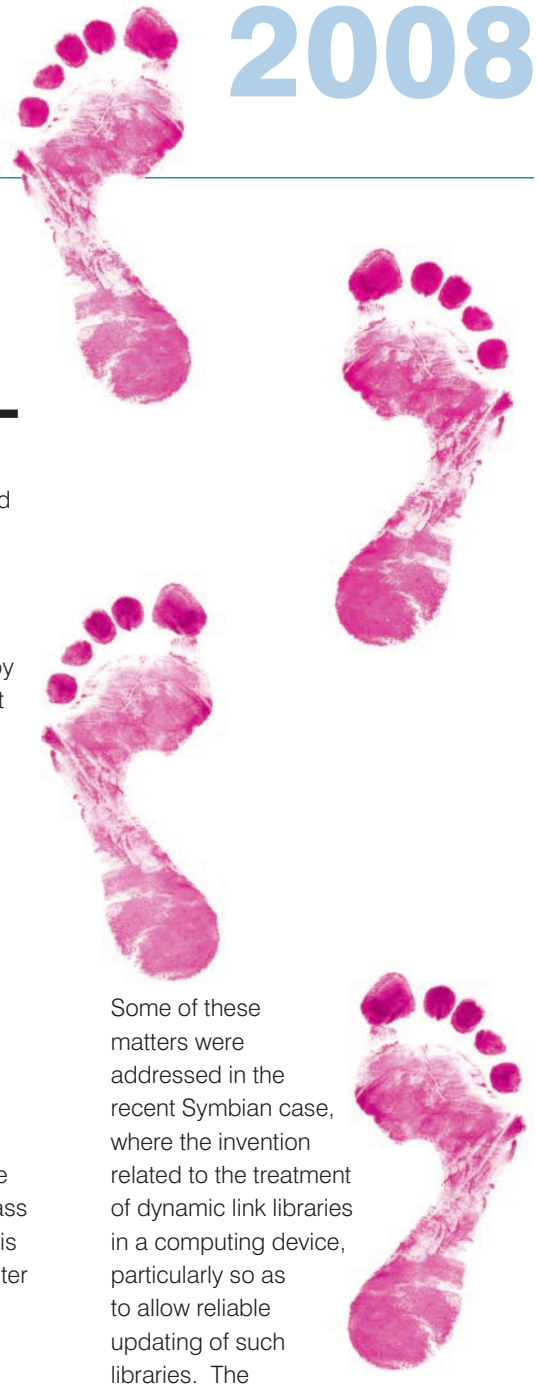
D YOUNG & CO

PATENT NEWSLETTER

June 2008



COMPUTER-IMPLEMENTED INVENTIONS TAKE 4 STEPS BACK TO THE COURT OF APPEAL

The first half of this year has seen a flurry of cases relating to computer-implemented inventions reaching the UK courts. Some of these have been appeals from refusals by the UK Intellectual Property Office (UKIPO), while others have been as part of infringement proceedings.

In theory, the treatment in the UK of computer-implemented inventions was resolved by the Court of Appeal judgement in Macrossan/Aerotel from 2006. This decision set out a 4-step test to be applied in the assessment of patentability for such cases, namely:

1. Construe the claim.
2. Identify the contribution.
3. Does the contribution fall solely within excluded subject matter?
4. Check whether the contribution is actually technical in nature.

Following the Macrossan decision, the UKIPO issued a Practice Notice dated 2 November 2006, which indicated that henceforth the UKIPO would follow the 4-step test. The 4-step test does not have any counterpart in the practice of the European Patent Office (EPO), despite the fact that UK law and European law are aligned in this area. The Practice Notice recognises this difference, but states that: "we [the UKIPO] consider that the end result will be the same in nearly every case irrespective of whether the approach followed is the Court of Appeal's or that of the EPO".

The UKIPO has generally become a more restrictive forum for computer-implemented inventions since Macrossan. In particular, the manner in which the UKIPO identifies the "contribution" in the second step of the 4-step test often makes it difficult to pass the third step, since the "contribution" is frequently regarded as solely a computer program, and hence is excluded subject matter. Many practitioners now see a significant divergence in practice between the UKIPO and the EPO, despite the statement to the contrary in the Practice Notice.

Some of these matters were addressed in the recent Symbian case, where the invention related to the treatment of dynamic link libraries in a computing device, particularly so as to allow reliable updating of such libraries. The application was refused by the UKIPO

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EDITORIAL

The articles presented in this and earlier editions of this newsletter reflect the diversity in technology of the D Young & Co patent attorneys. We also regularly issue a trade mark newsletter; to receive a copy please email rjd@dyoung.co.uk.

