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The ten minute read that highlights topical issues for bio and life science sector participants

The changing face of US patent prosecution

The last two years have seen a number of significant changes to US patent prosecution. As European practitioners we understand the importance of keeping abreast of developments across the Atlantic to ensure a consistent approach to the management of worldwide patent portfolios. Here we review the most recent US developments and the implications of these to our practice.

In March 2013 the America Invents Act (AIA) came into force (as reported **here**) heralding a move from a "first to invent" to a "first to file" system. This change has more closely aligned the US with the patent filing system already operating in Europe and has therefore not largely altered our filing strategies. However, it has made it even more important for patent applications to be filed as soon as there are sufficient data to support an application. The AIA has also revised and expanded the post-grant procedures available to Patentees and third parties in the US, something we are already familiar with in Europe.

In something of a landmark decision, the Supreme Court created uncertainty surrounding the future of diagnostic method claims in the US by deciding that claims to methods which merely apply a law of nature are not patent eligible (*Mayo Collaborative Services v Prometheus Laboratories Inc.*). Further uncertainty in this area was created when the Supreme Court decided that a naturally-occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated (*Association of Molecular Pathology v. Myriad Genetics*; reported **here**).

Following the Supreme Court's decisions in Myriad and Prometheus, the USPTO issued in March a Guidance document clarifying the procedure to be used for evaluating subject matter eligibility of claims considered to relate to laws of nature, natural phenomena or natural products (reported **here**). The Guidance sets out a three-part test for assessing whether a claim relates to patent-eligible subject matter. Once it has been established that the claim is directed to one of the four statutory patent-eligible subject matter categories (process, machine, manufacture, or composition of matter) and recites or involves one or more judicial exceptions (abstract ideas, laws of nature/ natural principles, natural phenomena and natural products), the Examiner is required to determine whether the claim as a whole recites something significantly different than the judicial exception. The Guidance document highlights multiple factors which should be considered in this analysis. Our ongoing strategic challenge is to work within the guidelines to obtain commercially useful patent protection for products and methods which may have been developed from naturally-occurring products or methods relating to "natural correlations".

Most recently, the Supreme Court has unanimously ruled that a defendant cannot be liable for inducement of infringement of a method claim where there is no direct infringement, i.e. where no single party has carried out all the steps of the claimed method (*Limelight Networks, Inc., Petitioner vs Akamai Technologies, Inc., et al. No. 12-786*; reported **here**). This decision adds a further layer to the challenge of developing alternative claim strategies complying with the new guidelines for overcoming patent eligibility issues since patentees will now first be required to demonstrate that there has been a direct infringement.

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AUTUMN ISSUE

NEWS FROM THE BIOTECH TEAM

> Boults Biotech team has recently welcomed **Dr James Legg** to the team as a qualified attorney in the Cambridge office. James is an experienced attorney in the bio and life sciences field and has expertise in technology areas spanning biological and small molecule therapeutics, genetic engineering, stem cell technology and biomedical products and devices. James will be presenting at the sixth annual conference on RNA Therapeutics to be held in London, 16-17 February 2015. For more information about this conference, see **here**.

> In September, **Claire Baldock** and **Joanna Peak** attended the AIPPI World Intellectual Property Congress in Toronto. As reported in our **Summer newsletter**, prior to the Congress, Claire and Joanna led the AIPPI UK Working Committee in putting together a report focusing on the patenting and enforcement of second medical use claims. This topic was debated at an international level during the Congress, and AIPPI have now adopted a Resolution, the purpose of which is to seek harmonisation to the laws in this area internationally. Copies of the UK report and the AIPPI Resolution can be found **here** and **here**. Claire recently followed up her work as Chair of the AIPPI UK working committee by presenting the results of this AIPPI debate at a Reception hosted by Allen & Overy.

> **Matthew Spencer** has recently published an article in Nature's BioPharma Dealmakers commenting on the recent guidance from the USPTO relating to patent-eligible subject matter. In this article, Matthew questions whether the guidance given threatens to stifle investment and innovation. The full article can be found **here**.

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The issues discussed above have had a real impact on our strategies for drafting patent applications intended for prosecution in the US, as well as our approach to prosecuting these applications as we seek to obtain worldwide protection for our clients. However, it must also be noted that in response to significant lobbying following issuance of the USPTO's Guidance a replacement set of guidelines for addressing patent eligibility issues is expected imminently. It is hoped that this revised Guidance will allay real concerns that the previous Guidance was making new law and went far beyond the Supreme Court decisions on which it was based. As implementation of the law progresses we will continue to expand and develop strategies for addressing the complex issues arising from recent changes in the US.

> And finally, the Boults Biotech team has been celebrating yet more exam success with **Naomi Stevens** passing the European Qualifying Examination this summer. Naomi's paper B answer has been selected for publication in the annual EQE Compendium as a model answer.

HEADLINE ARTICLES

UK Patents Court interprets CJEU's decision in *Eli Lilly v HGS* (C-493/12)

In December 2013, the CJEU handed down its ruling in *Eli Lilly v HGS* (**C-493/12**), providing clarification as to interpretation of Article 3(a) of the SPC regulation (469/2009/EC). In that judgment the CJEU ruled that a functional definition of an active ingredient in a claim is enough to obtain an SPC, provided the claims relate *"implicitly but necessarily and specifically to the active ingredient in question"*. The UK Patents Court has now interpreted the CJEU's judgment and concluded that a claim directed to an antibody that binds specifically to a recited antigen is considered to implicitly but necessarily and specifically define an active ingredient. The UK Court's decision (see **here**) indicates that SPCs based upon functional claims can be valid in the UK. However, Eli Lilly have been granted leave to appeal, so we may not have heard the final word on this issue.

Please click **here** for full bulletin.

A broader research exemption from patent infringement in the UK

The Legislative Reform (Patents) Order 2014 was placed before Parliament on 6 May 2014 to amend the UK Patents Act 1977 in order to extend the existing exemptions for certain clinical trials from patent infringement. This Order came into effect on 1 October 2014, and changes section 60 of the UKPA such that in certain cases, the testing of patented innovative drugs is exempt from infringement. In particular, it is now possible for companies to use patented products when carrying out testing or other activity to provide information to the regulatory authorities who decide upon marketing authorisations. It is also possible to use patented products in testing or other activities carried out to supply information for health technology assessments. This broadening of the so-called "Bolar" exemption is a welcome change to UK law and should make the UK a more attractive place for drug companies conducting trials relating to innovative drugs.

Please click **here** for full bulletin

The CJEU rules in favour of SPCs for safeners in plant protection products (C-11/13)

In a referral from the German Federal Court (**C-11/13**), the CJEU was asked to clarify whether safeners fall within the scope of the term "active substances" within the meaning of Regulation 1610/96 relating to SPCs for plant protection products. Safeners are an interesting class of chemical compounds, which enhance the phytotoxic effects of herbicidal compounds typically by reducing the herbicidal injury to the desired crop species whilst providing no protection to competing weed species. The CJEU has ruled that substances intended to be used as safeners in plant protection products can, in principle, be the subject of an SPC provided the substance has a toxic, phytotoxic or plant protection action of its own. It has however, been left to the national courts to decide on a case-by-case basis whether a particular safener has the activity required to fall within the definition of an "active substance" according to the SPC Regulation.

Please click **here** for full bulletin.

We aim to work with our clients, not just for them

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