many years from hearing the final EPO decisions in respect of these cases.

Notes:

1. D1: Baron C: "Implementing a Web shopping cart", DR. Dobbs Journal, September 1996 (1996-09)

Useful links

Full text of decisions:
T1244/07: http://bit.ly/t124407
T1616/08 http://bit.ly/t161608

Author:
Bénédicte Moulin

Historic Changes to the US Patent System
House of Representatives Approves America Invents Act

Historic changes to the US patent system are another step closer after the US House of Representatives recently approved the America Invents Act (AIA) by a margin of 304 to 117. This follows the US Senate's overwhelming approval (95 to 5) of similar legislation in March. The two bills must now be reconciled before an enrolled bill goes before the President. While the President has the power to veto the Bill, it is believed that the President supports patent law reform and will make the Bill law.

This legislation will bring about fundamental changes to the way that novelty and inventive step requirements are assessed. Perhaps the most important change will see the US system for assessing what is, and what isn't, prior art come closer to that used in Europe and many other national patent systems throughout the world.

Another important proposal is for the introduction of a post grant review of patents where, within nine months of grant of a patent, a third party can request cancellation of one or more claims. The third party must file a petition presenting any legal challenge to the validity of said claim(s), including internal requirements such as enablement and written description, and external requirements such as excluded subject matter, novelty and inventive step.

Presently under 35 USC § 102

Section 102 of United States Code (USC) concerning patent law (35 USC § 102) defines when an invention is publicly known, and therefore not patentable. This section states that in order to be entitled to a patent, the subject matter of the alleged invention must not have been patented or described in a printed publication anywhere in the world, or known or used by another in the US before the date of invention (§102(a)). However, regardless of the date of invention, there is a statutory bar to obtaining patent protection if more than one year before the application the alleged invention has been on sale in the US, or patented or described in a printed publication anywhere in the world (§102(b)).

The so called 'first-to-invent' system has long characterised US patent law; however, this system is set to be swept away by the AIA in view of the major amendments contemplated to 35 U.S.C. § 102. The proposed amendments will replace the first-to-invent system with essentially a first-to-file system whereby the critical date by which the prior art is judged is the date the application is filed rather than the date of invention. This date will often be significantly later, potentially leading to exposure to a greater amount of prior art.

The America Invents Act would bring about historic and fundamental changes to the US patent system

The new 35 USC § 102

Proposed new 35 USC § 102(a) will exclude patent protection for an alleged invention that had been patented or described in a printed publication anywhere in the world, or in public use, on sale or otherwise available to the public before the date on which an application was filed. This amendment would remove the territorial restriction on disclosure by sale or use, meaning that any sale or use of the alleged invention anywhere in the world, prior to filing, would be prejudicial to novelty. This standard is in line with the absolute novelty requirements imposed in many other jurisdictions across the world. However, the proposals still maintain a form of the grace period wherein disclosure within one year prior to the filing date by the inventor, or co-inventor, or third party acting on information supplied by the inventor/co-inventor will not be prior art.

Additionally, 35 USC § 102 proposed by the AIA refers only to an effective filing date rather than an effective US filing date. At present, a US patent or patent application which claims priority from a foreign application is deemed effectively filed on the actual date of filing at the US Patent and Trademark Office (USPTO) and not the date of foreign priority. This is to be contrasted with US patents or applications which claim priority of a US non-provisional application or PCT application designating the US, where the effective filing date is that of the US priority document. This leads to a situation where patents/applications claiming a foreign priority when used as prior art against other patents/applications may not take advantage of their priority whereas those with a US priority can; the so called 'Hilmer doctrine' has led to many applicants filing US provisional applications in addition, or in favour of foreign priority filings. Such practice will no longer be required if the AIA passes into law due to elimination of the effective US filing date requirement.

In summary

The AIA proposes fundamental changes to the US patent system; these changes seek to take another step in the direction of harmonization with other patent systems around the world, as well as improving the quality of patents and reducing the backlog of applications at the USPTO.

We will continue to monitor the situation closely, and will publish further details of the changes along with their implications as the final details emerge.

Author:
Matthew Johnson

EPO Technical Board of Appeal Decision T0663/02
Risk Matrix to Assess Health Risks Relating to Surgical Methods

Does decision T0663/02 provides guidance to IP practitioners to determine whether or not a method would be excluded as a surgical method?

