EIP

Medical use claims are increasingly vulnerable to Lack of Sufficiency attacks at the EPO - a recent decision gives some hints

Article 83 EPC (Sufficiency) requires a European patent to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Case law regarding the sufficiency of medical use claims has developed over the years through several EPO Board of Appeal decisions and has held that a claim to a second medical use is sufficiently disclosed if there is evidence that the claimed therapeutic effect can be achieved. This evidence of a therapeutic effect can be in the application or can be derivable from common general knowledge, meaning that experimental results in the application, although strongly desirable, are not always required to establish sufficiency. The standard to be met for this has traditionally not been considered too burdensome by Patentees, because the onus of proving lack of sufficiency has been placed on the examiner or opponent raising the objection, who must provide "serious doubt substantiated by verifiable fact".

In recent years, various jurisdictions, including the EPO, have been increasing the standard of evidence required for second medical use claims; in particular, that a therapeutic effect is plausible and works for every indication claimed. The Technical Board of Appeal decision handed down in October 2019, T-713/15, is in line with this.

The patent under appeal in T-713/15 was EP1707215 (the vasculitis patent), which claimed the medical use of an IL-6 receptor antibody for preventing and/or treating

vasculitis. A marketing authorisation was obtained for the antibody in question, and it is distributed under the name tocilizumab. During the appeal proceedings the BoA
p2 overturned the decision of the opposition division to uphold the patent and revoked it for lack of sufficiency.

At the time of filing, the vasculitis patent contained clinical data for two patients showing that their symptoms were reduced by the administration of an IL-6 receptor antibody. During prosecution and the subsequent opposition proceedings these case studies were considered adequate evidence that the antibody could treat vasculitis. However, in the appeal decision it was noted that little mechanistic explanation was provided in the patent to support applicability of the treatment to all forms of vasculitis.

During the opposition and appeal proceedings, the opponent/appellant cited two documents, each published almost 10 years after the filing date of the patent, which, they alleged, demonstrated that the anti-IL6 receptor antibody was not effective in treating a rare form of vasculitis caused by Beçhet's syndrome. Each document described a patient who had an adverse reaction to tocilizumab, and speculated that the lack of efficacy was due to differing cytokine profiles between Beçhet's syndrome and more well-known types of vasculitis. In their decision revoking the patent, the Board explained that it was this evidence which lead them to conclude that the patent lacked sufficiency.

It is not unusual for patents to be granted at the EPO based on minimal evidence in the form of case studies, although there are signs that this is changing. In a recent decision T-1045/13 by the same Board, a lack of sufficiency was found, since the examples provided in the application in question related to a single patient each and did not give rise to statistically significant data. The issue in T1045/13 seemed to be that the Board did not consider the claimed therapeutic effect to be plausibly disclosed in the patent. For the vasculitis patent, the Board appeared to consider the strength of evidence provided on filing to be inadequate to outweigh the later published findings of lack of efficacy in Beçhet's syndrome. Hence, the issue in T-713/15 was not whether the threshold test of plausibility was met at the filing date, but that a therapeutic effect was not obtainable in every form of vasculitis.

What will be uncomfortable for patentees is that even with more substantial evidence at the time of filing, it is unlikely that the vasculitis patent would have been protected against this attack, which was based on evidence arising in a rare disease, and almost 10 years after the filing date. This is especially the case, because it is not uncommon for new insights to be gained into treatable populations well after a filing date, since a therapy is always tested more widely after being brought to market. The life sciences sector has, for a long time, faced the dilemma of striking a balance between filing an application early

and delaying until full data is gathered. However, information arising many years later, as a result of the wider use of a drug, is challenging to account for.

p3

With this in mind, what can patentees do to ensure that their medical use patents will not be revoked or invalidated as a result of research performed many years after filing? It will not always be possible to anticipate such events. However, if it is known that the disease group recited in a claim (vasculitis in this case) includes heterogenous subgroups with potentially different mechanisms at play, then it could help to include mechanistic rationale for why a therapeutic effect should be achieved across all disorders claimed. On the other hand, if there are concerns that the mechanistic explanation underlying the claimed medical use may not apply to all subgroups of the broader disease recited in the claims, drafting appropriate fallbacks directed to subsets of diseases, and especially to the subsets exemplified is always sensible. During the appeal proceedings in question, the patentee did request to narrow the claims to specific forms of vasculitis during the oral proceedings; however, this request was denied as late filed.

The biggest take home message from these proceedings is for opponents; Lack of Sufficiency has traditionally been a challenging ground to assert at the EPO for several reasons, including the burden of proof being on the opponent. Because of this, Sufficiency has often been seen as a subsidiary attack, to be included only once prior art and added matter grounds for opposition have been established. However, in cases where evidence of a lack of technical effect across the full claim scope can be identified, Lack of Sufficiency is becoming a much stronger attack against medical use claims, which can knock out entire patents or clear the path for certain indications.