

# Mitigate Patent Infringement Risk with an FTO



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Companies understand the value in filing for patent protection on their products prior to launch. Obtaining patent protection adds value to the company's patent portfolio and keeps competitors out of the marketplace for the covered products.

Unfortunately, many companies do not understand the value or benefits that come with the performance of a Freedom to Operate (FTO) or product clearance opinion. The FTO opinion's main purpose is to serve as a risk management tool for the company. It meets this goal by identifying and analyzing third-party patents or trademarks that may negatively impact a new product launch because of the risk of patent infringement liability. It should be clearly understood that FTO and clearance opinions do not imply absolute clearance or the total elimination of liability risk, but rather the opinions provided are relative to the current IP landscape for the specific product at a given point in time for a defined geographic location.

The FTO process typically comprises three stages: 1) product deconstruction, 2) patent search with geographic location and 3) claims review and assessment.

## Stage 1: Product Deconstruction

Stage 1 involves dissecting the planned or existing product into its various component parts. The product as a whole will be reviewed as well as the critical components that the company has identified as new or innovative.

In addition, how the component parts and proposed product are manufactured or assembled should be reviewed, because third-party patents could exist that would block a company's ability to manufacture the proposed product.

## Stage 2: Prior Art Search

Typically, most companies and patent attorneys will outsource the performance of the prior art search to entities that specialize in this service and have access to proprietary patent databases. The patent attorney will develop search criteria, including a detailed product description and all identified components. In addition, any associated methods or processes that were discovered during the product dissection should be described in the search criteria. Further information included in the search criteria may be a listing of known competitors, any already identified relevant patents and geographic limits.

Most companies focus only on U.S. patents because they have no plans to make use or sell their products outside the U.S. However, an increasing number of countries are looking to Europe to perform clinical trials of new products, thus for these cases, European patents must also be included in such a search.

Once the search criteria are finalized, the appropriate patent databases are searched and results compiled. The returned prior art is then ready for the next stage of the FTO process.

## Stage 3: Claims Review and Assessment

In this stage of the FTO process, the company or patent attorney determines the likelihood of whether the product or methods infringe upon any of the identified third-party patents. The focus of the patent review is on the claims and, more specifically, the broad independent claims. The claims of a patent provide a qualitative description of the inventors' structural or step limitations. When reading the claims, the scope of the language used will determine what or how much is covered by particular claims.

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***Performing an FTO search and obtaining an opinion regarding the results is a critical tool for mitigating litigation risk when developing a new product.***

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Infringement of patent claims can occur in several ways. "Literal infringement" occurs when the product or proposed product literally or actually infringes the claims as it reads in the patent. For example, the claim states "A red wagon with four wheels and a pull handle" and the product is a red wagon with four wheels and an elongated handle. The proposed product literally infringes or "reads on" the claim.

Another form of infringement falls under the "doctrine of equivalents." In this situation, infringement is found even though the proposed product does not fall within the literal scope of the claim; however, the product is determined to be substantially equivalent to claimed inventions referenced to the claimed red wagon example above. The infringement under the doctrine of equivalents would likely be found for a pro-

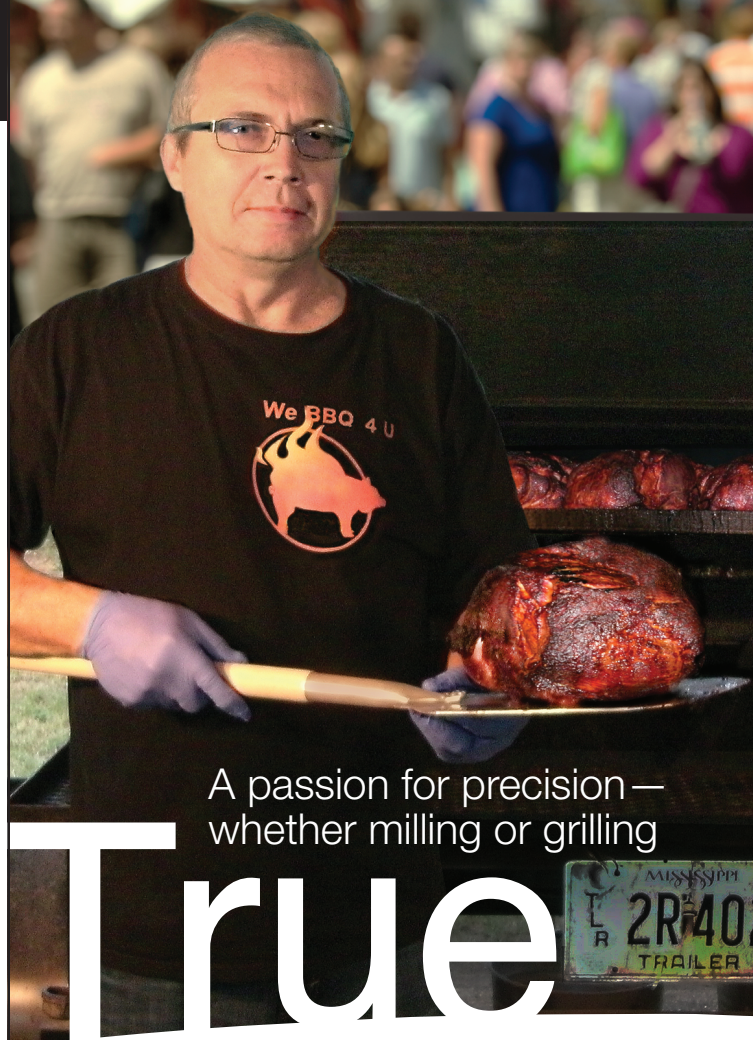
posed product that included a red wagon with four wheels and a pull bar, instead of a handle. It would likely be found that the bar element was “substantially equivalent” to the pull handle because it functioned similar to the handle with similar results relevant to the wagon. Therefore, the red wagon with the four wheels and pull bar would likely infringe the claim under the doctrine of equivalents.

