D YOUNG & CO PATENT NEWSLETTER no.50

December 2015
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Editorial

It is again refreshing to see the EPO listening to its users and changing previously implemented rules to remove unnecessary constraints (see article on page 8). This follows on from amendments to the divisional rules and does raise a question as to whether more consultation with European patent attorneys and applicants should be undertaken prior to implementing rule changes which can have a significant impact on applicants and attorneys alike. In the present instance even the Examining Divisions and Opposition Divisions seemed to find the need to file amendments in electronic form at oral hearings burdensome. Hopefully future changes can include more consultation in the process.

With 2015 drawing to a close, your friends and colleagues here at D Young & Co wish you season's greetings and a very happy and prosperous New Year.

Editor:
Aylsa Williams

Events

15-16 March 2016
Wearable Technology Show, London UK
Now in its third year, the annual Wearable Technology Show returns to London, ExCel. The show will bring together over 6,000 delegates and 200 speakers to exchange views, network and do business. The show will feature cutting edge technology from fields including smart home, healthcare, fashion fitness, performance sports, enterprise and augmented reality. The show will run in conjunction with the Augmented Reality Show and IOT Show. We will be exhibiting at the show and speaking about IP in the wearables, smart technology and IOT landscape.

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Nagoya Protocol
European regulation now in force

The EU Regulation setting out compliance measures for users of genetic resources in the EU under the Nagoya Protocol, came into effect on 12 October 2014.

The specific provisions concerning the obligation to carry out due diligence, declarations of compliance and checks on compliance, did not come into immediate effect. They were deferred for a year while further national implementing provisions were put in place.

The one year period came to an end on 12 October 2015, hence the EU Regulation, and its various obligations on users of genetic resources, are now in force. Local legislation, such as that recently put in place in the UK, sets out separately the potential penalties for noncompliance.

The EU implementation of Nagoya focuses solely on use of genetic resources which have been accessed from fellow Nagoya Protocol territories (and not access of such resources within the EU – that has been left to individual Member States, should they wish to impose access obligations).

EU implementation means therefore that, as from 12 October 2015, any entity that may be performing research and development on genetic resources in the European Union (EU), must comply with the obligations and requirements in the EU Regulation mentioned above.

The European Commission is preparing guidance on compliance with the EU Regulation and has published this in draft. It is not clear, however, when it will become final and some aspects are still being debated.

Notwithstanding the delay in EU guidance, what should your company be doing to be compliant?

Determine the date and place of access

Genetic resources accessed (although not necessarily utilised) before 12 Oct 2014 are not covered by the EU Regulation. This is therefore the first thing to try to establish.

In addition, the EU Regulation only applies to genetic resources accessed from a country that has ratified the Nagoya Protocol. (There are some other detailed legislative requirements which may affect the applicability of the EU Regulation but these are not addressed here.)

Thus the origin of a genetic resource accessed after 12 Oct 2014 should be checked in order to determine whether it has been accessed from a relevant 'Nagoya country'. If so, and you are intending to carry out research and development on that resource in the EU, you will need to comply with the due diligence obligations in the EU Regulation.

Nagoya Protocol due diligence in the EU

Due diligence will need to be carried out to determine whether access to the genetic resource in question was in compliance with local access consent and benefit sharing requirements in the Nagoya Protocol country from which it was accessed. The documentation showing the due diligence checks and the outcome must be retained for 20 years (considerably longer than most document retention policies). Ensuring all relevant employees are aware of the EU Regulation and the Nagoya Protocol, and the obligations this places on the companies they work for, is essential.

> If there is any concern about whether the genetic resource has been accessed in compliance with local access and benefit sharing obligations in the Nagoya Protocol country from which it has been accessed, then any research may need to be stopped and future marketing of a product comprising that genetic resource may be compromised.

G 1/15
EPO allows stay of proceedings pending Board of Appeal decision

In short - actions for researchers

1. Ensure all materials accessed prior to 12 October 2014 are documented as having been accessed before that date (as the EU Regulation will not be retroactive).

2. Put in place systems to ensure that materials accessed after 12 October 2014 are documented to confirm compliance with the EU Regulation and relevant Nagoya Protocol access requirements.

3. Ensure employees know about the Nagoya Protocol and associated regulations and understand that legal possession of a genetic resource does not necessarily imply the right to do any work on it.

