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Boult.bites Biotech

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

How may Brexit affect SPCs and PVRs?

On 23 June 2016, the UK voted to leave the European Union (EU) and the upshot of this result is that a great deal of uncertainty exists in many sectors. Importantly, both the UK and current European Patent Systems remain wholly unaffected by this vote to leave since the European Patent Convention (EPC) is completely independent of the EU. European Patent Attorneys in the UK will retain the right to represent their clients before the EPO and it will still be possible to obtain patent protection in the UK via the European patent system. There are however, other IP rights that may be affected by the Brexit vote due to the involvement of EU law, and in the biotechnology sector these rights include Supplementary Protection Certificates (SPCs) and Plant Variety Rights (PVRs).

Notwithstanding any future changes to SPCs and/or PVRs, until the UK leaves the EU, practice relating to these IP rights remains unchanged. However, certain issues for future consideration are summarised below.

As the situation currently stands, the granting of SPCs in the UK is governed by EU legislation, in particular **Regulation (EC) 1610/96** concerning SPCs for plant protection products and **Regulation (EC) 469/2009** concerning SPCs for medicinal products. At the point at which the UK leaves the EU, provisions will need to be in place for SPCs in the UK and it remains to be seen how this will be managed. It is possible that if the UK becomes part of the European Economic Area (EEA) similar to Norway, the EU SPC Regulations will continue to apply. Alternatively, the UK may take the opportunity to enact independent UK SPC legislation, similar to the situation in Switzerland. In addition to the uncertainty surrounding the legal framework for granting of SPCs in the UK, there are a number of further issues to be considered. These include the impact of the new Unitary Patent system and Unified Patent Court (if these come into effect) and the potential for a "Unitary SPC" in the future which may or may not include the UK. Of course, the fate of the Unitary Patent and UPC has been called into question with the UK's vote to leave the EU and more information on this separate topic can be found on our website **here**. In addition, the relationship between obtaining SPC protection and the EU-wide authorisation of medicines by the European Medicines Agency (EMA – currently based in London) will mean that any changes to marketing authorisations covering the UK could impact future SPCs.

For plant varieties, IP protection in the UK is currently available either via stand-alone UK Plant Breeders' Rights (PBRs) or via EU-wide Community Plant Variety Rights (CPVRs). Whilst UK PBRs will be unaffected by the exit of the UK from the EU, the impact on CPVRs extending to the UK is unclear and will depend on the UK's relationship with the EU post-Brexit. As for SPCs, it may be that the EU CPVR legislation will continue to apply. In this scenario, the impact is expected to be minimal: we would expect CPVRs in force at the time to continue to extend to the UK, although entities without a presence in an EU country may not be able to act directly at the CPVO. Alternatively, CPVR legislation may cease to apply when the UK leaves the EU and CPVRs in force at the time may cease to extend to the UK. In this instance, we would expect transitional provisions to be enacted allowing existing CPVRs to be converted into stand-alone UK PBRs. Subsequently, IP protection for plant varieties

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AUTUMN ISSUE

News from the Biotech team

> The Biotech team has recently welcomed **Dr Jason Rutt** as an attorney in the London office. Jason has nearly 20 years' experience in the patent profession including in-house experience as ex head of Pfizer's UK patent department and emerging market experience with an international law firm. Jason's background is in organic chemistry and his patent practice focuses primarily on the Life Sciences industry.

> The partners in the Biotech team have been highlighted as "IP Stars" in the Managing Intellectual Property 2016 rankings. Head of the Biotech team **Claire Baldock** has been described as "one of the very top life science patent attorneys around" and is ranked in the top 250 women worldwide in IP. **Nina White** and **Matthew Spencer** are also recommended for work in the biotech sector.

> **Claire Baldock** recently attended the 2016 AIPPI World Congress in Milan. As Chair of the AIPPI International Biotech Committee, Claire was responsible for compiling a report summarising recent developments in biotech practice worldwide ahead of the Congress. If you would like to contact Claire to discuss her involvement with AIPPI or the reports drawn up by the Biotech Committee, please see **here**.

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in the UK would need to be via a direct UK PBR, for example one filed alongside any CPVR application. If you are thinking of applying for IP protection in the EU and the UK is particularly important, a parallel UK PBR application in addition to any CPVR application should be considered. It should also be kept in mind that for plant-related inventions where the technical contribution is not confined to one plant variety, patent protection may also be available.

A final consideration is the impact of Brexit on entry of varieties onto the UK National List and EU Common Catalogue of varieties approved for marketing in the EU. Currently, varieties approved for entry on the UK National List are automatically entered onto the EU Common Catalogue. We would not expect varieties already in the Common Catalogue by virtue of a UK National Listing to be removed as a result of the UK leaving the EU. Once the UK has left the EU, however, varieties newly entered on the UK National List are unlikely to be included in the Common Catalogue. Instead, marketing approval of the variety in an EU member state would likely be required.

