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ROI in Establishing a Robust Freedom to Operate Program

The costs associated with patent litigation can prove ruinous for many organisations – and even the threat alone can create uncertainty that stymies business and restricts creativity. Taking steps to address and avoid the risk of patent litigation is thus key to many companies' success, and obtaining a 'freedom to operate' opinion can be crucial for this.



Intellectual property counsellor Keith Gilman speaks with us in this article, outlining the importance of freedom to operate investigations and what return on investment can be expected by companies that choose to pursue them.

Most businesses familiar with the cost and disruption of a patent litigation – often costing millions of dollars each year for several years and uncertainty in the outcome – take steps to avoid or at least properly prepare for patent litigation as they develop new products or processes. The avoidance of patent litigation keeps employees

focused on serving customers and developing new generations of products rather than allowing the interruption of litigation to sidetrack them into supporting a multi-year battle towards trial and appeal. The extent to which businesses take steps to avoid or minimise litigation often dictates their success.

A patent right is granted by the federal government in exchange for a disclosure of an invention that meets many requirements. It is a measured grant of rights because the right is limited in time and extends only to that aspect of an invention that reaches a certain level of inventiveness beyond the 'prior art' – prior art being anything that existed or was described publicly before the invention. Moreover, the granted right is a *right to exclude others* from making, using or selling the invention as defined in the patent. This 'negative right' leaves room for others to patent improvements. This fulfills the Constitutional objective *"to promote the progress of science and useful arts."*

Patent litigation is among the most complex areas of commercial litigation and is under the exclusive purview of the federal courts. It concerns the infringement of an invention, which is defined in the claims of a patent, which is granted by the US Patent & Trademark Office (USPTO) after examination by a patent examiner to determine the appropriate scope of the invention to define over that which came before the invention.



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Patent claims are crafted – often in what has been considered arcane and cryptic language – to describe the bounds of an invention over the prior art. Claim language is thus subject to difficult interpretation challenges. Despite the apparent strength of a patent claim, each patent infringement action is subject to defences; mostly noninfringement of the claims or invalidity of the claims.

A patent litigation requires judges, juries and the lawyers to have or gain an understanding, at least to some level, of the subject technology and the federal patent laws. The technology may be quite complex and the laws are grounded in complex principles and procedures that in most jurisdictions require their own set of rules beyond the Federal Rules of Civil Procedure. The patent laws are so complex that

Congress established a single appeals court – the Federal Circuit Court of Appeals – to bring consistency and a strong voice to the underlying principles.

Thus, as companies develop products, some may exercise diligence by seeking a ‘freedom to operate’ opinion, also known as a ‘right to use’ opinion, from a competent patent attorney. An opinion may result from the knowledge of certain third-party patents. Ideally, however, an opinion should result from diligence investigations undertaken to locate previously unknown patents that may create an obstacle to the introduction of a product, process, pharmaceutical formulation or software.

Freedom to operate investigations constitute diligence to measure and address the risk of an infringement action. Patent attorneys experienced in the technology and the law conduct research in the patent arts, focusing on the invention-defining claims of third-party patents. If the investigation reveals a patent with a scope that may cover the product, further investigation is undertaken to determine if a noninfringement defence exists.

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While a solid defence of noninfringement is enough to carry the day for an accused infringer, an investigation can continue to determine if the claims can be proven overly broad in light of the prior art and are thus invalid. Significantly, invalidity must be proven by clear and convincing evidence, which complicates the opinion and any ensuing litigation.

Interestingly, an opinion of invalidity can prove useful in a post-grant proceeding put in place by Congress a decade ago – e.g. an *inter partes* review (IPR). While an IPR can be brought at any time, it is a tool most often employed by accused infringers as an adjunct to a patent litigation. In essence, an IPR is a mini trial on invalidity conducted before a panel of patent experts at the USPTO. It is attractive as a less expensive alternative to litigation. Critically, invalidity is adjudged under the preponderance of evidence standard, which is far less stringent than the clear and convincing standard required in a patent litigation.

If an opinion of noninfringement or invalidity is reached in the investigation, the strength of the opinion may dictate whether a company moves forward. If moving forward, a written opinion can be prepared and issued to the client respecting the lack of liability from making and selling the product. An opinion letter provides a business with guidance on moving forward not only with the specific product but also in the future for improved generations of that product. Ideally, the business always has a well-thought planning tool it can rely on to explain how it can move forward to best

avoid an expensive and disruptive patent litigation. An opinion letter also serves as the initial road map for a litigation brought against an accused infringer by a patent owner.

Moreover, the opinion letter is the best evidence of a good faith belief that it is not treading on anyone's intellectual property. Such evidence can be used to rebut a charge of willfulness by a patent owner seeking treble damages should it prove that the infringement, if found over the defences, was a willful act by the infringer.



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Prior to reducing an opinion to writing, the evaluation of the strength of the positions underlying an opinion may guide a decision to redesign a product or process to establish or improve a defence of noninfringement. Here, it is all about creativity and socialising the efforts so ideas for a redesign are generated and pressure tested. The right patent attorney can be invaluable in achieving a successful redesign to avoid infringement.

Even more so, redesign efforts often lead to a more marketable product. Forced to creatively solve the problem of infringement, designers often find solutions that improve upon the original design. Significantly, that improvement may very well be patentable so that the product enjoys exclusivity, preventing others from making, using or selling a competitive product that uses the redesign.

Thus, robust diligence efforts may result in more than developing solid defences to an assertion of infringement. Value can be realised when a redesign results in a superior product that will perform better in the marketplace.

Robust freedom to operate programs establish a culture within a company that maintains the focus of management and others to consider third-party rights prior to making moves in the marketplace that can be extremely disruptive and even detrimental to a business. An investment in such a program facilitates prophylactic steps to avoid or minimise litigation and a byproduct may be an improved product. Finally, as an overall return on investment, regular investigations provide critical

knowledge of third-party patent filings in the industry, and companies gain a keen understanding of the technology development within the industry.

Keith Gilman, Managing Partner

[Lerner David LLP](#)

20 Commerce Drive, Cranford, New Jersey 07016, USA

Tel: +1 908-518-6308

E: kgilman@lernerdavid.com

Keith Gilman is a leading intellectual property counsellor and managing partner of Lerner David. Involved in all facets of the firm's IP practice, he counsels clients on maximising the value of their IP assets and advises on risks associated with new product designs and acquisitions. With an extensive background in litigation, licensing and due diligence, Keith was also an original Master of the John J. Gibbons Inn of Court, the first IP Inn of Court of its kind in New Jersey involving attorneys and judges, which is now considered the preeminent Inn of Court for federal practice in New Jersey.

Lerner David is a boutique law firm that specialises solely in providing intellectual property counsel. Established in 1969, the firm's expert team of counsellors boast extensive experience and broad international resources, and strives to obtain peerless results for their corporate clients both in court and before the United States Patent and Trademark Office.