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Impact of Actavis UK Ltd and others v Eli Lilly and Company

In July 2017 the UK Supreme Court issued its decision in **Actavis UK Ltd and others v Eli Lilly and Company ([2017 UKSC 48])**, which we previously reported on **here**. The central issue decided upon by the Supreme Court was the direct infringement of Lilly's EP1313508B patent, with claims directed to use of pemetrexed disodium, by Actavis' pemetrexed diacid, pemetrexed dipotassium and pemetrexed ditromethamine products. This is being hailed as a landmark decision in the UK, essentially introducing a doctrine of equivalents into UK patent practice.

Introducing a doctrine of equivalents into the UK effectively broadens the scope of protection afforded by a patent claim, at least insofar as it relates to potential infringement by a variant, and shifts the focus from the wording of a patent claim to the core inventive concept underlying the claimed invention. Here we review the effects associated with the introduction of a doctrine of equivalents into the UK on the drafting and prosecution of patent applications, freedom to operate opinions and infringement actions.

Effect on the drafting and prosecution of patent applications

The introduction of a doctrine of equivalents is likely to impact the way in which patent applications destined to become patents enforceable in the UK are drafted and prosecuted. As Applicants seek to ensure that any granted patent is interpreted as broadly as possible in order to provide the greatest scope of protection and catch the greatest number of infringers changes to patent practice are likely to be seen.

It is apparent from the present decision that upon considering the infringement of a patent by a variant, the core inventive concept of the claimed invention will now be fundamental. Therefore, upon drafting a patent application Applicants should ensure that the core inventive concept is fully understood. Of course, the application should fully describe the invention, but it appears as though it is also now particularly important to describe how components of the invention produce the technical effect which represents the core of the invention. In doing so, Applicants increase their chances of extending the scope of protection of any granted patent to variants which produce substantially the same result in substantially the same way. The inclusion of this information in the application as filed could be particularly important if it is not apparent from the invention itself that a potentially infringing variant would achieve substantially the same effect in substantially the same way. A shift in the relevant date for assessing the understanding of the skilled person from the publication date to the date of the alleged infringement presents a further challenge since future technical developments cannot be fully contemplated upon drafting a patent application.

During prosecution, the claims of a patent application may be amended for a variety of reasons, including validity in view of the prior art, added matter, sufficiency, clarity and unity. Previously, making such limitations would have been considered to have a real limiting effect on the scope of the claims. However, the present decision suggests that making limitations during prosecution may not actually represent a real limitation on the scope of protection if variants demonstrating the core inventive concept are considered to infringe a claim. Of course, the most straightforward way to ensure that a variant will eventually be considered to fall within the scope of a granted patent is to maintain broad claim language during prosecution. Nevertheless, we may see Applicants less reluctant to limit claims during prosecution if they consider that the newly introduced doctrine of equivalents will retain protection over infringing variants demonstrating the core inventive concept of the invention.

Continued

AUTUMN ISSUE

News from the Biotech team

> **Jennifer O'Farrell** has recently been appointed a partner of the firm. Jennifer was recently mentioned in the **IAM Patent 1000** as a "life sciences ace", and will continue to work with other members of the team to develop Boult Wade Tennant's biotech practice.

> **Jennifer** will be attending the **BIO-Europe** convention in Berlin from 6-8 November 2017. If you would like to arrange to meet Jennifer at the convention, please do not hesitate to contact us.

> **Joanna Peak** will be attending the **AIPLA Annual Meeting** in Washington from 19-21 October 2017 with partner, and Head of Chemical and Materials, **Adrian Hayes**. If you would like to arrange to meet the team in Washington, please let us know.

> The Biotech team would like to congratulate **David Wortley**, who recently passed the European Qualifying Examinations (EQEs), and is now qualified as a UK and European Patent Attorney.

> **David** will be attending the **Chemistry and Industrial Biotechnology Showcase** in York on 20 & 21 September 2017, and will be offering free IP advice via the one-to-one meeting platform. If you would like to arrange to meet David at the showcase, please do not hesitate to contact us.

> Former head of the Boult Wade Tennant Biotech team and current consultant, **Claire Baldock** will be attending the annual **AIPPI World Congress** in Sydney from 13-17 October 2017. If you would like to arrange to meet Claire at the Congress, please let us know.

