

Boult.bites Biotech

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

News from the biotech world

The last few months have seen a number of judgments handed down by the UK courts. In this edition of Boult.bites Biotech we feature a selection of these cases covering *Arrow* declarations, SPCs and the core concept of plausibility.

Arrow Declarations

In a landmark decision by the UK High Court, *Fujifilm Kyowa and AbbVie* [2017] EWHC 395 (Pat), the first *Arrow* declaration has been granted, providing Fujifilm with the clearance needed to launch their biosimilar of the blockbuster drug Humira once AbbVie's SPC expires. This decision was preceded by a Court of Appeal judgment, *Fujifilm Kyoma and AbbVie* [2017] EWCA Civ 1, in which it was confirmed that *Arrow* declarations are, in principle, a permissible remedy that may be granted under particular circumstances. Although the High Court decision is notable as the first time an *Arrow* declaration has been awarded in the UK, it has been emphasised that such declarations will not be available when a claimant simply wants to know whether a patent application will result in a valid patent – rather, they should be available when the usual statutory remedies are being frustrated by the shielding of subject matter from scrutiny by the national courts. See below for more information relating to both judgments.

SPCs

The interpretation of Article 3 of the SPC Regulation (469/2009/EC) continues to frustrate the UK courts and there have been two recent referrals to the CJEU from the UK High Court in the cases *Teva UK Limited & Ors and Gilead Sciences Inc* [2017] EWHC 13 (Pat) and *Abraxis Bioscience LLC and The Comptroller-General of Patents* [2017] EWHC 14 (Pat). The first referral concerns the interpretation of Article 3(a) and asks yet again, what are the criteria for deciding whether “the product is protected by a basic patent in force”. The second referral concerns Article 3(d) and in particular, whether an SPC can be granted for a product which is a new formulation of an old active ingredient. Despite the frustrations concerning interpretation of the SPC Regulation, the UK High Court was able to rule in the recent case *Teva UK Limited & Ors and Merck Sharp & Dohme Corporation* [2017] EWHC 539 (Pat) that MSD's SPC for the combination HIV product, Atripla, was invalid because it did not comply with Article 3(a) or 3(c). These referrals and the recent High Court decision are discussed in more detail below.

Plausibility

The issue of “plausibility” is a key concept in patent law and we have previously discussed a significant number of UK court decisions where the outcome has turned on this issue (see [here](#)). The consideration of plausibility continues to feature in UK decisions and was at the forefront of the judgments in both *Idenix Pharmaceuticals Inc and Gilead Sciences Inc* [2016] EWCA 1089 and *Merck Sharpe and Dohme Limited and Shionogi & Co Limited* [2016] EWHC 2989 (Pat). Both of these judgments are discussed in more detail below.

SPRING ISSUE

News from the Biotech team

> **Nina White** has succeeded **Claire Baldock** as Head of the Biotech and Life Sciences team. Nina will work together with **Matthew Spencer**, who heads-up the Cambridge Biotech practice, to lead the team when Claire retires at the end of April.

> **Joanna Peak** and **James Legg** have recently been appointed partners of the firm, and will continue to work with Nina and Matthew to develop Boult Wade Tennant's London and Cambridge Biotech practice.

> **Matthew** and **James** will both be attending the **BIO International Convention** in San Diego from 19-22 June 2017. Matthew will be moderating a panel session exploring the impact of Brexit on the future for patent prosecution, litigation and commercial transactions involving patents in Europe. If you would like to arrange to meet the team at BIO, please do not hesitate to contact us.

> The Biotech team would like to congratulate **David Wortley**, who recently passed the UK Qualifying Examinations FD1 (P2) and FD4 (P6), and also **Nadia Tyler-Rubinstein**, who passed the Certificate in Intellectual Property Law postgraduate course at the Queen Mary University of London with distinction.

> And finally a warm welcome to **Matthew Cornwall** who has joined the Biotech team as a trainee patent attorney in Cambridge. Matthew was recently awarded a PhD in Chemical Biology & Molecular Medicine from the University of Cambridge.

Court of Appeal discusses impact of common general knowledge

The UK Court of Appeal recently issued a decision in *Idenix Pharmaceuticals Inc and Gilead Sciences Inc* [2016] EWCA 1089. This case concerned Idenix's EP(UK) 1,523,489 patent, which is directed to a family of nucleoside analogues for treating hepatitis C virus (HCV) infection, and which Idenix considered to be infringed by sales of Gilead's sofosbuvir drug. At first instance Mr Justice Arnold had revoked the patent for both insufficiency and lack of inventive step because the common general knowledge was not considered to make it plausible that the invention would work across the scope of the claims. The Court of Appeal has now endorsed the first instance decision and confirmed that a patent is considered to be insufficient and to lack inventive step if the technical effect relied upon is not demonstrated across the scope of the claims. See [here](#) for our full bulletin.

