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Best Practices for Clearances and Opinions

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Last week, Mintz Member Lisa Adams moderated a panel discussion between in-house attorneys that covered best practices for conducting patent clearances and obtaining non-infringement and invalidity opinions. The panel discussion, which was hosted by the Boston Patent Law Association, focused on key practical considerations that ensure product clearances and opinions are used as effective tools in a comprehensive intellectual property protection strategy. Here are some key takeaways from the panel's conversation:

1. **Start the clearance analysis for a product well in advance of the product launch, and update it throughout the lifecycle of the product**

It can be too advantageous to start the process of clearing a product for market as far in advance of the product's marketplace launch as possible. Taking a proactive approach to product clearance can help avoid the possibility of having to perform a costly product redesign just prior to the product's launch. An efficient approach to clearing a product may be to perform an initial landscape search to understand the scope of the art in a product's technical area when the development of the product is in its earliest stages, to monitor the progress of product development and update the search accordingly as additional product details are learned/finalized, and to focus the clearance effort with freedom-to-operate analyses as the product moves closer to launch. The analysis does not end with product launch, but instead updated searching should be performed throughout the lifecycle of the product.

2. **Consider keeping clearance/freedom-to-operate work product and analysis with outside counsel**

A paper trail of conversations and assessments on product clearances, landscapes, and freedom-to-operate analyses between employees could become discoverable in litigation, which could be detrimental to your position in the litigation. The likelihood of the content of the analysis becoming inadvertently discoverable can be minimized by outsourcing the clearance work to outside counsel and having outside counsel maintain and manage the analysis.

3. **Consider varying the approach to clearances based on the circumstances and the value/risk to the business**

The decision of whether to commission a detailed and highly documented freedom-to-operate analysis should be based on the consideration of a variety of factors, such as the level of importance of the product, where the product is in the life cycle and the risks in play for the business. While one may consider involving outside counsel if the analysis of whether a product is cleared for launch is complex, it may not be necessary for simpler analyses with fewer issues. In-house counsel can prepare opinions, but it is recommended to have a second in-house attorney review the opinion.

4. **Pay attention to the timing of the opinion you obtain**

The timing for delivery of an opinion can be crucial to its effectiveness. For example, if the business is on the eve of product launch or is anticipating litigation, it ideally should be in a position in which outside counsel has studied the relevant patents in detail and provided an opinion well in advance before the launch of a product. It is important that an opinion be delivered such that there is an opportunity to convey that analysis to the decision-makers in the business so that the business has a meaningful opportunity to pull a product from the market based on the opinion if that is the decision that needs to be made. In circumstances where a written opinion cannot be completed in a timely manner, an oral opinion can be rendered in advance of the product launch and subsequently documented in a written opinion after the product launch. Obtaining an opinion on a product or patent as far in advance as practical increases the effectiveness of the opinion (by improving one's ability to rely on it in any ensuing litigation) and shows objective intent to avoid willful infringement (and treble damages).

5. **Make sure the business is trained to communicate with discovery in mind so they don't inadvertently undermine clearance/opinion efforts**

Communication hygiene is critical. The business should be trained to understand that they should not discuss whether a product potentially infringes a patent or whether it is invalid. To the extent those conversations occur within the business, it is best to avoid having them in writing. In short, if there is a question about a competing product or a patent, it can be helpful to pick up the phone and consult with in-house counsel rather than putting a question in email form to in-house counsel.

6. **Consider splitting up non-infringement and invalidity opinions**

To maximize options in litigation, it can be beneficial to split non-infringement and invalidity opinions into separate documents/efforts. Doing so can provide litigation counsel with the ability to rely on one opinion but not necessarily waive privilege for communications associated with the other opinion.

7. **Consider addressing reasonable alternative claim constructions**

An opinion of counsel must be competent. When deciding which arguments to include in an opinion, it can be beneficial to address alternative claim constructions. While conclusions reached by counsel do not need to be correct in order to insulate an accused infringer from a finding of willful infringement, it may be more challenging to demonstrate that an opinion is reasonable if it is based on a claim construction that ultimately fails during litigation. While alternative claim constructions are acceptable, unreasonable arguments should not be included in an opinion as they can weaken the opinion by undermining the objective assessment of the reasonableness of the business's reliance on the opinion.

8. **Carefully consider to whom the opinion should be addressed and how the opinion should be delivered to the business**

Ideally, an opinion should be addressed to the in-house patent counsel who requested the opinion and delivered to a key decision maker in the business by the in-house patent counsel. It can be beneficial to document all steps in the delivery and to obtain a form of written record documenting that the decision maker has read and understood the opinion. Such documentation can potentially serve as supporting evidence in any ensuing litigation to support the position that the business did not willfully infringe a patent-in-suit.

Authors

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