Effect on freedom to operate analysis, oppositions and invalidity actions

Many third parties conduct freedom to operate analysis in advance of launching a product which they consider may be the subject of patent protection. Should this analysis identify a relevant patent, opposition proceedings and invalidity actions are often brought in advance of a product launch. The present decision may have an impact on the validity of previously issued opinions, the scope of opinions issued in the future and the decisions taken regarding the relevance of a patent upon clearing the way for a product launch.

Freedom to operate advice provided in the future will need to account for the change in claim analysis provided by the present decision. Specifically, analysis will need to utilise the two-step approach to claim interpretation and the reformulated Improver questions set out in the Supreme Court's decision. Patent practitioners providing such advice are likely to be cautious in the coming months and years, as we determine the full impact of the present decision and the effective increase in claim scope provided by it. In the immediate future it seems likely that advice will suggest a broad claim interpretation, and that third parties will be advised to take appropriate precautions before launching a variant product, particularly if the variant product is considered to share the core inventive concept of a patented invention. This may lead to an increase in the number of invalidity proceedings, including UK national proceedings and EPO opposition proceedings taking place before the launch of a variant product. Such clearing the way strategies could resemble the approach currently taken by third parties looking to clear the way prior to the launch of a biosimilar or generic product.

Effect on infringement actions

The present decision may lead to an increase in the number of infringement actions brought in the UK courts, as Patentees seek to take advantage of the doctrine of equivalents. Patentees may now consider bringing actions against third parties marketing variants of patented products which may previously not have been considered to fall within the scope of a granted patent claim.

Questions may be asked by the courts if a Patentee has knowingly allowed a variant to be marketed without bringing an infringement action, only to start an infringement action several years later, and it remains to be seen whether the introduction of the doctrine of equivalents will be considered a viable defence. Of course, the statute of limitations will preclude an action being brought more than six years after a potentially infringing event, but it is still possible that we will see an increase in the number of actions being brought in the coming months and years.

Adapted from original article by Jennifer O'Farrell in Practical Law.

HEADLINE ARTICLES

"Plants and animals obtained by an essentially biological breeding process" excluded from patentability

The **Administrative Council of the EPO** has announced that it has taken the decision to amend the relevant Regulations in order to exclude from patentability "plants and animals exclusively obtained by an essentially biological breeding process". The EPO has also removed the stay previously applied to all proceedings in which the invention is a plant or animal obtained by "essentially biological processes". The new provisions were brought into force on 1 July 2017. This is contrary to the Enlarged Board of Appeal's decisions in **G2/13** and **G2/12** (**Broccoli II** and **Tomatoes II**), which held that plant products produced by "essentially biological processes" (for example, sexual crossing) were patent eligible even if the only method available at the filing date for generating the plant product is such a process. See **here** for our full bulletin.

UK High Court provides guidance on Supplementary Protection Certificates based on Markush claims

In a recent judgment (**Sandoz Limited and G.D. Searle LLC [2017] EWHC 987 (Pat)**) the UK High Court has upheld the validity of an SPC where the specific compound for which marketing authorisation has been granted falls within the scope of a claim defining a class of alternative compounds (a so-called Markush claim), but is not itself specifically identified in the claims. In this decision, the High Court provided an analysis of what is meant by "protected by a basic patent" in Article 3(a) of the SPC Regulation (EC No. 469/2009) and held that Searle's SPC granted for the anti-retroviral drug darunavir is valid despite the compound not being specifically identified in the claims of the patent on which the SPC is based. See **here** for our full bulletin.

Plausibility - EPO confirms requirements for using post-filed data to support a technical effect

The EPO's Board of Appeal recently revoked a **patent** covering Bristol-Myers Squibb's blockbuster oncology drug dasatinib (marketed as Sprycel®). In this decision (**T488/16**) the Board of Appeal agreed that whilst it is not always necessary to include experimental data in an application, it is however essential that it is shown that the technical problem underlying the invention was at least plausibly solved at the filing date. The Board judged that it is not acceptable to merely draw up a generic formula covering millions of compounds, vaguely indicate an "activity" and leave it to the skilled reader to establish which compounds may be suitable to treat a certain disease. See **here** for our full bulletin.

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