4. Be cautious of the origin of material that you might wish to use for research – this applies in particular to materials obtained from suppliers: due diligence requires obtaining relevant evidence of compliance from such suppliers.

5. Consider setting best practices to conform to the legislation.

Further advice

If you believe this legislation may impact your activities and would like further advice, then please contact Richard Willoughby (rww@dyoung.com) or Aylsa Williams (aaw@dyoung.com).

Authors:
Richard Willoughby & Aylsa Williams

Related articles

The Nagoya Protocol - Actions for genetic researchers, 01 August 2014: www.dyoung.com/article-nagoyaprotocol.

Nagoya Protocol - Implementation in the European Union, 05 February 2015: www.dyoung.com/article-nagoyaeu.

Proceedings to be stayed in cases where decisions depend entirely on G 1/15

As some readers may know, questions relating to partial priority and to poisonous divisional applications have recently been referred to the Enlarged Board of Appeal of the European Patent Office (EPO) as case G 1/15.

In view of this pending referral, the President of the EPO has now decided to take an exceptional measure and to allow the proceedings before the examining and opposition divisions to be stayed in cases where the decision from these divisions will depend entirely on the outcome of G 1/15.

More specifically, in its notice, the EPO defines the four conditions to be met for the proceedings to be stayed as:

1. an invention to which a claim is directed is not novel and/or inventive in the light of the prior art (including applications belonging to the same family, and the application from which priority is claimed), if the claim is not entitled to partial priority;

2. the claim in question encompasses, without spelling them out, alternative embodiments having all the features of the claim (known as a generic 'OR'-claim), ie, is directed to subject-matter defined by one or more generic expressions, such as a chemical formula, a continuous range of numerical values or a functional definition;

3. the priority document discloses only one or more (specific) embodiments covered by the claim in question (ie, the claim is a generalisation of the disclosure of the priority document), but not the subject-matter of the entire claim itself; and

4. the outcome of the proceedings depends entirely on how the Enlarged Board of Appeal answers the points of law referred to it.

While items 1-3 relate to the question of whether a claim is entitled to partial priority, the last item seems to have been included to avoid having proceedings stayed where a decision could be reached by the EPO on other grounds. For example in cases where the examining or opposition division believes that the claims do not meet the added-matter requirements of the European Patent Convention (EPC), the proceedings would not have to be stayed as a decision to refuse the application or patent could be reached by the division, regardless of the outcome of G 1/15.

Last but not least, in all cases where the proceedings will be stayed, the examining and opposition divisions will inform the parties and any communications setting a deadline for responding will be withdrawn. The proceedings will resume once the decision on G 1/15 has been issued.

This decision will ensure that all parties are treated fairly which is of course laudable but, at the same time, it is also adding to the considerable weight already on the shoulders of the Enlarged Board of Appeal, which already has to deal with one of its most difficult and debated referrals.

Author:
Bénédicte Moulin

Further information

Notice from the European Patent Office dated 2 October 2015 concerning the staying of proceedings due to referral G 1/15: http://dycip.com/epostay2oct

Merck Sharp & Dohme v Ono Pharmaceutial
Plausibility of immunotherapy second medical use claims

This is a UK patent case concerning EP(UK) 1 537 878 to Ono Pharmaceutical Co. Ltd (Ono)[1]. Ono has developed an anti-PD-1 antibody called nivolumab (brand name Opdivo) and Ono alleged that Merck Sharp & Dohme's (MSD) anti-PD-1 antibody called pembrolizumab (brand name Keytruda) infringed the patent. MSD alleged that the patent was invalid. Both antibodies have obtained clinical approval for the treatment of some cancers. The judge, Birss J, found that the patent was valid. In this article we will particularly review MSD 's plausibility attack under priority, sufficiency, AgrEvo obviousness, and also novelty.

Claims 1 and 3 read:

1. Use of an anti-PD-1 antibody which inhibits the immunosuppressive signal of PD-1 for the manufacture of a medicament for cancer treatment.

3. Anti-PD-1 antibody which inhibits the immunosuppressive signal of PD-1 for the use in cancer treatment.

Common general knowledge

The judge noted that, in the field of cancer immunotherapy in the mid-2000s, the concept of trying to use agents associated with the immune system to attack cancer is old, but that whether these ideas work in practice is another matter entirely.