What is a 'surgical method'? In the wake of Enlarged Board of Appeal (EBA) decision G1/07, which supposedly provided clarity on this point, many patent attorneys have had sleepless nights when formulating claims which require a step of 'injecting' a compound into a subject.

Do we have guidance now on how to assess if a method falls within the exclusion of a surgical method?

A recent Technical Board of Appeal decision, T0663/02, promises hope!

Note from author: *Yes, this is recent! Don't be fooled by the 2002 designation, this decision was only issued on 17 March 2011 after long delays first awaiting the outcome of G1/04 (diagnostic methods) and then G1/07 (surgical methods).*

In G1/04 the EBA confirmed that:

> *"a method claim falls under the prohibition of Article 52(4) EPC [1973] if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy".*

Therefore, the surgical or therapeutic nature of a method claim can be established by a single method step.

In G1/07 the EBA pleaded for a narrow construction:

> *"Hence, a narrower understanding of what constitutes by its nature a 'treatment by surgery' within the meaning of Article 53(c) EPC is required"* (Reasons 3.4.2.3).

The wording used by the EBA in G1/07 ('is required') was suggested in T0663/02 to underline the necessity of a new definition consistent with the today's technical reality in the medical field.

In order to find elements of a 'narrower understanding', the EBA in G1/07stated that:

> *"any definition of the term 'treatment by surgery' must cover the kind of interventions* ***which represent the core of the medical profession's activities,*** *ie, the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility"* (Reasons, 3.4.2.3). [emphasis added]

However, specific guidance was lacking in G1/07 of how to assess whether an action belongs to the 'core of the medical profession's activities'.

In T0663/02 it was necessary to assess whether the injection of a magnetic resonance contrast agent into a vein belongs to this core, because claim 1 of the granted patent EP 0 812 151 B (the subject of T0663/02) included the following step:

> *"…injecting the magnetic resonance contrast agent into a vein remote from the artery…"*

> *Useful links*
Full text of decisions:
T0663/02:
http://bit.ly/t066302

G1/07:
http://bit.ly/g107tbs

In practice, this step would be carried out by the placement of an intravenous catheter through which the contrast agent may then flow into the vascular system.

It must be borne in mind that the point of the exclusion is to free the medical profession from constraints by patents and differentiation must be made between major physical interventions on the body which should be excluded from patentability and uncritical methods for which the exclusion clause should not apply.

T0663/02 makes it clear that when assessing what is the 'core of the medical profession's activities' this must be made in the light of the technical development in the medical field at that time.

In the present case, the placement of an intravenous catheter is one of the most common invasive procedures performed in hospitals and consulting rooms.

An intravenous injection can today be delegated by a physician to a qualified paramedical professional.

In T0663/02 it was decided that this gives an indirect hint at the fact that such an injection may be considered as representing a minor routine intervention which does not imply substantial health risks when carried out with the required care and skill.

As such, it was not considered as an intervention which represented the 'core of the medical profession's activities' as required by G1/07 and thus was not excluded by A53(c) EPC.

Risk Matrix

Importantly T0663/02 provides a possible way of assessing health risks by using a risk matrix. The matrix combines the levels of likelihood and health impact of a complication of a medical act with regard to a large number of patients, so as to obtain statistical health risk scores.

The Board described the so-called risk matrix as follows:

"The likelihood that a complication of an intravenous injection may happen is represented on a first scale (x-axis). The health impact of that complication is represented on a second scale (y-axis). According to a simple model, the likelihood is subdivided in three levels, ie, 'unlikely', 'likely' and 'very likely'. The health impact is also subdivided in three levels, ie, 'minor', 'moderate' and 'major', wherein 'minor' would cover negligible effects which do not need any treatment, 'moderate' reversible effects which can be easily treated, and 'major' serious irreversible effects or even death. The risk matrix thus permits to combine the levels of likelihood and health impact of a complication with regard to a large number of patients so as to obtain statistical health risk scores which may be used to decide what action should be taken, for instance whether or not the intravenous injection may be delegated to a paramedical professional.

Due to its definition, the risk matrix is subdivided in various sectors. A first sector is defined by the levels 'unlikely' and 'minor', a second sector by the levels 'likely' and 'minor', and so on up to the last sector corresponding to the levels 'very likely' and 'major'. The heath risk score assigned to each sector increases when moving from the first to the last one."