We have a reputation for excellence in the field of intellectual property. Patent and trade mark attorneys at D Young & Co often work in teams either for particular clients or for particular work projects. This promotes an open, rewarding and successful culture within the firm and our clients benefit enormously from this culture. We are renowned for professionalism, business sensitivity, creativity and flexibility; attributes that are contributing factors of how D Young & Co remains at the forefront of the IP profession.

We are a dynamic partnership that is constantly improving and in this edition of our newsletter we introduce you to our chemistry and biotechnology patent group in a contact reference guide.

Readers with a keen interest in mechanical and electrical subject matter need not fear as we will be introducing you to our mechanical and electrical patent group in the August newsletter.

Until then, please enjoy the current articles.

COMPUTER-IMPLEMENTED INVENTIONS TAKE 4 STEPS BACK TO THE COURT OF APPEAL
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as being a computer program per se (excluded subject matter). This refusal was then appealed to the High Court, where the case was heard by Justice Patten. Note that a counterpart application has been allowed by the EPO without (non)statutory subject matter being an issue.

After reviewing previous cases, Justice Patten allowed the appeal. In particular, it was held that the handling of the dynamic link libraries improved the reliability of the computing device, and hence the invention should not be regarded as purely a computer program. Hence the application did not represent excluded subject matter.

This decision has not gone down well with the UKIPO, which issued a press release on 18 March 2008 stating that: "The UKIPO believes that when deciding whether this computer-implemented invention is patentable, Mr Justice Patten did not apply the so-called 'Aerotel/Macrossan test' [i.e. the 4-step test] ... in the way intended by the Court of Appeal".

It is relatively unusual for the UKIPO to criticise a judge in this manner. The UKIPO then indicated that it would appeal to the Court of Appeal against the decision in Symbian "with a view to seeking clarification". The appeal is likely to be heard later this year.

It is difficult to be certain of the outcome of the appeal. Certainly it appears feasible to interpret the 4-step test from Macrossan/ Aerotel in the manner of Symbian, with the result that UK practice would then be much more closely aligned with EPO practice. The UK courts have recently emphasised the desirability of such alignment (such as in the Astron Clinica case, as discussed in our last newsletter), and it would also be welcomed by practitioners.

FURTHER REFERRAL TO THE ENLARGED BOARD OF APPEAL (G2/08)

G2/08 is now pending before the European Patent Office (EPO) Enlarged Board of Appeal following a referral that has recently been made in decision T 139/04. The questions due to be considered by the Enlarged Board of Appeal are outlined here:

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?

2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?

3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

SUPPLEMENTARY PROTECTION CERTIFICATES - EXTENDING THE LIFE OF PHARMACEUTICAL AND PLANT PROTECTION PATENTS

New medicines and agricultural products require extensive testing to ensure they are effective and safe before they can be released onto the market. The safety and efficacy data must be submitted to government agencies for detailed review before marketing authorisation can be granted. As the authorisation requirements become more stringent, the research required becomes ever longer and more costly; it can take 12-14 years and cost up to $1bn to bring a new drug from its initial discovery to the marketplace. As patent applications for new pharmaceuticals are typically filed at an early stage in the research cycle, the patent holder may only be left with 6-8 years exclusivity before expiry of the normal 20-year term of a patent.

Supplementary Protection Certificates (SPCs) were introduced in Europe in the early 1990s and are aimed at compensating the patent holder for the time lost in exploiting the patent due to the requirement to first obtain marketing approval. The function of an SPC, effectively, is to extend the term of patent protection for medicinal (human or veterinary) or plant protection products which have had to undergo a marketing authorisation process. However, in Europe, an SPC only covers the actual compound (or combination of compounds) which is the subject of the marketing authorisation; it is not an extension of the entire claim scope of the basic patent.

In order for a pharmaceutical or plant protection compound to obtain SPC protection in the UK and other EU and EEA countries, four criteria must be fulfilled. Firstly, the product must not already be the subject of an SPC. Secondly, it must be the subject of a basic patent in force (usually, but not always, the original patent covering the compound itself). Thirdly, the product must be the subject of a valid marketing authorisation under the relevant EC Directive (either that relating to medicinal products or that relating to plant protection products). Finally, the marketing authorisation must be the first authorisation to place the product on the market under the relevant EC Directive.