Particularly in relation to PD-1, the judge noted that, before the patent, although the skilled team regarded the PD-1 pathway as an inhibitory pathway, they were aware of evidence of a discrepancy, in that its ligands PD-L1/L2 had been shown also to have a co-stimulatory effect.

Priority/insufficiency/lack of technical contribution

MSD's objections included arguments about insufficiency, AgrEvo obviousness (lack of a technical contribution) and loss of priority. These points are not identical although they all cover very similar territory. If priority was lost it was not in dispute that the claims were invalid in the light of an intervening paper. There is no disclosure of an anti-PD-1 antibody being generated or tested in the priority document. Ono argued however that the priority document contained crucial *in vivo* mouse tumour model experiments in PD-1 knockout mice and expressly taught that anti-PD-1 inhibitory antibodies would be expected to have a similar effect. They argued that the experiments in the priority document were evidence that blockade of PD-1 inhibits tumour growth in two different types of cancer.

The skilled person would recognise that these results have a broad application in the treatment of cancer because the blockade treats the immune system rather than being directed to an attribute of any particular cancer. This makes it plausible that the invention is effective for treating a wide range of cancers.

Ono alleged that MSD's pembrolizumab infringed the patent for nivolumab

The question of plausibility was considered by the Supreme Court in HGS[2] primarily in the context of Art 57 EPC (susceptible of industrial application) and sufficiency. The contrast drawn in that case was between "speculation" on one side and a "plausible" or "reasonably credible" claimed use on the other.

The judge noted that while a low standard might work to Ono's advantage in the context of arguments about priority and sufficiency, there was a tension in the context of novelty as one of Ono's submissions was that the lack of such *in vivo* tumour data in the prior art did not deprive the claims of novelty because the art did not make the treatment plausible.

In HGS it was found to be plausible that the

Notes

1. *Full decision of Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co Ltd & Anor [2015] EWHC 2973 (Pat) (22 October 2015): http://dycip.com/msdvonopharma*
2. *Human Genome Sciences Inc v Eli Lilly and Company [2011] UKSC 51 (2 November 2011): http://dycip.com/hgs11dec*
3. *Synthon BV v. Smithkline Beecham plc [2005] UKHL 59 (20 October 2005): http://dycip.com/synthonvsb*

product claimed would have some sort of therapeutic utility. At the level of individual diseases one could not say which might be treated but that did not matter because the claim was not so limited. For a purpose limited medical use claim, more specificity is likely to be required than was necessary in HGS but on the other hand, material which is too narrowly focussed may not support a wide claim. The principle applicable to purpose limited medical use claims must be that the material relied on to establish plausibility must be both sufficiently specific, and have a sufficient breadth of application, to fairly support the claim both in terms of the nature of the agent claimed to have an effect, and in terms of the effect claimed.

The judge went on to say he was satisfied that to a skilled person reading the patent application when it was filed in 2003 (or the priority document in 2002), the document makes a soundly based and reasonable prediction that the therapy will work to treat cancer in general. Success in this context does not mean success in every patient in all circumstances, no treatment will achieve that. Nevertheless given the patent described the invention at a fair level of generality, the claims were found to be entitled to priority, sufficiently disclosed and commensurate with the technical contribution of the patent.

Novelty

For anticipation to be established there must be disclosure of the invention by the prior art and that disclosure must be enabling[3] . For medical use claims (Swiss style/EPC 2000) there must be an enabling disclosure of the same therapeutic effect in the prior art, since those claims derive their novelty from the intended medical use.

The judge found that as a matter of disclosure (rather than enablement), the main prior art citation discloses the idea of using an anti-PD-1 agent, which could be an anti-PD-1 antibody, for the treatment of cancer. An anti-PD-1 agent is not the only agent disclosed and cancer is not the only disease proposed to be treated but nevertheless there is an individualised disclosure of that combination in the citation. The issue was therefore enablement.

The citation was not only long, it hedged its bets. Overall the judge decided that the content of the citation while sufficiently broad to render plausible the idea of using an agent which acts on the PD-1 pathway in medicine generally; the content was not specific enough for cancer, to render plausible the use of that agent in the treatment of cancer. The citation was not enabling and therefore the claims were novel.

