

Litigation misconduct during patent infringement lawsuit can result in invalidation

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Introduction

Inequitable conduct in failing to disclose a reference is a defence to patent infringement that requires a showing of the materiality of a withheld reference and specific intent to deceive the US Patent and Trademark Office (USPTO) by withholding the reference during prosecution of the patent application. If proven, inequitable conduct renders the entire patent unenforceable.

In *Regeneron Pharmaceuticals, Inc v Merus NV* the Federal Circuit surprisingly affirmed that specific intent to deceive the USPTO can be inferred as a result of misconduct during a patent infringement lawsuit, even if such misconduct occurs several years after prosecution of the patent.

'018 patent

Regeneron owns US Patent 8,502,018 (the '018 patent'), which is generally directed to a genetically modified mouse equipped to produce antibodies that can be used by humans. Regeneron sued Merus for infringement of its '018 patent in the Southern District of New York, and Merus asserted inequitable conduct as a defence to infringement. Merus claimed that Regeneron's patent attorneys withheld four references from the USPTO during the evaluation of Regeneron's patent application. Regeneron did not deny awareness of these references during the pendency of the '018 patent, but asserted that failure to disclose the references did not amount to inequitable conduct.

To prove inequitable conduct, the accused infringer must first show that the withheld references were 'but for' material, meaning that the claim would not have been allowed if the USPTO had known of the withheld reference during prosecution. Regeneron stated that the withheld references were cumulative references already before the USPTO.

Broadest reasonable interpretation

Regeneron also claimed that under the broadest reasonable interpretation, the claims were directed only to a mouse that produces a specific type of antibody. A representative claim read as follows: "a genetically modified mouse comprising in its germline human unrearranged variable region gene segments inserted at an endogenous mouse immunoglobulin locus." Regeneron argued that this claim covers a mouse with human segments inserted into only the variable regions, implying that all other regions of the germline are mouse. Under such an interpretation, the withheld references were likely immaterial.

However, the Federal Circuit noted that the use of the word 'comprising' in the claim language indicated that the claim was open ended. Therefore, the claim could include antibodies of multiple types, such as those with human genes inserted in areas other than the variable region. Under such broadest reasonable interpretation, the Federal Circuit held that the withheld references were material.

Specific intent

Having shown materiality, the accused infringer must then show that the patent owner withheld the material references with the specific intent to deceive the USPTO during prosecution before the patent examiner. Specific intent is often difficult to prove. A finding of specific intent is subject to a heightened evidentiary standard, and unearthing evidence to support such a finding is often an arduous or impossible task. Fortunately for Merus, the district court relieved the burden to prove this second requirement for the accused infringer by inferring specific intent as a penalty for purported misconduct during the materiality portion of the trial.

During the trial for materiality, Regeneron repeatedly failed to produce documents that were either not privileged or documents for which the district court held that privilege had been waived. As a result of this "pattern of misconduct", the district court penalised Regeneron by drawing an adverse inference "that Regeneron failed to disclose the withheld references to the [USPTO] during prosecution of the '018 patent with the specific intent to deceive the [USPTO]". Therefore, the second requirement to prove inequitable conduct was met without an actual trial on the issue of specific intent.

Remarkably, the Federal Circuit upheld the district court's adverse inference of specific intent and affirmed a finding of inequitable conduct during prosecution. Therefore, despite there being no evidentiary record on Regeneron's specific intent to deceive, the '018 patent was rendered unenforceable in its entirety.



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Comment

Considering the broad ramifications of this holding, this case provides a concerning precedent for patent litigators and IP owners currently engaged in patent infringement disputes in the United States. As pointed out by the dissenting judge in the case, purported litigation misconduct has "no relation to whether there was inequitable conduct in the prosecution before the patent examiner".

Notwithstanding this disconnect, the Federal Circuit affirmed an adverse inference of specific intent to deceive the USPTO as a penalty for such litigation misconduct. Despite occurring years after patent prosecution, litigation misconduct may therefore result in an inference of the intent required for a finding of inequitable conduct during such prosecution. Given that inequitable conduct makes the patent unenforceable, patent owners should prudently evaluate their litigation strategies when suing for infringement. If litigation tactics amount to misconduct, the entity could be left with one less patent in its portfolio.

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