In T0663/02 the Board suggested that such an assessment based on the risk matrix would be in agreement with the understanding of the EBA in G1/07. In particular, the sectors with low health risk scores, at least that with the levels 'unlikely' and 'minor', would correspond to the uncritical methods involving only a minor intervention and no substantial health risks. The sectors with high health risk scores, at least that with the levels 'very likely' and 'major', would correspond to the physical interventions on the body which require professional medical skills to be carried out, which involve substantial health risks even when carried out with the required medical professional care and expertise, and for which the physicians assume a particular responsibility.

The Board used the risk matrix to confirm that intravenous injections may be considered as minor routine interventions involving no substantial health risks, and thus confirming their decision that the claim was not excluded as a surgical method.

A further point of interest in T0663/02 is that during the appeal proceedings a serious complication of intravenous injections of a specific magnetic resonance contrast agent was mentioned. Patients with acute or chronic renal insufficiency who receive a gadolinium-based contrast agent appear to be at an increased risk for developing a Nephrogenic Systemic Fibrosis (NSF). This complication, however, only depends on the injected substance. As a further complication, allergic reactions may be mentioned which also depend on the injected substance.

In this respect, T0663/02 confirmed that there was an exclusion from patentability as a surgical method only if the health risk was associated with the **mode of administration** and not solely with the agent as such (confirming G1/07). Therefore, the complications concerning NSF and allergies are irrelevant for the issue of assessing whether the claimed method should be excluded from patentability under Article 53(c) EPC.

In summary

This decision provides guidance on how to determine whether or not a method would be excluded as a surgical method. From the decision two interrelated aspects should be assessed. Firstly, whether the action belongs to the **'core of the medical profession's activities'**, and secondly, the health risk associated with the intervention. In T0663/02 a risk matrix is provided for determining the latter. It is clear from this decision that when making the assessments it is important to consider the actual technical developments in the medical field and whether a procedure can be delegated by a physician to, say, a qualified paramedical professional.

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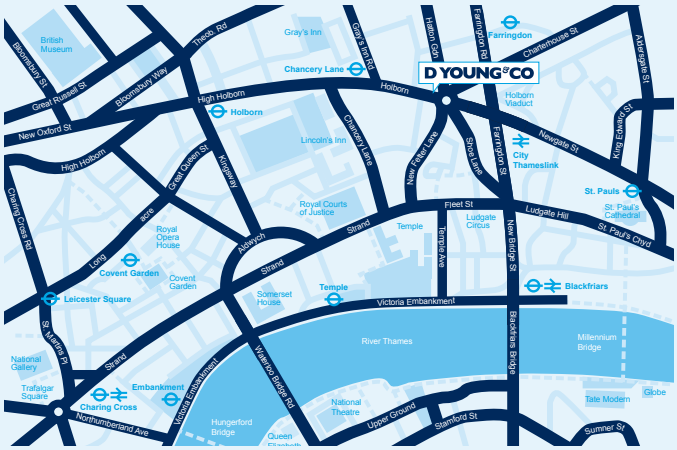

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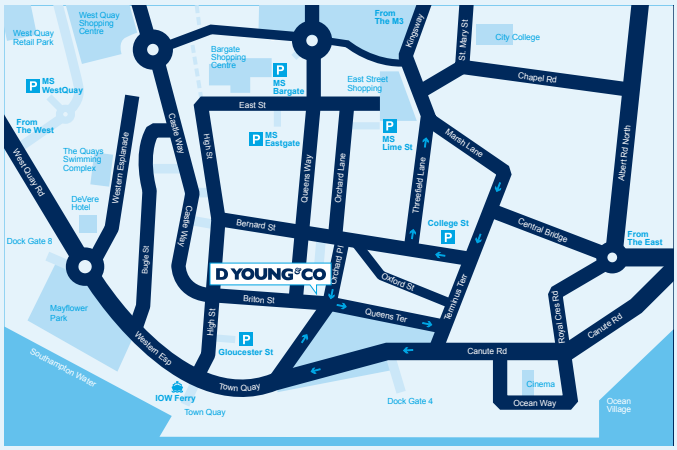

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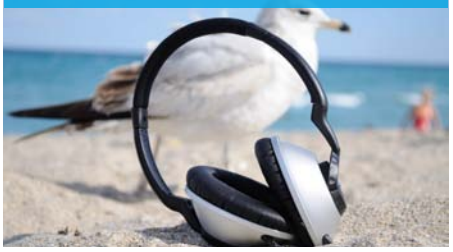

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