



Pre-Suit Willfulness Sufficiently Pleaded Where Detailed Facts Support Defendant's Involvement in Opposition Proceeding of Related Patent and Participation in Relevant Industry

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By: Megan R. Mahoney, Matthew George Hartman, Jonathan James Underwood

The district of Delaware recently denied a defendant's partial motion to dismiss pre-suit willful infringement from the litigation, finding instead that the allegations taken as a whole were sufficient to support pre-suit willfulness at the pleading stage. Specifically, the court found that the allegations as to the defendant's involvement in a related foreign opposition proceeding and participation in the relevant industry were accompanied by detailed factual support that sufficiently pleaded willful infringement for the pre-suit period.

The patent owner accused the defendant's blood tests of infringing its patented methods directed to obtaining genomic copy number information from a sample of genomic material. According to the patent owner, the patented methods were an improvement in the field of early cancer detection. The patent owner further alleged that the defendant's pre-suit infringement was willful, making several allegations upon information and belief. In particular, the patent owner alleged that the defendant would have become aware of the asserted patents by participating in the early cancer detection industry and while researching the patentability of its own patents and developing its blood tests. The patent owner also alleged that the defendant acquired knowledge of the asserted patents through its prior involvement in a European Patent opposition proceeding for a related patent having the same title and similar claims.

In response, the defendant moved to dismiss pre-suit willfulness from the complaint. The defendant argued that the patent owner's allegations regarding industry participation and

research for its own patents were too conclusory to support a claim of willful infringement. The defendant also argued that involvement in the foreign opposition proceeding only supports knowledge of that related patent, not the asserted patents.

The court rejected the defendant's arguments, finding sufficient factual allegations to support pre-suit willfulness at the pleading stage. In particular, the patent owner's allegations were accompanied by exhibits and additional information concerning the European patent claims and the defendant's interest in the foreign proceeding, the defendant's patents in the relevant technology, the specialized knowledge in the field, and how the accused blood tests allegedly practice the patented methods. The court accepted that if each of the allegations had been made in isolation then there would have been insufficient support for pre-suit willfulness. But the court explained that taken together, the numerous allegations and factual support created a plausible basis to infer that the defendant had knowledge of the asserted patents and notice of its potential infringement. Accordingly, the court denied the defendant's partial motion to dismiss pre-suit willfulness.

Practice Tip: General allegations that a defendant had pre-suit knowledge of asserted patents based on participation in the relevant industry or awareness of related patents have been found to be too speculative to support a claim for willful infringement. Thus, at the pleading stage, a patent owner seeking enhanced damages for pre-suit willful infringement should provide detailed factual support for the defendant's knowledge of the asserted patents and that the defendant knew or should have known that it was infringing the asserted patents. The factual support may include exhibits and information describing defendant's activities in the relevant industry; similarities between the asserted patents, the defendant's own patents, and any related patents defendant was aware of; facts about the defendant's involvement in any proceeding challenging a related patent; and information detailing how the defendant's accused product practices the claims of the asserted patents.

Cold Spring Harbor Lab'y v. Guardant Health, Inc., Court No. 1:25-CV-00263-JCG, 2025 WL 2898942 (D. Del. Oct. 10, 2025)

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