D YOUNG & CO
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Welcoming the D Young & Co Dispute Resolution & Litigation Group

Bringing Extensive Experience in All Forms of IP Enforcement and Exploitation

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Events

10-11 Feburary 2011
Vaccine Research and Innovation Conference 2011, London
Simon O'Brien is speaking at this conference, which will explore global opportunities in vaccine research and development, and is designed to implement successful strategies and innovative technologies to develop more effective vaccines.

23-24 February 2011
Stem Cells Conference 2011, London
Robert Dempster and Steve Blance will be leading a workshop entitled 'Practical Steps and Strategies for Obtaining Patent Protection for Stem Cells'. This interactive session will provide practical tips on drafting, filing and prosecution strategy for stem cell patent applications in order to provide flexibility and maximise protection in each jurisdiction.

23-25 March 2011
PepCon 2011, Beijing
PepCon 2011 has the theme 'New Leaders in Protein and Peptide Science' and will share the most important aspects of the rapid advances in peptide and protein research. Aylsa Williams and Zöe Clyde-Watson will be presenting 'How to Protect Your Investment in Europe' at the 'Biotechnology and Technology Transfer' workshop.

For more information: www.dyoung.com/events

Editorial

Welcome to the February 2011 edition of our patent newsletter.

This is the first patent newsletter of 2011, and already 2011 looks like being another exciting year for D Young & Co. At the beginning of January we welcomed our new Dispute Resolution & Litigation Group to the firm. The additional services the group will offer to our clients are eagerly anticipated. Full details are provided in the adjoining article and on our website at www.dyoung.co/litigation.

We look forward to continuing our work with clients in 2011 and aim with our newsletter to bring you informative and interesting articles throughout the year.

Editor:
Tim Russell

Article 01

Welcome to the D Young & Co Dispute Resolution & Litigation Group

Bringing Extensive Experience in All Forms of IP Enforcement and Exploitation

We are pleased to introduce our Dispute Resolution & Litigation Group. We are the first firm of patent and trade mark attorneys to establish a legal disciplinary practice in the UK.

Partners Ian Starr and Tamsin Holman, and associates Cam Gatta and Anna Reid, join us from the law firm, Ashurst, and have extensive experience in all forms of IP enforcement and exploitation, particularly alternative dispute resolution and general litigation.

The group have acted for a number of household names, as well as smaller clients, and particular areas of expertise include luxury goods, the fashion industry, FMCG, engineering/construction, pharmaceuticals, financial services and media/publishing. The group's services include:

High Court Litigation: Pursuing and defending IP infringement and other proceedings, including, in appropriate cases, emergency interim injunctions on short notice.

Patents County Court Litigation: Cost-effective, simplified proceedings aimed at SMEs requiring speedy resolution of disputes with cost-capping.

Opposition Proceedings: Working directly before the UK IPO, OHIM, EPO and worldwide via our network of trusted overseas lawyers.

Mediation: One of a variety of alternative dispute resolution methods available for the resolution of IP and other commercial disputes, either as a stand-alone process or within the context of court proceedings running in parallel.

Arbitration: ICC, LCIA and *ad hoc* arbitrations, often between international parties, for the resolution of technology and other complex IP-related commercial disputes, with the advantages of procedural flexibility and confidentiality inherent in arbitration proceedings.

Domain Name Disputes: Recovery of infringing domain names from opportunistic registrants and cybersquatters including, where necessary, UDRP proceedings at WIPO and equivalent proceedings at Nominet and other national registries.

Company Name Disputes: Actions to secure the change of infringing company names, including proceedings before the Company Names Tribunal.

Anti-Counterfeiting and Border Measures: Securing border control assistance from Customs authorities, to identify and seize counterfeits at the point of entry into the EU and elsewhere. Anti-counterfeiting actions may also include covert investigations and liaising with Trading Standards and equivalent enforcement agencies.

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> *D Young & Co Patent Newsletters*
http://bit.ly/pnl0609
http://bit.ly/pnl0610

> *Legal Board of Appeal Interlocutory Decision*
http://bit.ly/j0208

Divisional Applications and 'Pending' Parent Applications
Enlarged Board of Appeal Decision in Case G1/09

The time limits for filing divisional applications continues to be a hot topic at the European Patent Office (EPO). Our June 2009 and June 2010 newsletters contained articles about the new time limits being introduced by the EPO for filing divisional applications. According to new Rule 36(1) EPC, a voluntary divisional application filed from a pending European patent application must be filed within two years from the date of the Examining Division's first substantive communication. Furthermore, for many currently pending older applications for which this two year period had already expired, the deadline was 1 October 2010.

