



Why you should worry about a patent's priority date

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In the case of *Edwards Lifesciences AG v Cook Biotech Inc* earlier this year, the English Patents Court handed down a unique and important decision that determines the priority date that should be given to a patent ¹. The decision resulted in a loss of priority and the introduction of new prior art that invalidated the patent. This article considers the commercial implications of this decision for pharmaceutical companies.

Factual Background

The issue arose in litigation between Edwards Lifesciences and Cook Biotech on the revocation of a patent for Cook's artificial heart valve. The disputed claim to priority was of importance because, if priority was lost, a particularly significant scientific paper published between the original US priority application and the later PCT international application became relevant prior art.

The original US application was filed in the names of three individuals, all as joint inventors. One was a Cook employee when the invention was made, but the other two were not.

Cook filed the later PCT application in its name, but when filed the only ownership rights Cook had was as employer of one of the three co-inventors. Nearly two years later the other two inventors assigned their rights to Cook; this was after the application entered the European regional phase but before grant of the litigated patent.

The Decision

This is the first time that such an attack has been made in patent litigation in the UK. It depends upon the correct interpretation of Article 4 of the Stockholm revision of the Paris Convention. This specifies that a person is to enjoy a right of priority if he has filed a relevant application for a patent or if he is the successor in title to such a person (ie in the context of a patent this must mean successor in title to the invention).

The Patents Court held that the effect of Article 4 was clear:

- A person who files a patent application for an invention can only claim priority if he himself filed the earlier application from which priority is claimed, or if he is the successor in title to the person who filed that earlier application. If he is neither then he cannot claim priority.
- Moreover, his position is not improved if he subsequently acquires ownership of the invention. It still remains the case that he was not entitled to the right to priority when he filed the later application. Any other interpretation would introduce uncertainty and the risk of unfairness to third parties ².
- The alternative argument run by Cook was that it had always owned its employee's interest in the invention, and that was sufficient in itself for Cook to be entitled to priority. However, the Court held that the US patent application had been filed by the three individuals as joint inventors. It had not been filed by the employee alone, and therefore he was not "a person" who had "duly filed an application for a patent" within the meaning of Article 4A(1) ³.

The Patents Court therefore held that Cook's subsequent acquisition of 100% of the rights did not allow Cook to claim the earlier priority from the US application, but only entitled Cook to the later priority date. This meant that the important scientific paper became materially relevant prior art for the purposes of validity, and indeed as a direct result of the priority date being pushed back, the Patents Court held all claims of Cook's patent to be obvious over this scientific paper and another piece of prior art.

The Implications For Pharmaceutical Companies

This case has potentially wide-reaching and significant consequences, and is more than just a new tactic for litigants. Its implications affect considerations of ownership, filing practice and commercial exploitation.

This will particularly be the case in the pharmaceutical and life sciences field, where the pace of innovation can be fast. Typically the patent owner will itself often be making extensive further filings to enhance its patent coverage in that area, and competitors may be making their own filings and publications. Such activity dramatically increases the potentially materially relevant prior art that might invalidate a patent if its priority date is pushed back – a shift of a year or so could prove fatal to validity.

The lessons for applicants for patents are clear. Priority claims must be carefully considered. Having a connection with the priority application is insufficient - what is needed is a common applicant or an explicit chain of title. This must be properly dealt with before the priority claim is made, as dealing with these matters after filing but before grant is now clearly unsafe. Ownership and all the relevant interests of any co-inventors must have been properly assigned before filing - had Cook done so here then it would have been able to retain the earlier priority date with impunity.

Extra attention will now need also to be given to potential priority issues in corporate and licensing transactions. This may well have considerable consequences on indemnities, warranties, and on valuations. Most investors or acquirers will be reluctant to proceed where the transaction turns on a particular patent or family with suspect priority, or at least not without a substantial reduction in price. And where loans have been secured on such patents the lender may now find that the value of the security is considerably reduced.

Companies must consider the following points in any acquisitions or licences that involve patents: due diligence, warranties and disclosures, and patent audit.

Due Diligence

Patents are usually so significant to a pharmaceutical company's business that it may well be inadequate due diligence merely to rely on the seller's or licensor's records, or on searching the official register.

The buyer/licensee should normally carry out its own investigations into the potential extent of third party rights in the area by reviewing the prior art cited on the file against the subject patents. Where the patent is of potentially central importance a full prior art search and validity review should be carried out, along with a review of the breadth of the claims (and, if relevant, an assessment of any potential third party infringements).

Attention should also now be given in the light of *Edwards v Cook* to whether there may be any priority issues, and to what those consequences might be. This will mean that any later priority date must be carefully identified, and the prior art searches carried out to that point even though such searches are after the priority date on the register.

Warranties And Disclosures

Patent owners are often most reluctant to give any kind of unqualified representation or warranty about the patent itself (for example as to validity, whether it will proceed to grant (if still an

application), or whether it is being infringed). This will now almost certainly extend to any priority issue, especially in relation to any effect it may have on validity.

Because the pace of innovation can be so fast in the pharmaceutical field the patentee may well – and understandably - have no idea whether there has been any intervening publication, disclosure or filing which may invalidate or cut down the scope of the patent.

This will force the buyer/licensee to carry out its own searches as best it can. Whilst this may seem unsatisfactory, such a stance by the patentee is based on the extent to which it is prepared to accept risk. This is highly unlikely for priority issues, unless the commercial balance of power is against it.

The patentee will often make formal disclosures of potential problems with third parties or technical patent-related problems (these will now include any priority issues). Such disclosures are designed to nullify the effects of any warranty or representation that has been given (whether or not qualified).

Where this is the case it is up to the buyer/licensee to evaluate the risks and carry out its own searches. Any priority-based issues must be considered with great care and, where appropriate, the buyer/licensee should seek an indemnity for any loss which may be subsequently incurred. Because of the uncertainties surrounding the effects of a loss of priority, it may well be sensible for the buyer/licensee to withhold part of the purchase price or licence fees and keep them in escrow in case it suffers any loss from this.

Patent Audit

This judgement may well have severe consequences for a number of granted patents as it has been a common practice for patentees to get in the relevant rights after filing, rather than beforehand. Companies who have may have done so hitherto should consider auditing their key patents to determine whether any are at risk, and devise strategies to mitigate the position.

1. *Edwards Lifesciences AG v Cook Biotech Inc [2009] EWHC 1304 (Pat), 12 June 2009.*

2. *It should be noted that the EPO Board of Appeal has adopted the same approach to the interpretation of Article 87 EPC in two cases: J 0019/87 and T 0062/05.*

3. *The Patents Court's approach on Cook's alternative argument (employee-based ownership of an interest) is consistent with the EPO Board of Appeal in case T 0788/05.*

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