Mending the Fence: Commercial Success and the Blocking Patent Defense in Pharmaceutical Litigation

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Commercial success often is evaluated in patent litigation. It usually entails assessing whether a patented product has achieved success in the marketplace and whether that success is due to the patented features of that product. If the answer to both questions is "yes", then the implication is that the at-issue patent was not obvious because others would have had the incentive to develop the invention instead of the patent owner. Conversely, if the product practicing the at-issue patent is either not successful or if that success is not due to the at-issue patent, then the evidence may not support a finding of the non-obviousness of the at-issue patent.

In pharmaceutical litigation, the blocking patent defense increasingly has been invoked to counter a patent owner's reliance on a showing of commercial success. The core blocking patent argument is that the success of the patented invention stems not from its inherent merit, but instead from the preclusive effect of an earlier, pre-existing "blocking" patent that prevented third parties from pursuing inventions that led to the at-issue patent. In other words, the blocking patent argument is that the success of a patented product is likely due to the restrictive barrier (or fence) created by the blocking patent – effectively keeping competitors out – rather than the inherent advantages of the patented invention at issue.

Patent owners often respond by arguing that the alleged blocking patent(s) did not or could not prevent earlier invention, that is, the success of the patent-practicing product reflects the technical merits of the patent at issue, not the exclusivity afforded it by another patent. While sometimes the counter argument has been successful, the Court of Appeals for the Federal Circuit ("Federal Circuit") increasingly has embraced the blocking patent defense in pharmaceutical cases involving claims of commercial success. From 2003 to 2013, the Federal Circuit issued opinions in four (4) pharmaceutical cases involving the defense, finding a blocking patent in two (2) instances. From 2014 to 2024, the Federal Circuit decided twelve (12) such cases, finding a block in seven (7) instances. As such, there appears to be an increase in the use of the blocking patent defense in pharmaceutical cases, with many such arguments proving successful.

Despite its growing use and acceptance, the foundations (or footers) of the blocking patent defense are less solid than they may seem. Legally, the defense cannot be applied categorically and universally to explain the commercial success of an at-issue patent. Courts repeatedly have emphasized that determining whether a patent blocks earlier invention is a fact-specific inquiry that must be resolved on a case-by-case basis. Empirically, patents rarely block all forms of innovative activity. Promising (and often lucrative) research and development efforts and associated commercial endeavors are seldom abandoned altogether due to the existence of a supposed blocking patent. Logically, determining whether a patent qualifies as blocking involves consideration of numerous factors, many of which courts already have identified explicitly. Critical to that inquiry, though, is a description of what has been blocked and when; courts have been less systematic or clear on those considerations. From an economic perspective, commercial success reflects the impact of marketplace dynamics. A blocking patent rarely eliminates all forms of competitive activity.

In most blocking patent cases, the issue has been addressed without any real-world evidence that anyone was blocked. While commercial success is valuable in a nonobviousness analysis because it is intended to be rooted in real-world evidence, courts often discount this evidence based solely on an expert's opinion that blocking may have occurred. Just as troubling is that courts often overlook or fail to consider real-world evidence showing that others were actively working in the field of the claimed invention. This position may undervalue certain patented inventions because it is based on assertions, not facts, suggesting that the patent owner's success was not for nonobviousness reasons.