Just five days before this deadline, the Enlarged Board of Appeal (EBA) of the EPO issued its decision in the case of G1/09, concerning when a parent application can still be considered to be pending for the purposes of filing a divisional application. The specific question referred to the EBA was:

> *'Is an application which has been refused by a decision of the Examining Division thereafter still pending within the meaning of Rule 25 EPC 1973 (Rule 36(1) EPC) until the expiry of the time limit for filing a notice of appeal, when no appeal has been filed?'*

The facts of the case which resulted in this question being referred to the EBA can be summarised as follows:

25 November 2005 - a parent application was refused by the Examining Division in an oral decision given at the end of oral proceedings.
14 December 2005 - the applicant filed a divisional application.
27 January 2006 - the written decision to refuse the parent application was notified to the applicant. The applicant did not appeal against it.
9 August 2007 - the Receiving Section decided that the divisional application had not been validly filed, as the parent application was not pending at the time the divisional application had been filed, nor was an appeal filed (with its consequent retroactive suspensive effect on the decision to refuse). Furthermore, it was established EPO practice at the time (following EBA decision G12/91) that an oral decision was immediately effective.

The EPO's Enlarged Board of Appeal has issued its decision in G1/09

In appealing against the Receiving Section's decision, the appellant's central argument was that the parent application was still pending when the divisional application was filed because the time limit for filing a notice of appeal had not yet expired at that time. The appellant argued that because an appeal could still be filed, which could potentially overturn the decision to refuse, the application should still be considered as pending during the appeal period. When considering the appeal, the Legal Board of Appeal found (see J2/08) that the notion of a 'pending application' was not precisely defined in the EPC and referred the above question to the EBA.

The EBA's consideration of the referred question focused on the fact that the term 'pending' is used in different ways within the EPC itself. On the one hand the term is used in the context of pending patent applications (as in the referred case of Rule 36(1) EPC), but on the other hand it is also used in the context of proceedings pending before the EPO (for example the suspension of pending proceedings under Rule 13(3) EPC 1973).

Having considered the meaning of the term 'pending' in the context of a 'pending application', the EBA concluded that (at least in the context of Rule 25 EPC 1973) a pending application is one in which substantive rights deriving therefrom under the EPC are (still) in existence.

In the particular case of an applicant's substantive rights following refusal of a European patent application, the EBA took note of the provisional protection afforded by a published patent application, which according to Article 67(4) EPC is deemed never to have existed when the application has been 'finally refused'. With regard to the meaning of 'finally refused' the EBA agreed with the referring Board's observation that it is a well-established concept in the EPC contracting states that the 'final' character of a first instance decision only ensues upon expiry of period for legal redress. On this basis, the EBA concluded that a patent application which has been refused by the Examining Division is thereafter still pending within the meaning of Rule 25 EPC 1973 (Rule 36 EPC) until the expiry of the period in which an appeal may be filed.

The EBA's decision is welcome news for applicants, in particular in the light of the recent restrictions imposed on an applicant's ability to file divisional applications. This decision allows applicants to file divisional applications during the appeal period even in circumstances where an appeal is not subsequently filed, therefore providing a useful option which avoids previous expensive and procedurally inconvenient requirements.

Author:
Nicholas Malden

Essentially Biological Processes
Enlarged Board of Appeal Comes to Decision in Broccoli and Tomato Cases G2/07 and G1/08

The European Patent Office's Enlarged Board of Appeal (EBA) has now reached its consolidated decision in the so-called broccoli (G2/07)[1] and tomato (G1/08)[2] cases.

In its decision published on 9 December 2010, the EBA considered the meaning of the term 'essentially biological processes for the production of plants'. This term is used in the European Patent Convention (EPC) to exclude such processes from patentability.

The EPO's Enlarged Board of Appeal has reached its decision in G2/07 and G1/08

EBA decision

The EBA concluded that a non-microbiological process for the production of plants which contains the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being 'essentially biological'.

Such a process does not escape the exclusion merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

What is needed to transform the process from an excluded one to a patentable one is an additional step of a technical nature, which step:

> *by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced*

so that the introduction or modification of that trait is not the result of mixing of the genes of the plant chosen for sexual crossing.

