

# How do you solve a problem like... valid and infringed patents?

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Whilst being wary of placing too much emphasis on statistics (the phrase “lies, damn lies and statistics” comes to mind), the authors have seen figures which suggest that the last ten years have consistently seen English patent litigation outcomes which are overall less favourable to the patentee than their opponents. That is until 2017, when the tide turned and more UK patents were found to be valid than invalid. But with that, the English Courts have also recently given a series of judgments about the remedies which should then be awarded. For example, quite apart from the mammoth FRAND judgment of Birss J in the Unwired Planet v Huawei case, readers will recall Henry Carr J’s decision of January 2017 in GSK v Wyeth when he considered whether Wyeth was entitled to an account of profits from GSK for future infringements (no injunction had been requested) and whether the Court had jurisdiction to grant such relief.

In the last week, two further judgments relating to remedies have been handed down. The first is the judgment of Lord Justice Kitchin on behalf of the Court of Appeal in Regeneron v Kymab. The second, handed down the following day, is the judgment of Arnold J on the form of order in Edwards Lifesciences v Boston Scientific (which had been remitted from the Court of Appeal).

In **Regeneron** the Court of Appeal, having earlier found the patents to be valid and infringed, refused to grant Kymab permission to appeal to the Supreme Court, but still went on to consider the extent to which the injunction and order for delivery up against Kymab should be stayed whilst Kymab applied directly to the Supreme Court for permission to appeal. Kymab argued that it should be allowed

to fulfil its existing and future collaborations with the Bill & Melinda Gates Foundation and others in respect of various antibodies which were in development for a range of diseases, including those designated as having an unmet clinical need. Regeneron argued that under the English regulatory use exemption Kymab was already free to undertake acts that were required to prepare for and conduct pre-clinical and clinical trials, so such a stay was unnecessary and would allow Kymab to develop a “springboard” – a head start which would allow Kymab to be in a commercially advantageous position come the expiry of Regeneron’s patents in suit. (Notably the parties had already agreed that there would be an exemption from the scope of the injunction to allow Kymab to take steps to use infringing products to produce non-infringing products and in that way to preserve a series of technical advances which were unrelated to the inventions of the patents in suit.)

Interestingly, the Court of Appeal was of the view that the potential serious harm to Kymab and the disruption the injunction would have on Kymab’s existing collaborations were “*powerful overarching factors in assessing where the balance of justice lies*”. The Court of Appeal recognised the potential for Kymab’s continuing commercial activities to provide it with a springboard and that in the past Kymab had entered into partnerships and collaborations which otherwise Regeneron could have enjoyed. However the Court was nevertheless prepared to allow the stay of the injunction as requested by Kymab, on certain conditions. These included, subject to the final determination of its appeal, Kymab giving undertakings not to commercialise certain products even after patent expiry. The Court also granted **Regeneron** liberty to apply to the Court for an injunction to restrain Kymab from securing a commercial advantage due to the stay.

Back in March 2017, in **Edwards v Boston** HHJ Hacon found one of the patents in suit valid and infringed by Edwards’ medical device. When considering whether to grant an injunction, he noted that if the case were not going any further, he would “certainly be limiting that injunction by reference to the cohort of patients whose lives or health would potentially be put at risk by the grant of an injunction.” However, given that he had granted both sides permission to appeal, he opted to grant an unqualified injunction and stay it pending the appeal. The Court of Appeal subsequently found the same patent to be valid and infringed, but opted to remit the case to the High Court to determine the appropriate form of Order.

Arnold J was assigned the case on its return. By this stage the parties had agreed that the injunction should be further stayed to allow for doctors to be retrained to

use non-infringing devices (replacement heart-valves). The parties had also agreed that once the stay was lifted, there should be some sort of qualification to the injunction to allow Edward's valves to continue to be used in patients for whom it was the only option. Arnold J therefore had to decide how long the stay should be and the scope and duration of the qualification. Given the considerable uncertainty over how long the re-training process would take, and especially as there was no suggestion that continued sales by Edwards would cause Boston irreparable harm, he granted an initial stay of twelve months, with liberty for Edwards to apply to extend this period. He also held that even after that stay, the injunction should be qualified such that Edwards' valves could continue to be used for patients for whom there is no alternative (on condition that clinicians signed a declaration to this effect). Boston were given leave to apply to terminate this qualification in the event that a non-infringing valve became available for these patients.

Readers will have to wait for a decision on the nature of any financial remedy to be payable by Edwards for future infringing sales as the parties had agreed that this should be determined separately (and in parallel with the assessment of the remedy for past infringement). Indeed, Arnold J noted that "fortunately" it was not at this stage necessary for him to express a view on this question, which had been grappled with by Henry Carr J in the **Wyeth** case.

In conclusion, the English Courts are clearly considering carefully how to weigh up the balance of justice between the patentee and the public, and also between the patentee and potential infringer. This is in order to produce an outcome, or preserve a situation, which is as fair as possible. Although the textbooks continue to tell us that an Order "not to infringe the patent" is the standard remedy, it may be that this could soon become more honoured in the breach than the observance. The authors await with interest what future judgments bring in this area. For example, in addition to those points raised above, an area which has been subject to much debate is the appropriate remedy for cross-label infringement of second medical use patents - this may come as a result of the Supreme Court's pending decision in **Warner-Lambert v Actavis** (if the patent is found to be valid and infringed), or we may have to wait a little longer.