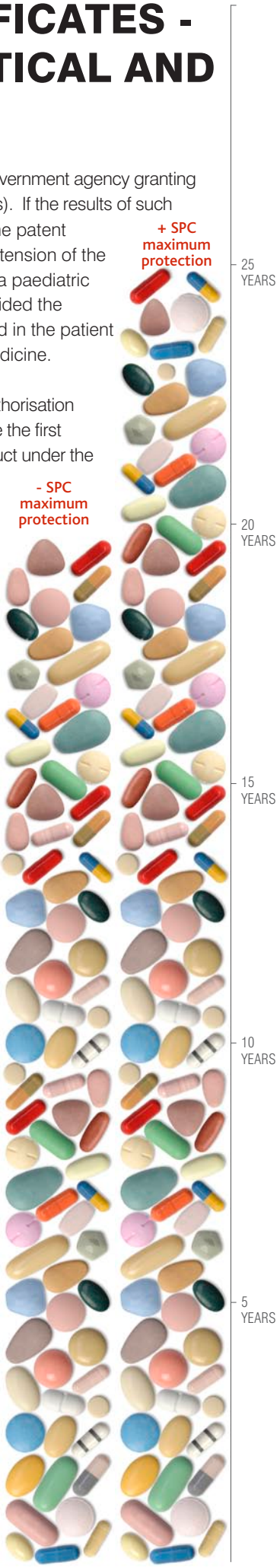
Although the legal basis for SPCs is derived from EU legislation, applications for SPCs must be made at the national Patent Office of each country where protection is required. An SPC application must be made within 6 months of the grant of marketing authorisation in that country (or within 6 months of the date of grant of the patent, if later). The national Patent Office then examines the application to establish whether the above criteria are fulfilled and, if so, grants the SPC. Although, strictly speaking, SPCs are a distinct IP right from the patent on which they are based, any action for infringement of an SPC is generally carried out in a similar manner to the basic patent.
The duration of an SPC in Europe is 15 years from the date of the first marketing approval in the EU or EEA, subject to a maximum of 5 years from the normal expiry date of the basic patent. However, if a Swiss marketing authorisation predates the first EU or EEA authorisation, the Swiss authorisation is considered the first authorisation for the purposes of calculating the 15-year period. This is because, although Switzerland is not part of the EU or EEA, Swiss marketing authorisations extend to Liechtenstein which is an EEA member.

Under recently-introduced EU legislation, when applying for marketing authorisation of a medicinal product, applicants are now required to include the results of paediatric studies on the product (or a decision from the relevant government agency granting a waiver or deferral of such studies). If the results of such paediatric studies are included, the patent holder is entitled to a 6-month extension of the SPC period. This applies even if a paediatric indication is not authorised, provided the results of the studies are reflected in the patient information provided with the medicine.

As noted above, the marketing authorisation required to obtain an SPC must be the first authorisation granted for the product under the relevant EC Directive. However, if a second marketing authorisation is granted for a later version of the product (such as a combination or improved formulation), it is possible in certain circumstances to obtain a further SPC for this product. To obtain a second SPC, the later product should, generally, itself be the subject of a specific granted patent claim; a claim to the compound itself would not usually suffice.

In addition to Europe, many countries, including the US and Japan, have provisions in their law allowing patent term extension for pharmaceutical and plant protection compounds. However, the level of harmonisation of patent term extension laws is less advanced compared to some other areas of intellectual property and some major countries, such as Canada, still have no legal provisions for patent term extension.