The EBA decided that it is not relevant whether this step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

The decision makes it clear that it only applies where such additional step is performed within the steps of sexual crossing and selection independently from their number of repetitions. Otherwise the exclusion from patentability of sexual crossing and selection processes could be circumvented simply by additional steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed, or downstream steps dealing with the further treatment of the plant resulting from such crossing and selection process. Any such additional technical steps which are performed either before or after the process of crossing and selection should therefore be ignored when determining whether or not the process is excluded from patentability. For the previous or subsequent steps *per se* patent protection is available.

The EBA makes it clear that the exclusion does not apply to genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant. However,

> *in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.*

This means that while the presence in a claim of one feature which could be characterised as biological does not necessarily result in the claimed process as a whole being excluded from patentability, this does not apply where the process includes sexual crossing and selection.

Notes

1. Referred to the EBA in Technical Board of Appeal decision T83/05
2. Referred to the EBA in Technical Board of Appeal decision T1242/06

What does this mean for applicants attempting to obtain patents in the field of non-microbiological processes for the production of plants?

Alternative ways of claiming technical processes for the production of plants now need to be developed in light of this EBA decision. This is obviously case and fact dependent.

It is fair to say that, invention allowing, patent claims for Europe should be preferably formulated to exclude the sexual crossing and selection steps.

By way of example only, method claims relating to the production of a plant with elevated levels of a compound of interest, which method comprises crossing and selecting plants and includes a step of a technical nature (such as where molecular markers are used to select hybrids with a defined genetic combination encoding expression of elevated levels of the compound of interest) may need simple reformulation to remove the crossing and selecting steps and to direct the claims to the technical step alone. For example, such a method claim may be reformulated to a method of identifying a plant with elevated levels of a compound of interest which method comprises the step of a technical nature only.

Obviously the 'test' provided in this EBA decision relates to determining whether or not a process is excluded from patentability as being an 'essentially biological process'. Any claims formulated to avoid this exclusion still need to be novel and inventive *per se* to be patentable.

Please contact a D Young & Co attorney if you require advice with regard to formulating methods for the production of plants before the European Patent Office in light of this EBA decision.

Author:
Aylsa Williams

Article 04

Business Method Patents
EPO Board of Appeal Overturns Rejection by Examining Division in T1051/07

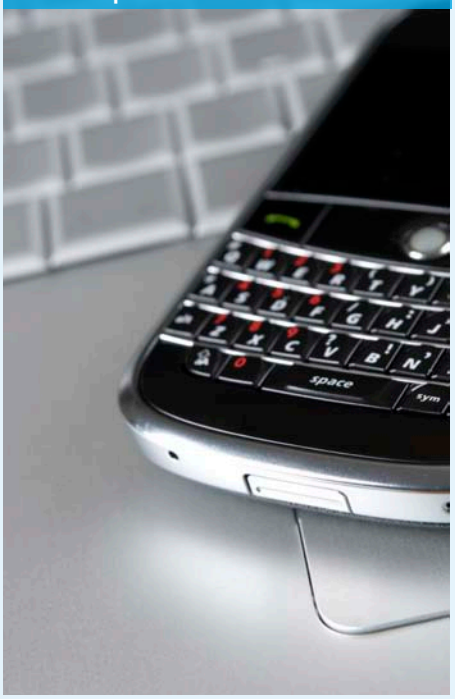
In a recent decision, T1051/07, a European Patent Office (EPO) Board of Appeal has overturned a rejection by the Examining Division of a case relating to a transaction system that allowed users to charge accounts on a host computer with a mobile telephone. The Examining Division treated this case as a computer-implemented business method.

The rejection rate from both the Examining Divisions and also the Boards of Appeal is generally high for this sort of case, so the positive result in T1051/07 (from the perspective of the applicant) is relatively unusual.

The conventional approach of the EPO for handling such computer-implemented cases was set out most fully in the decision in T154/04 (Duns Licensing). According to this approach, it is accepted that such inventions do not represent excluded subject matter under Article 52(2) and (3) EPC by virtue of the computer (technical) implementation. However, when considering inventive step, those features that do not contribute to the technical character of the invention are discounted. In many cases it is considered that all that is then left is a standard computer, which is regarded as known or obvious, leading to a rejection under Article 56 EPC.