Infringement of a claim can also occur directly or indirectly. Direct infringement is found when a person directly makes, uses, sells or imports any patented invention during the term of the patent. Indirect infringement may occur when a person actively and knowingly induces another to infringe a patent. For example, a third party supplies a product or component that can only be reasonably used to make a patented invention or is used in a patent invention. Indirect infringement is generally seen with patented sub-components that are material to the patented invention.

Indirect infringement includes contributory infringement, which is codified in 35 U.S.C. 271(c). This type of patent infringement imposes liability on a company that knowingly sells either a special-purpose component of a patented device or a special-purpose device that is used to practice a patented method, provided that the component or device is not “a staple article or commodity of commerce suitable for substantial noninfringing use.” It should be noted that for there to be contributory infringement, there must be an underlying direct infringement by a third party for which the company is held liable. Indirect infringement may also be described as active inducement of infringement and is codified in 35 U.S.C. 271(b). This type of indirect infringement covers situations in which a person or company actively induces the infringement of a patent by encouraging, aiding or otherwise causing another person or entity to infringe a patent. Importantly, to prove liability, it must be shown that the potential inducer must have actually been aware of the patent and intended that their actions would have resulted in a third party infringing that patent.

Following the task of comparing the product or proposed product to the construed claims of the patent found in the prior art search, the patents are broken into three categories that reflect the corresponding infringement risk. Typically, the highest priority art that may require additional investigation are called “show-stoppers,” because these patents are likely to be infringed and block the product development or launch. The second category of art includes patents that may be infringed depending upon how the claims are interpreted and the breadth of the claim scope. Finally, the third category comprises patents that are clearly outside of the field of the product and have no infringement risk.

If all of the patents found fall within this last category of art, the FTO opinion will be “clear” and the company may be able to move ahead with the continued development or launch of the product. However, even in the case



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of a “clear” opinion, one must keep in mind two attributes of patents. The first is that patents last only for a certain period of time (20 years from the date of filing). Therefore, old patent rights expire while new rights are granted regularly from the Patent Office. What this means to a company is an FTO opinion may become stale over time, and it is a good business practice to continually update the FTO search to ensure that new rights have not emerged that could negatively impact the sales of the current product or the ongoing development of the new product. Refreshing an FTO is also an excellent tool to use in monitoring the marketplace and the competition.

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The second attribute to keep in mind with patents is that they are territorial, not worldwide in nature. What this means is that infringement is only possible in a country where a patent is in force. Therefore, if the FTO was performed for the U.S. only, and as time passed the company decided to expand into the European marketplace, a second FTO for Europe would need to be performed to assess infringement risk in this new geographic location.

In the event that any of the patents found to be troublesome fall within the “show-stopper” or alternatively, middle category, then several strategies may need to be considered. Business-based strategies may include taking a wait-and-see approach. The downside to this is that litigation could occur at any point. A second business-based approach is to abandon the product, but such action could be costly with the in-house write-offs and lost opportunity costs. A third business-based approach may be to propose a merger with or acquire the owner of the problematic IP. The negative side to this approach is the possible inherent cost and loss of business focus of the purchaser.

If problematic IP is found, two research and development strategies may be employed. First, there is the option to modify the product. Such an action may not be possible due to lack of alternatives to address the target marketplace or problem being solved by the product. The second strategy is to invent or design around the “show-stopper” patent. The downside to this approach may include delays for the product launch and costs of redesigning the product.

Legal-based strategies that may be used in the event troublesome patents are discovered include licensing-in the technology from the patent owner. Problems that may arise with this approach may be an unwilling licensor or one who demands a royalty rate that makes the product unprofitable.

Another legal approach may be to enter into a cross-license with the patent owner. The difficulty with this strategy is that the company may not have technology that is of value to the owner of the issued patent.

The final legal-based strategy would be to attempt to invalidate the problematic patent. This approach is viable when the FTO results return invalidating prior art that the U.S. Patent and Trademark Office failed to identify during examination of the application.

Since the new patent law went into effect, two new mechanisms have become available that are less costly than initiating litigation. These include the Post-Grant Review procedure that allows a challenger to file a petition within nine months after the issuance of a patent based on any invalidity grounds. The second mechanism is the counter-part to post-grant review procedure, called Inter Partes Review. Inter Partes Review can only be instituted the later of nine months from the issuance of the target patent or the date of termination of the Post Grant Review procedure. The basis for invalidating the patent during the Inter Partes review procedure is limited to lack of novelty and/or business.

Performing an FTO search and obtaining an opinion regarding the results is a critical tool in mitigating litigation risk when developing or getting ready to launch a new product. Conducting an FTO may also provide important marketplace information to a company that will allow it to identify, minimize and manage other business risks. Finally, the performance of an FTO will also allow the company the opportunity to identify areas of possible patent coverage for its new and developing products, as well as the IP standing of its competition in the target product marketplace. Companies would be well served to institute the use of FTOs on a regular basis during the product development process.

The contents of this article are for informational purposes only and should not be interpreted or construed as legal advice. Please consult with a license attorney if you have any questions.

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