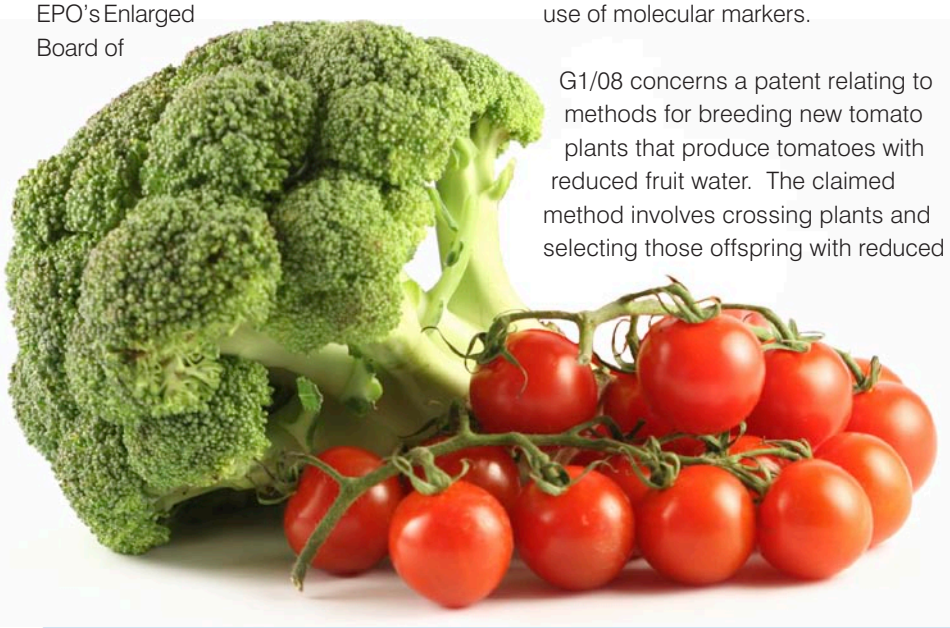
Obtaining and enforcing SPCs and other forms of patent term extension forms a key part of pharmaceutical and agricultural product companies' strategy in maximising the value of their marketed products. D Young & Co work in partnership with a global network of expert independent agents to obtain the fullest possible SPC protection for our clients. For further information, please contact your usual D Young & Co representative.



ARE METHODS OF BREEDING PLANTS PATENTABLE IN EUROPE?

European patents cannot be granted before the European Patent Office (EPO) for 'essentially biological processes' for the production of plants or animals (Article 53(b)EPC). A process for the production of plants or animals is defined as being 'essentially biological' if it consists entirely of natural phenomena such as crossing or selection (Rule 26(5)EPC).

The scope of this patentability exclusion is currently being reviewed before the EPO's Enlarged Board of Appeal under cases G2/07 and G1/08 (which were consolidated into one case in April 2008).



G2/07 relates to a patent concerning methods for producing new Brassica plants, in particular broccoli, with elevated levels of anti-carcinogenic glucosinolates. The claimed method involves crossing plants and selecting those offspring with elevated levels of anti-carcinogenic glucosinolates by the use of molecular markers.

G1/08 concerns a patent relating to methods for breeding new tomato plants that produce tomatoes with reduced fruit water. The claimed method involves crossing plants and selecting those offspring with reduced fruit water content indicated by extended preservation of the ripe fruit on the vine and wrinkling of the fruit skin.

The referred questions ask for guidance on how non-excluded processes differ from excluded processes and what 'an additional feature of a technical nature' might be. For example, is the use of molecular markers in the selection step, which requires human intervention, sufficient to escape the exclusion of Article 53(b)EPC? Is the use of 'non-natural' crossing and selection based on human criteria sufficient to escape the exclusion of Article 53(b)EPC?

Once the Decision of the Enlarged Board of Appeal is available, we will update you on the outcome. In the meantime, if you have an application which may fall within the exclusion (i.e. depending upon the decision of the Enlarged Board of Appeal) – then the EPO should stay the processing of your application until after the Enlarged Board of Appeal's decision has been handed down.

We will publish updates in future editions of this newsletter.

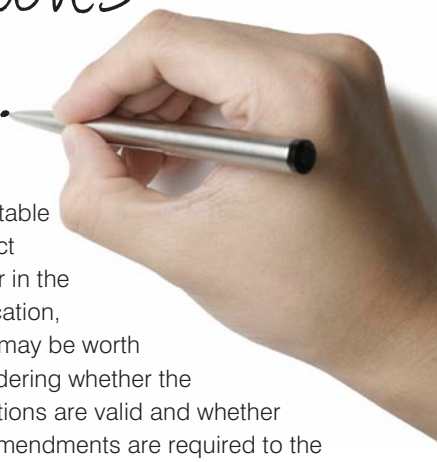
LONDON AGREEMENT - UK TRANSITIONAL PROVISIONS

Since 1 May 2008, the London Agreement (LA) has been in force. As far as we are aware, no significant surprises occurred over the days of the transition. However, earlier in April there was an unwelcome development in the UK regarding the transitional arrangements. This affects French or German language European patents validated in the UK.

The UK Intellectual Property Office (UKIPO) had previously issued a guidance note on the transitional arrangements, which is published at www.ipo.gov.uk/p-law-londonagreement. This advised it was not necessary to file an English translation for "any EP(UK) granted on or after 1 February 2008". Actually, since an automatic 2-month extension is allowed on the 3-month period, the UKIPO advice was effectively that no translation was needed for any case granted on or after 1 December 2007.