Combination products must be "distinct inventions" for SPC protection

A recent decision from the UK High Court has shed further light on the granting of multiple SPCs to protect single ingredient products and related combination products, *Teva UK Limited and Merck Sharp & Dohme Corporation* [2017] EWHC 539 (Pat). In this case the claimants, Teva, Accord and Mylan, challenged the validity of MSD's SPC, which was directed to an antiretroviral combination product for the treatment of HIV. The claimants contended that the SPC did not comply with either Article 3(a) or Article 3(c) of the SPC Regulation (469/2009/EC). In finding MSD's SPC invalid, the judge reviewed recent case law from the CJEU concerning Article 3 and confirmed that, at least in the UK, a combination product including an active ingredient for which an SPC has already been granted must represent a "distinct invention" in order for a combination SPC to be granted. See [here](#) for our full bulletin.

Arrow declarations – a permissible remedy

In an ongoing dispute between *Fujifilm Kyoma and AbbVie*, the English Court of Appeal has ruled that *Arrow* declarations are, in principle, a permissible remedy that can be granted by the Patents Courts to parties seeking to establish freedom to operate (see *Fujifilm Kyoma and AbbVie* [2017] EWCA Civ 1). This is an interesting decision for companies in the biotechnology and pharmaceutical sectors, who may be looking to achieve commercial certainty prior to launch of a generic product. More generally, *Arrow* declarations may be the relief needed to protect against infringement claims from innovator companies who own large secondary patent portfolios and who attempt to shield their patents from challenges before the national courts. See [here](#) for our full bulletin.

HIV drug patent found invalid; plausibility is key once again

In a recent case before the UK Patents Court, *Merck Sharpe and Dohme Limited and Shionogi & Co Limited* [2016] EWHC 2989 (Pat), MSD has succeeded in its action for revocation against European patent EP 1422218B, owned by Shionogi & Co Limited. Shionogi alleged infringement of their patent by MSD's product raltegravir, an anti-HIV therapy that has been on the market since 2007. MSD denied infringement and sought revocation. In finding the claims of the patent invalid for lack of inventive step and insufficiency, the judge reinforced the need to plausibly demonstrate therapeutic efficacy across the full scope of second medical use claims in order to achieve robust patent protection. See [here](#) for our full bulletin.

UK High Court makes attempt to clarify SPC Regulation

Over the last decade it has become apparent that interpretation of European Regulation 469/2009/EC (the SPC Regulation) is far from straightforward. To seek further clarification, the UK High Court has referred yet more questions to the CJEU. The first referral concerns the interpretation of Article 3(a) and what is required for a product to be considered "protected by a basic patent in force". The SPC at issue is for an HIV combination treatment, Truvada®, and the issue of patent protection turns on whether both specific ingredients of the combination need to be explicitly recited in the claims. The second referral relates to whether SPCs can be granted for new formulations of known products or whether Article 3(d) precludes this. See [here](#) for our full bulletin.

Landmark case awards first Arrow/Fujifilm declaration

In *Fujifilm Kyoma and AbbVie* [2017] EWCA Civ 1, the Court of Appeal ruled that *Arrow* declarations are, in principle, a remedy able to be awarded by the Patents Court. A subsequent decision (*Fujifilm Kyowa and AbbVie* [2017] EWHC 395 (Pat)), has shown that such declarations will be awarded in circumstances where a party is frustrating the normal statutory remedies. This judgment is notable as the first time a declaration such as this has been awarded in the UK. Such "Fujifilm declarations" could provide a mechanism for companies to clear the way even when no patent has been granted. However, it has been emphasised that such declarations will not be available when a claimant simply wants to know whether a patent application will result in a valid patent. See [here](#) for our full bulletin.

And finally, a message from Claire...

*"As some of you may know, I will be retiring at the end of April. I am very sad to be stepping down as Head of the Biotech group but leave behind an incredibly talented team who I know will be able to help you with all future Biotech matters. I will be continuing my work with AIPPI and look forward to seeing many of you at the **AIPPI Congress** in Sydney in October this year."*



EDITOR

Joanna Peak, Partner

CONTRIBUTORS

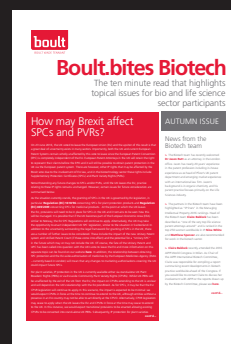
Jennifer O'Farrell, Patent Attorney

Edward Ronan, Patent Attorney

Jason Rutt, Patent Attorney

Nadia Tyler-Rubinstein, Trainee Patent Attorney

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