Although not discussed here, the judge went on to find in favour of Ono on inventive step. Interestingly, the patent was also found valid by the Opposition Division in parallel proceedings and is now under appeal at the EPO.

Author:
Catherine Mallalieu

The judge noted this case is complex and summarised some of his reasons for reaching the conclusion that the patent is valid as follows:

i. At the priority date the common general knowledge of the person skilled in the art included the idea that the PD-1 pathway was an important aspect of the immune system with a role in self-tolerance. It could be a target for therapeutic manipulation. This knowledge included the concept that PD-1 was an inhibitory receptor. However it also included knowledge of a debate about the PD-1 pathway. It was known that ligands to PD-1 also had a co-stimulatory effect and it was known that a proven explanation had not emerged.

ii. The *in vivo* mouse data contained in the first priority document, in which two different kinds of tumour are transferred to PD-1 knockout mice, represent an important advance. The data make plausible the idea that an agent which blocks the PD-1 receptor can manipulate the immune system in such a way as to treat cancers in general, not only those tumours which express PD-1 ligands. Nevertheless, while the reasonable prediction which the priority document supports is a wide one, it does not purport to promise that every cancer patient in all circumstances can be treated. Claims 1 and 3 are plausible and are entitled to priority.

iii. The patent enables the skilled person to make and use anti-PD-1 antibodies as anti-cancer medicines. Moreover, and crucially, the evidence today shows that anti-PD-1 antibodies have been approved to treat a number of different cancers and are worth investigating in a very wide range of cancers. The evidence today also shows that anti-PD-1 monotherapy probably does not treat prostate cancer and most colorectal cancers, but this does not demonstrate a lack of technical contribution or undue burden. The law does not require perfection.

iv. The prior art document discloses the idea of manipulating the PD-1 pathway and includes the idea of an anti-PD-1 agent as a therapeutic agent to be used to treat a number of diseases including cancer. That agent could be an anti-PD-1 antibody. However the document includes evidence of both the inhibitory effect of the PD-1 receptor and the co-stimulatory effect of PD ligands. While its disclosure may be enough to support the general idea of using an agent which acts somehow on the PD-1 pathway in medicine, it does not make plausible the specific idea of an anti-PD-1 agent to treat cancer. Therefore claims 1 and 3 are novel.

v. The claims involve an inventive step because the common general knowledge includes knowledge of the existence of the debate about the cause of the co-stimulatory role of PD-1 ligands. Although it was known that the PD-1 receptor was inhibitory, the existence of the debate meant that a skilled person who conducted a test of PD-1 blockade against a tumour in a mouse, would not have a fair expectation of success. The mouse tumour results in the patent were exciting and were not predictable from the prior art. Claims 1 and 3 are not obvious.

ORoPO
The Open Register of Patent Ownership

Earlier in 2015, Aistemos, the IP strategy, analytics and risk management company with headquarters in London, announced the launch of ORoPO, the Open Register of Patent Ownership as part of a non-profit, voluntary and open data initiative to solve the problems associated with the accuracy of patent ownership records:

> ORoPO is committed to assembling the first global patent database of who owns which patents.

The register requires applicants to report any change of patent ownership on a voluntary basis and the information is stored as comma-separated values (CSV) files in a table-structured format. With the backing of organisations such as, ARM, BAE Systems, IBM and Microsoft, the aim is to establish a global and accurate register of patent ownership accessible to everyone at no cost.

Although information about who owns the world's patents is held at the various patent issuing authorities around the world, a combination of data entry and translation errors, non-existent naming harmonisation and the absence of regulation requiring ownership changes to be recorded, means that a substantial amount of the patent ownership data these authorities hold is inaccurate or incomplete. Even if ownership data are correct when filed, the impact of mergers, acquisitions, business name changes and corporate transactions means that often patent registry information is simply out of date. There is no central mechanism to update every patent register. This provides a challenge to purchasers and licensees of patents who require confidence in patent ownership information in order to reduce the risks to licensees and bring extra value to the intellectual property owner.