What occurred in April was a discussion amongst UK practitioners about whether the UKIPO guidance note was correct. An alternative reading of the relevant UK statute provision (Section 77 of the Patents Act 1977) leads to the conclusion that a translation must still be filed on any patent granted before 1 May 2008, i.e. the same position as most other LA countries, except Switzerland, which has adopted a position similar to that stated in the UKIPO guidance note.

Written Opinions, Search Opinions and Examination Opinions...



After filing a European or International patent application, a "Search Opinion" or "Written Opinion" is normally issued by the European Patent Office (or other International Searching Authority) together with the Search Report. While the Search Report simply lists prior art documents which are considered to be relevant to the application, the Search or Written Opinion is similar in form to an Examination Report and provides a more detailed discussion of patentability of the claimed invention. Although there is no obligation to respond to the Opinion, it can give the applicant an early indication of possible objections and may be useful in helping to formulate amendments before publication of the application.

Since 1st April 2004 the UK Intellectual Property Office (UKIPO) has also been issuing an Opinion on certain UK patent applications together with the Search Report. The UKIPO refers to this as an "Examination Opinion", although it is very similar to the Search or Written Opinions issued on European or International applications. This practice is separate from the optional "Combined Search and Examination" procedure which can be requested at the UKIPO.

The Opinions issued on European and International applications at the search stage may be familiar to many applicants, since they are provided in all cases regardless of whether their content is positive or negative. On the other hand, the UKIPO only issues an Examination Opinion if the Examiner believes there are "major issues" with the application, such as extensive lack of novelty or unpatentable subject matter. Most UK Search Reports, even those citing novelty-destroying documents, are still not accompanied by an Examination Opinion. Currently an Opinion is issued only on those 10-15% of applications which are perceived by the Examiner to be the most problematic.

The issue of an Examination Opinion by the UKIPO does not mean that there is no patentable subject matter in the application, but it may be worth considering whether the objections are valid and whether any amendments are required to the claims. There is no requirement to respond to an Examination Opinion, and amendments can still be filed later during the substantive examination stage. However the Opinion is intended to encourage applicants to respond to the Examiner's observations or to make an early amendment to speed up the examination process. If no response if filed, the Opinion may form the basis of the first examination report at substantive examination.

Thus UKIPO Examination Opinions can be useful to applicants as a way of highlighting cases which may require additional consideration or amendment before proceeding to substantive examination.

An in depth discussion of the relevant legal provisions and the alternative interpretations thereof can be found in an article dated 16 April 2008 on our website www.dyoung.com/publications/londonagreement0408.htm. In response to this debate, UKIPO has made it clear that it still holds by its guidance note.

Patentees that took advantage of what they believed to be the early abolition of the translation requirement in the UK now have to revisit that decision in view of the uncertainty. On the one hand, UKIPO has made it clear that it still believes its guidance note is correct. On the other hand, the sanction of not filing the translation in time is total loss of the UK patent rights. Clearly, most patentees will now file translations on affected cases given the fact there is a risk, even if the risk is thought to be small.

Responsible individuals need to urgently establish whether they have any affected cases, since the normal period for filing translations is running out, if it has not already done so. Moreover, even if the normal period has recently expired, UKIPO will almost certainly give a further discretionary extension in view of the uncertainties. As stated above, any French or German language European patent with a grant date between 1 December 2007 and 30 April 2008 should be checked.

EPO AND USPTO TO PILOT A PATENT PROSECUTION HIGHWAY

The European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) announced in April 2008 that they intend to launch a new trial cooperation initiative called the Patent Prosecution Highway in September 2008.

The aim of the Patent Prosecution Highway is to use fast-track patent examination procedures already available in both offices to allow applicants to obtain corresponding patents faster and more efficiently. It is also designed to permit each office to exploit the work previously done by the other office and reduce duplication.

The hope is that the initiative will reduce examination workload and improve patent quality.

This is the EPO's latest attempt to try to "keep its head above water". It is the EPO's and USPTO's hope that this will ultimately reduce backlogs while still maintaining high patent quality.

Under the Patent Prosecution Highway, an applicant who has an application filed with either the EPO or the USPTO which contains at least one allowable claim may request that the other office fast track the examination of corresponding claim(s) in corresponding application(s).