Despite the many unknowns, we will continue to keep you updated in this area as things progress, and if you have any concerns regarding SPCs or PVRs, please do not hesitate to contact the partners in our Biotech team for more information.

> **Nina White** was recently invited to speak at the Michael Best Summit for Life Sciences in Chicago, Illinois. Nina's presentation focussed on recent developments in European case law relating to Supplementary Protection Certificates (SPCs). To contact Nina to discuss any SPC queries, please see **here**.

> The Biotech team is pleased to welcome **Jennifer O'Farrell** back from maternity leave. Jennifer was recently mentioned in the IAM Patent 1000 as being a "first-class attorney, on top of the law and possessed of fantastic personal skills", and we are happy to see her return to the London office.

HEADLINE ARTICLES

USPTO issues updated guidance relating to subject matter eligibility

In May 2016, the United States Patent and Trademark Office (USPTO) issued further guidance regarding the assessment of US patent applications relating to laws of nature, natural phenomena or natural products, with a focus on biotechnological inventions (see **here**). This guidance follows the initial USPTO guidance issued back in 2014, which attempted to clarify the law relating to subject matter eligibility in light of US Supreme Court decisions including *Association for Molecular Pathology v. Myriad Genetics Inc.* and *Mayo Collaborative Services v. Prometheus Laboratories Inc*. The new guidance is welcome in that it requires US Examiners to offer a much more detailed rationale to support patent-ineligibility type objections, and offers a number of helpful examples that will allow applicants to rebut such objections and/or amend claims to overcome such objections. For more information, see our full bulletin **here**.

UK Patents Court rules prior use of Meningitis B vaccine not an "enabling disclosure"

A recent decision concerning *GlaxoSmithKline* and *Wyeth Holdings* (see **here**) has provided the High Court an opportunity to review what constitutes an "enabling disclosure" in the context of assessing novelty. In these proceedings, GSK had lodged a claim for revocation of Wyeth's patent relating to a Meningitis B vaccine. Wyeth counterclaimed for infringement by GSK's Bexsero vaccine. The novelty of Wyeth's patent was questioned based on the prior use and prior description of vaccines that contained the same active ingredients. However, the High Court decided that neither the use nor the description constituted "enabling disclosures". Ultimately, Wyeth's patent was held to be valid, and GSK's Bexsero vaccine was found to infringe. For more information, see our full bulletin **here**.

UK High Court confirms that dosage regimen patents can be considered inventive

Tadalafil is a phosphodiesterase type 5 (PDE5) inhibitor marketed by Eli Lilly under the brand name Cialis® for the treatment of erectile dysfunction and under the brand name Adcirca® for the treatment of pulmonary arterial hypertension. Global sales of Cialis alone totalled $2.29 billion in 2014, whilst the US sales of Adcirca totalled another $1 million. In Europe, SPCs derived from ICOS Corporation's original tadalafil patent (EP0740668) are due to expire in November 2017. However, ICOS Corporation owns two European follow-up patents, for which Eli Lilly holds an exclusive licence. These patents were attacked by Actavis, Actelion, Teva and Generics (UK) as they sought to clear the way for launch of their own generic products. Here the **UK High Court** has confirmed the inventive step of a dosage regimen patent (EP1173181), but revoked a follow-on patent relating to a specific formulation of tadalafil (EP1200092). For more information, see our full bulletin **here**.

New Referral to the CJEU on Article 3(b) of the SPC Regulation

A reference has been made to the Court of Justice of the European Union (CJEU) by Mr Justice Arnold on the Supplementary Protection Certificate (SPC) Regulation in *Merck Sharp & Dohme v Comptroller-General of Patents* **[2016] EWHC 1896**. The main issue in question is whether a so-called "end of procedure notice" can be considered equivalent to a granted marketing authorisation for the purposes of Article 3(b) of the SPC Regulation. In the event that the answer to this question is "no", the referral also seeks to clarify whether in the absence of a granted marketing authorisation at the date of application for an SPC, this irregularity can be cured under Article 10(3) of the SPC Regulation once the marketing authorisation has been granted. For more information, see our full bulletin **here**.

We've listened to what our clients told us. Now we're acting on it

We know that it makes business sense to get to know our customers and to build our services around their needs. For us, our service is about people, not just IP. That means responding to our clients with commercial understanding as well as technical and legal expertise if we are to guide them to the best solution for their needs. We want people to choose Boult Wade Tennant and stay with us because they know we will work with them, not just for them.

To strengthen our understanding of what excellent service means to our clients and to ensure we are well placed to respond to changing client needs, we have invested in a programme of client research, conducted by an independent agency. This research has measured our service against those indicators that really matter to our clients and has, for the first time, allowed us to accurately benchmark ourselves against competitors in our sector. You're invited to read our **Client Feedback Report**.

> Missed the last edition of boult.bites Biotech? Catch up by clicking **here**

WHAT WE DO >
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We aim to work with our clients, not just for them

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