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Swiss-type claims vs EPC2000 claims – equivalent or different?

In Europe, methods of treatment are not patentable per se. However, European patent law permits claims directed to therapeutic uses of known substances or compositions, including second or further medical uses of known pharmaceutical compounds. Under current EPO practice, second medical use claims are to be drafted as purpose-limited product claims according to the format: *Substance X for use in the treatment of disease Y*. However, prior to the entry into force of EPC2000, second medical uses could only be protected by Swiss-type claims of the format: Use of *substance X in the manufacture of a medicament for the treatment of disease Y*.

The Swiss-type and EPC2000 claim formats co-existed for a time until the Enlarged Board of Appeal at the EPO ruled in **G2/08** that Swiss-type claims were no longer required and would not be permitted in applications with an earliest priority date of 29 January 2011 or later. Although Swiss-type claims are being phased out of pending European applications, patents granted with such claims are still valid and will continue to exist for many years to come.

Unfortunately, a great deal of uncertainty exists as to whether or not Swiss-type claims and EPC2000 second medical use claims are equivalent in scope. This situation has been confused further by comments made in recent decisions from the EPO Board of Appeal and the UK High Court. As such, we provide below a roundup of key decisions in this area and explain why the situation may not be as divergent as it appears.

The EPO: In **G2/08**, it was noted that in the explanatory text to the revised EPC, the protection afforded by an EPC2000 claim was said to be equivalent, as far as further uses are concerned, to that offered by the Swiss-type claim. It was in fact stated that the limitation in an EPC2000 claim is "*intended to match as closely as possible*" the scope of protection provided by a Swiss-type claim. In this same decision however, the Enlarged Board went on to suggest at paragraph 6.5 that the rights conferred on the patentee by EPC2000 claims are "*likely broader*" than Swiss-type claims, thereby casting doubt on the equivalence of these claims.

At some levels, the EPO has continued to pursue a line in which these two types of claim are different in scope. In **T250/05**, the Board of Appeal held that converting a Swiss-type claim to an EPC2000 claim would extend the scope of protection and therefore this amendment could not be made post grant. More recently, in **T1780/12**, the Board held that an applicant could have two European patents, one with a Swiss-type claim and one with an EPC2000 claim, and this would not amount to double patenting because these claims are not equivalent in scope.

The UK Courts: In contrast to the approach taken by the EPO, the UK courts have generally accepted the artificial nature of Swiss-type claims as a means of protecting second medical uses, and have viewed

SUMMER ISSUE

NEWS FROM THE BIOTECH TEAM

> Claire Baldock, Head of the Biotechnology and Life Sciences team has recently been appointed Senior Partner at Boult Wade Tennant. With her International reputation in the life sciences field, Claire will continue to lead the firm's biotechnology practice whilst taking on new roles as Head of the firm's partnership.

> Matthew Spencer and **Jennifer O'Farrell** will be attending the BIO International Convention in San Diego from 23 - 26 June 2014. BIO is one of the world's largest biotech conferences with delegates attending from across the globe. If you would like to arrange to meet Matthew and Jennifer at BIO, please do not hesitate to contact us.

> Claire Baldock and **Joanna Peak** have recently led an AIPPI UK Working Committee in putting together a report, which will form the framework for discussions at the AIPPI World Intellectual Property Congress to be held in Toronto from 14 - 17 September 2014. The report focuses on the patentability and enforcement of second medical use claims in the UK, and proposes ways in which laws in this area could be reformed and harmonised in order to achieve greater certainty for those in the pharmaceutical industry. The report is not yet available but will be published on the AIPPI UK website in due course. As a result of her contribution to the report, Joanna has been awarded this year's AIPPI UK Prize and will be attending the Congress with Claire in the autumn.

them as equivalent in scope to EPC2000 claims. In ***Ranbaxy v Astrazeneca [2011] EWHC 1831***, the High Court disagreed with the patentee's argument that their Swiss-type claim should be construed as a process claim not limited to the manufacture of specific products, and thereby rejected an interpretation of the claim which would have conferred broader protection than an EPC2000 claim. This approach has been followed in subsequent cases involving patents including both types of claim. In ***Regeneron Pharmaceuticals Inc v Genentech Inc [2012] EWHC 657***, the court made no distinction between the two types of claim for the purposes of assessing infringement. In the more recent judgment handed down in ***Actavis UK Ltd & Ors v Eli Lilly & Company [2014] EWHC 1511***, Mr Justice Arnold explicitly said at [57] that the scope of the two types of claim found in Lilly's patent was the same. He also rejected Lilly's argument that the Swiss-type claim and EPC2000 claim were directed to different "skilled persons" by virtue of the difference in claim language, and concluded that the Swiss-type claim should not be interpreted more as a "method of treatment" type claim.