The purpose of the trial program is to gauge the interest of applicants and determine if the program improves quality and efficiency and reduces the workload at each office. The trial period will be initially set for one year but apparently may be extended or terminated earlier depending on volume of activity and other factors. Both offices will provide notice of any adjustment in the trial period.

Full requirements for participating in the trial program will be issued by the EPO and USPTO prior to implementation in September 2008 – watch out for further updates in future newsletters.

SUFFICIENCY IN THE UK COURTS

Prominent in recent UK patent case law is the House of Lords 'Biogen decision' (Biogen v Medeva [1997] RPC 1, 45) in which a product claim to a DNA molecule defined partly by the way it had been made and partly by what it did, namely to express an antigen, was held to be insufficient because the specification described only one method of making the molecule by recombinant technology and disclosed no general principle. Ever since, this decision has to some extent changed the way practitioners have approached sufficiency in the UK. It introduced the concept of "Biogen Insufficiency" into UK law. However, some clarification has arrived in the form of a recent Court of Appeal decision (Lundbeck A/S v Generics (UK) Ltd et al).

In this recent case, a product claim to a single enantiomer (escitalopram) was held to be novel and inventive over the known racemate (50:50 mixture of two enantiomers). Novelty was acknowledged once the Court had agreed with the first instance construction of the claims, that a claim to a single enantiomer should be interpreted as the pure enantiomer, and does not therefore include the enantiomer when part of the racemate. Inventive step was acknowledged taking into account that enantiomers are difficult to separate and no common separation technique known to the skilled person would have provided "real prospect" of success.

The first instance judge held the product claims insufficient. He reasoned that everyone knew that the two enantiomers existed in the racemate and that one or other or both had a medicinal effect. What Lundbeck had discovered was one way of making it. In the opinion of the first instance judge this did not entitle them to a monopoly of every way of making it.

The Court of Appeal disagreed, reasoning that in an ordinary product claim, the product is the invention. When a product claim satisfies the novelty and inventive step requirements, the technical contribution is the product per se and not the process by which it is made, even if that process was the only inventive step. It is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. There is nothing to say that it must disclose more than one way to make it; one method is enough.

The first instance judge relied heavily on the Biogen decision in his reasoning. However, the Court of Appeal indicated that the Biogen decision is limited to the form of the claim which the House of Lords was there considering and cannot be extended to an ordinary product claim as in the present case.

It appears that the Court of Appeal sees the Biogen decision as unique to the facts and therefore has far less application to other cases than previously thought. As a result, "Biogen Insufficiency" may become a thing of the past.

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For advice in relation to any specific situation, please contact your usual D Young & Co specialist advisor.

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CHEMISTRY AND BIOTECHNOLOGY PATENT GROUP

D Young & Co's chemistry and biotechnology patent group has developed into one of the largest chemistry and biotechnology groups in Europe, with currently 17 qualified Patent Attorneys. The group is headed up by the following partners: Charles Harding, Catherine Mallalieu, Neil Nachshen, David Alcock, Aylsa Williams, Zöe Clyde-Watson, Kirk Gallagher, Louise Holiday and Jo Bradley.

We are always improving our service to clients and the quality of our product.

The patent attorneys in the chemistry and biotechnology group provide a depth of experience across a broad range of the biological, biotechnological and chemical sciences and are at the forefront of developments in IP law.

The group covers at least the following technologies:

- Immunology
- Biotechnology
- Molecular biology
- Biochemistry
- Embryo and stem cell technology
- Cytokines and growth factors
- Microbiology, plant science
- Vaccines and tissue sealants
- Virology, bioinformatics
- Genetic engineering
- Genomics and proteomics
- Nucleic acid and peptide chips
- Pharmaceutical chemistry
- Pharmacology
- Food science
- Cosmetics
- Chemistry
- Petro-chemicals
- Industrial chemistry
- Organo-metallic chemistry
- Plastics
- Polymer chemistry
- Synthetic chemistry
- Environmental sciences
- Electrochemistry

The group has a particular expertise in contentious matters including pan-European litigation, oppositions and appeals before the European Patent Office. In addition we advise on many aspects of IP law for a diverse range of clients. A significant proportion of our clients are direct clients that include multinational corporations, small and medium-sized enterprises, successful start-up companies, and prestigeous academic institutions.

Please visit our website for more information about D Young & Co Patent services: www.dyoung.com/expertise/patents.htm and see overleaf for an overview of our chemistry and biotechnology group attorneys.

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