Although T1051/07 follows the same general approach of considering the patentability of the application primarily under Article 56 EPC, it appears to take a somewhat broader view than the Examining Division did as to what features should be included (ie, not discounted) for the assessment of inventive step. In particular, the feature of loading money onto a user account on a host computer using a mobile telephone was, in effect, seen as a single technical feature, not merely as a (generic) host computer and a (generic) mobile telephone for performing some (non-technical) business function. Since the available prior art did not disclose or suggest this technical feature of loading money onto a user account on a host computer using a mobile telephone, the Board of Appeal overturned the rejection under Article 56 EPC.

T1051/07 concerned a secure payment system allowing users to pay a service provider using a mobile phone via a host computer



The Duns Licensing case was decided by Board 3.5.01, which has been the main driver of case-law in this area, whereas T1051/07 was decided by Board 3.4.03. It will be interesting to see whether or not T1051/07 becomes as influential as T154/04; if so, it is likely to expand the range of cases that might be allowed by the EPO.

Author:
Simon Davies

T1051/07 decision: http://bit.ly/t105107

T154/04 decision: http://bit.ly/t15404

Paediatric Exclusivity in Europe, So Far So Good?
Healthcheck for PIPs, PUMAs and SPCs

1,000 applications for a Paediatric Investigation Plan or Waiver have been validated by the European Medicines Agency since July 2007

The European Medicines Agency (EMA), the regulatory body responsible for the scientific evaluation of new medicinal products in Europe, has recently announced that it has validated the 1,000th application for a Paediatric Investigation Plan (PIP) or Waiver since its Paediatric Committee was established in July 2007[1].

With the passing of this milestone, this article summarises the original aims, obligations and rewards of EC Regulation 1901/2006 on Medicinal Products for Paediatric Use (the Regulation), and briefly considers to what extent these are being met in practice.

Aims and obligations

The Regulation came into force on 26 January 2007[2], with the stated objective of:

> *improving the health of children in Europe without subjecting children to unnecessary trials, or delaying the authorisation of medicinal products for use in adults.*

Under the Regulation, applicants seeking marketing approval for a new medicinal product, or any new therapeutic indication, pharmaceutical formulation, or route of administration of an existing medicinal product, that is the subject of patent protection in Europe, are obligated to conduct clinical paediatric studies as part of the development programme for that product. Details of the paediatric studies to be undertaken have to be submitted to the EMA as a PIP. Once the content of the PIP has been agreed by the EMA, implementation of the PIP gives rise to the paediatric data that is required to support any new application for marketing approval.

Certain exemptions exist under the Regulation regarding the provision of a PIP as part of the marketing approval process for a new medicinal product. These are:

1. Where the applicant requests deferral of the provision of a PIP. Deferral allows the applicant to provide paediatric data at a later stage in the regulatory approval process (for example, after the successful completion of clinical trials in adult patient groups), but does not remove the requirement to provide such data prior to obtaining regulatory approval.

2. Where the applicant requests a waiver of the provision of a PIP. A waiver may be sought where the medicinal product has no perceived use in a paediatric population (for example, the product is to be used for treating Alzheimer's disease), and when granted, the waiver removes the obligation to provide paediatric data as part of the regulatory approval process.

In the absence of paediatric data where no prior request for exemption has been sought, the application for regulatory approval is

considered to be invalid irrespective of whether the product is intended for use in adults and/or children. Therefore, the Regulation clearly places a considerable burden upon applicants seeking regulatory approval for medicines in Europe.

The rewards

However, it is not all bad news. One of two 'rewards' is available for applicants who meet the obligations of the Regulation. These are:

1. A six month extension to the term of the supplementary protection certificate[3] (SPC) for the patented product
2. Where the medicinal product has an orphan designation, an additional two years of regulatory data protection (RDP)[4] for that medicinal product.

In order to be eligible for one of these rewards the applicant must meet the following three criteria:

1. The paediatric data provided must comply with an agreed PIP
2. The medicinal product to which the paediatric data applies must have been approved in all member states; and
3. Significant clinical studies must have been performed after 26 January 2007.

Encouragingly, where the requirements of the Regulation are met, the reward is granted to an applicant irrespective of whether the paediatric studies are 'successful' and give rise to a new paediatric indication for the medicinal product in question.

What about non-patented products?

Under the Regulation, it is not obligatory to conduct paediatric studies for medicinal products that are not the subject of a patent or SPC (so-called 'off-patent approved products'). Marketing authorisation holders for these products may voluntarily conduct clinical trials in paediatric populations under an agreed PIP which, if successful, may give rise to a Paediatric Use Marketing Authorisation (PUMA).