So far a total of eleven companies have made their patent holdings list available in the register:

ORoPO, the Open Register of Patent Ownership, was launched in 2015

- Allied Security Trust
- Finjan Holdings Inc
- Practice Insight Pty Ltd
- ARM Holdings PLC
- International Business Machines Corporation
- Shazam Entertainment Ltd
- BAE Systems PLC
- Inventor Holdings LLC
- Spherix Inc
- Conversant IP Management Inc
- Microsoft Corporation

To date the initiative appears to have attracted technology companies, whose patent portfolios are, arguably, mainly patents to protect technology essential to a standard (standard-essential patents or SEPs), and such accurate ownership data are probably already held in the official patent issuing authority register. It remains to be seen whether other, more diverse, companies adopt the register.

Nevertheless, the ORoPO register has at least provided an additional route towards improving transparency in patent ownership data accuracy in the public domain, which can only help the patent system to continue to promote and encourage innovation in business. Michelle Lee, Director of the US Patent and Trademark Office comments that:

> Ultimately, the marketplace works most effectively in an environment of transparency, allowing innovators to make smarter investments, create jobs, and drive economic growth. I would add that the economic benefits of greater ownership transparency are truly international in scope; the more awareness there is of the technologies out there, the more cross-licensing opportunities there are across borders.

Access to ORoPO

Instructions for providing your data to ORoPO and access to download either the full ORoPO dataset or individual company data can be found at the website for the Open Register of Patent Ownership: www.oropo.net.

Author:
Grayce Shomade

Exploring the patent landscape
Two new patent search and analysis tools

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

The already vast quantity of patent-related data increases with every new patent application filed. These data are a rich source of technological information, and many search tools, both free and subscription-based, exist to aid navigation and exploration. Nevertheless, the sheer volume of patents and applications worldwide can make meaningful searching difficult for the inexperienced. Help may be at hand, however, following the recent launch of two new search platforms. These are directed at specific areas, making it easier to target your data mining.

INSPIRE

In July, the International Standards and Patents in Renewable Energy (INSPIRE) platform was unveiled. This is a collaboration between the International Renewable Energy Agency (IRENA, based in Masdar City, the planned city project in Abu Dhabi built to rely on renewable energy and host environmentally friendly and clean-tech companies), the International Electrotechnical Commission (IEC), and importantly from an intellectual property perspective, the European Patent Office (EPO).

INSPIRE brings together patent documents and international standards relating to renewable energy and carbon reduction technologies. It therefore acknowledges the important link between patents and standards which is often recognised in the telecommunications industry with its frequent talk of standard-essential patents (SEPs), but can be less widely appreciated elsewhere. The patents section provides basic information about patents, gives access to information on more than two million patent documents in the green technologies field drawn from the global patent statistics database PATSTAT, and allows searching via the online patents search tool Espacenet. Emphasis is given to Espacenet's dedicated 'Y02' classification scheme for carbon mitigation technologies. The standards section allows searching of over 400 international standards, and provides general information about standards.

Besides dedicated patent searching in a specific field, it is intended that INSPIRE will enable the analysis of aspects of renewable energy policy and innovation. For example, identifying a trend in patent activity may indicate the effectiveness of particular policies, which in turn can inform future policy making. The grouping of patents and standards data from the renewable energy field and the comparisons and analysis thereby made possible aim to enhance collaboration and improve innovation in this important area.

PatentsView

The second platform targets a geographical rather than a technological area. September saw the launch by the US Patent and Trademark Office (USPTO) of PatentsView. This is described as a "patent data visualization platform", and does indeed return search results in an easy to interpret and interactive format combining text and graphics.

PatentsView is a patent search tool for exploring several decades of data relating to patents and patenting activity in the US, the data corresponding to over five million patents from 1976 to 2014 and being drawn from the USPTO's public bulk data files (which is not the official USPTO record). It is possible to search via a range of filters, including inventor, assignee (applicant or patentee), technology, location (US and worldwide), dates, subject matter classification and patent number.

Results can be returned as a list, an interactive table, or on a map, and provide links through to other data. For example, for an individual patent, found perhaps via an inventor or the assignee, the number of times it has been cited by the USPTO against subsequent patents is revealed, together with the geographic origins of those later patents, and networks of co-inventors. All bibliographic information for patents is provided, with a link to the abstract. Very particular information can be readily gleaned, such as all the companies in a given city that were granted patents in a specific technology sector in a given year.