It is clear from the above that there is a degree of inconsistency between comments made by the EPO and the UK courts. However, in real terms, the position may not be so different. The distinction made by the EPO with respect to claim scope in the decisions cited above is consistent with the fact that Swiss-type claims and EPC2000 claims belong to different claim categories and at this level, there is clearly a difference. It is noteworthy however, that the EPO typically does not distinguish between the two claim formats for the purposes of assessing validity.

It is also important to keep in mind that there is a distinction to be made between claim scope, which is governed in Europe by Article 69 EPC, and the rights conferred on a patent proprietor post grant, which are determined by national laws relating to infringement. Unlike the EPO, the UK courts are frequently concerned with the practical implications of granted claims and from an infringement perspective there may in fact be no real difference between the two types of claim. If, as indicated by the UK court decisions cited above, equivalence is to be found at the level of the rights conferred, then patentees should ultimately end up with the same protection irrespective of the claim format used.

> In March, **Matthew Spencer** hosted a One Nucleus roundtable event in our Cambridge office with a focus on patent strategy for personalised healthcare. This session explored the recent decisions from the US Supreme Court concerning the patentable subject matter requirement in the US and also the Guidance issued by the USPTO relating to patent eligibility. For more information about the discussions, **read more here**.

> And finally, Boults Biotech team has been celebrating exam success with **Joanna Peak** and **Naomi Stevens** achieving passes in the UK Finals examinations and **Ed Ronan** passing the European pre-examination with flying colours. Joanna has been awarded the CIPA Drafting Prize for the candidate achieving the highest mark in the P3 examination.

HEADLINE ARTICLES

UK High Court raises bar for inventive step of dosage regimens

The launch of Trastuzumab (Herceptin®), an anti-HER2 antibody, heralded the start of a targeted approach to cancer treatment. With the Supplementary Protection Certificate (SPC) for Genentech's original Trastuzumab patent about to expire, the High Court recently revoked one of Genentech's follow-on patents for lack of inventive step. It was concluded that the skilled person would not dismiss the claimed dosage regimen but would consult a pharmacokinetics expert who would not be dissuaded from performing a small scale clinical trial on the basis of the pharmacokinetic data available in the prior art. In the same action the High Court further cleared the way for biosimilar Trastuzumab by revoking a second of Genentech's follow on patents for lack of novelty (***Hospira UK Limited and Genentech Inc. [2014] EWHC 1094 (Pat)***, please **click here for full bulletin**).

USPTO Guidance for subject matter eligibility of laws of nature, natural phenomena and natural products

On 4 March 2014, the USPTO issued **Guidance** on a new procedure for assessing patent eligibility. This guidance is intended to take into account the recent Supreme Court Decisions ***Association for Molecular Pathology v. Myriad Genetics, Inc.*** and *Mayo Collaborative Services v. Prometheus Laboratories Inc.* The Guidance applies to all claims involving laws of nature, natural phenomena and/or natural products. The Guidance provides a three step test for assessing claims and lists factors that weigh towards and against eligibility. Also provided are practical examples, which confirm that the eligibility question will apply to all natural products and combinations (including proteins). The Guidance appears to be a positive step for applicants. In particular, conventional steps may be sufficient to overcome the eligibility question provided they impart limitations on the claim scope and relate to the natural products in a significant way. For more information on the Guidance issued by the USPTO, **see our full bulletin here**.

Non-infringement in Actavis v Lilly: prosecution history important for claim construction

In a recent High Court judgment handed down in the case of ***Actavis UK Ltd & Ors v Eli Lilly & Company [2014] EWHC 1511 (Pat)***, it was held that Actavis would not infringe Lilly's European patent EP1313508B by launching a generic pemetrexed product containing any one of the active ingredients pemetrexed diacid, dipotassium or ditromethamine. The claims of Lilly's Patent are directed to use of pemetrexed disodium (an antifolate) in combination with vitamin B12 for the inhibition of tumour growth in mammals. In concluding that the claims of Lilly's patent are not broad enough to encompass the pemetrexed salts used by Actavis, Mr Justice Arnold used "the Improver questions" as an aid to claim construction and made some interesting observations concerning the extent to which the prosecution history of a patent can influence claim interpretation. **Read more here**.

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