A PUMA provides an additional ten years regulatory data protection for use of the medicinal product in a paediatric population for the approved therapeutic indication(s). The introduction of this provision was intended to stimulate the development of off-patent products for use in paediatric populations.

So far, so good?

In part, yes. It has recently been reported[5] that six-month SPC extensions have been granted in certain EU member states for the following drugs: anastrazole (Arimidex®), abatacept (Orencia®), caspofungin (Cancidas®), losartan (Cozaar®), valsartan (Diovan®) and zoledronic acid (Zometa®).

However, despite this encouraging news, concerns remain. Some question whether the requirements of the Regulation are simply too onerous in practice, whilst others have criticised the language of the Regulation for being too vague and unclear. This latter concern has already given rise to disputes between national patent offices and applicants seeking rewards for their investments[6]. Disharmony in decisions at a national level will likely prompt referrals to the European Court of Justice in due course.

Interestingly, of the 1,000 applications for PIPs or waivers received the EMA reports that 'more than' 450 have received a positive opinion. Whether that equates to the glass being half empty or half full is perhaps dependent upon which side of the fence you happen to be standing.

Author:
Lawrence King

Footnotes

1. *http://bit.ly/emapip - European Medicines Agency receives 1,000th application for a Paediatric Investigation Plan or Waiver, 8 October 2010.*
2. *The Regulation came into force on 26 January 2007 and became applicable to off-patent approved products on 26 July 2007, to new medicinal products on 26 July 2008, and to patented approved products on 26 January 2009.*
3. *Where granted, an SPC provides independent, post-patent expiry protection for a medicinal product that is the subject of a basic patent. It is intended to compensate pharmaceutical companies for any loss in patent term associated with seeking regulatory approval for their products. The maximum term of the extension is five years.*
4. *In Europe, new medicinal products are protected by '8+2' years RDP; ie, during eight years from the date of the first marketing authorisation (MA) a generic company may not refer to the MA dossier of the originator product and file an abridged application. After eight years, they may do so but, for a further two years, they may not market a generic version of that product.*
5. *http://bit.ly/spcblog*
6. *See BL O/108/08 (Merck & Co, Inc), 14 April 2008 and BL/O/096/09 (EI Du Pont De Nemours), 9 April 2009 – the latter decision was reported in our October 2010 newsletter.*

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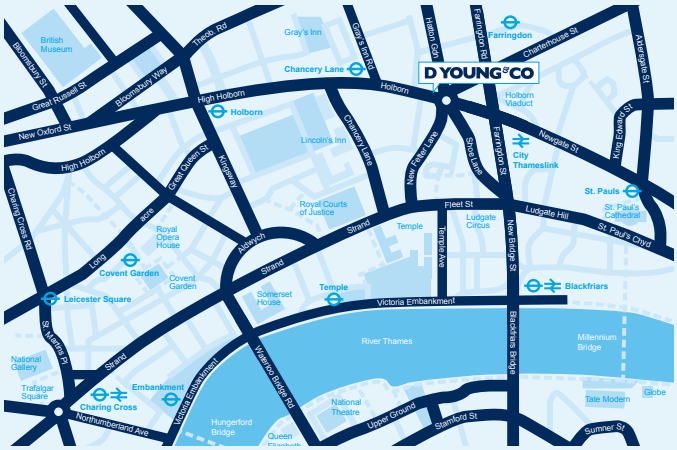

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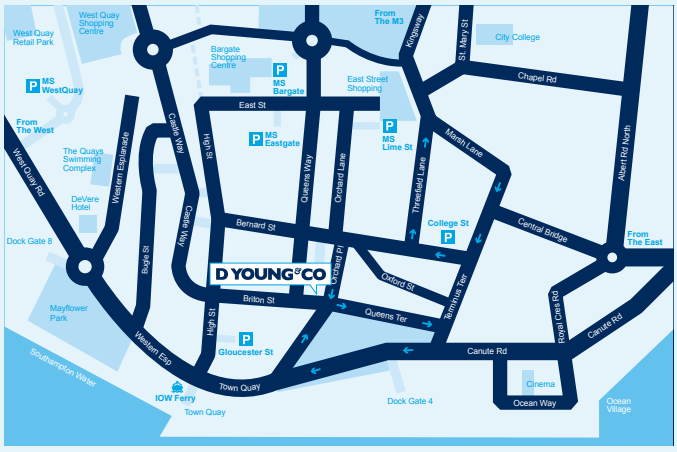

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