PatentsView is considered to be a key component of the US President's 'Memorandum on Transparency and Open Government', since it is addressed to the aim of encouraging the understanding of intellectual property and innovation, is freely available to all, and is considered as a 'public good' platform intended to "increase the value, utility and transparency of US patent data". It has been developed since 2012 by the USPTO in collaboration with a number of other bodies including the US Department of Agriculture and the University of California at Berkeley. The initial version is a beta platform, and public feedback is encouraged to inform future development and expansion.

So, should you be in need of data relating to patents on renewable energy or patents filed in the US, or perhaps both, these new tools might be just what you need.

How to access INSPIRE and PatentsView

The platforms may be found respectively at: inspire.irena.org and www.patentsview.org.

INSPIRE and PatentsView can be found at inspire.irena.org and www.patentsview.org

Author:
Cathrine McGowan

And finally…

EPO takes a common sense approach to handwritten amendments

The European Patent Office (EPO) has not accepted hand-written amendments since 01 January 2014. Replacement patent application documents such as amended claims and description pages have instead had to be filed in typed-up form.

Clearly when filing replacement claims or description pages during written proceedings, the preparation and submission of typed amendments is relatively straightforward. There is usually time to obtain or prepare a digital version of the specification and to review typed amendments before they are filed at the EPO. When replacement documents have to be filed during oral proceedings, however, the preparation of typed pages can be problematic.

Firstly there is an inevitable time pressure on a European patent attorney to prepare the amendments. The Examining or Opposition Division holding the oral proceedings will agree a time period for the amendments to be prepared and whilst there is some flexibility in this time period, there is still limited time for the amendments to be prepared and reviewed before filing.

Secondly the European patent attorney must have an editable version of the pending description and claims. This might require, for example, an Adobe PDF file to be converted into editable form or typed into a Microsoft Word document, which could result in typographical or formatting errors in the specification. In view of the time pressure when preparing amendments, errors such as these have the potential to go unnoticed.

Finally the typed amendments must be prepared and printed using the EPO computer facilities. There is, however, a limited number of computers at the EPO. There is also always a risk of technical problems with the computer and/or printing facilities.

Amended Rule 82(2) EPC

Thankfully, however, the EPO has amended Rule 82(2) EPC with the Decision of the Administrative Counsel of 14 October 2015, CA/D 9/15, so that it includes the following sentence: "Where, in oral proceedings, decisions under Article 106, paragraph 2, or Article 111, paragraph 2, have been based on documents not complying with Rule 49, paragraph 8, the proprietor of the patent shall be invited to file the amended text in a form compliant with Rule 49, paragraph 8, within the three-month period."

From 01 May 2016 it will therefore be possible to file handwritten amendments during oral proceedings. Where a patent is maintained on the basis of these amendments, the patent proprietor will then receive an invite to file a typed version of the amendments. This typed version must be filed within a three-month period (which is set by the Communication from the Opposition Division inviting the patent proprietor to pay the republication fee and file a translation of any amended claims in the official languages of the EPO other than the language of the proceedings).

Author:
Rachel Bateman

Contributors

Partner, Editor
Aylsa Williams
aaw@dyoung.com
www.dyoung.com/aylsawilliams

Partner
Catherine Mallalieu
clm@dyoung.com
www.dyoung.com/catherinemallalieu

Partner
Richard Willoughby
rww@dyoung.com
www.dyoung.com/richardwilloughby

Senior Associate
Cathrine McGowan
cmg@dyoung.com
www.dyoung.com/cathrinemcgowan

Associate
Bénédicte Moulin
bxm@dyoung.com
www.dyoung.com/benedictemoulin

Associate
Rachel Bateman
reb@dyoung.com
www.dyoung.com/rachelbateman

Patent Analyst
Grayce Shomade
gxs@dyoung.com

We are grateful to Grayce Shomade for her contribution to this edition of our newsletter. Grayce has recently joined the firm as a member of our patent search team, and is located at our London office.

Contact details

D Young & Co LLP
120 Holborn, London, EC1N 2DY
T +44 (0)20 7269 8550
F +44 (0)20 7269 8555

D Young & Co LLP
Briton House, Briton Street
Southampton, SO14 3EB
T +44 (0)23 8071 9500
F +44 (0)23 8071 9800

www.dyoung.com
mail@dyoung.com