Morton in Life Science Leader: USPTO Proposed 'Terminal Disclaimer' Rule Could Impact Life Science Patent Protections

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Haynes Boone Partner Jeff Morton authored an article for *Life Science Leader* following a new proposal from the United States Patent and Trademark Office (USPTO) focusing on terminal disclaimer practice.

Read an excerpt below.

On May 10, 2024, the United States Patent and Trademark Office (USPTO) issued a notice of proposed rulemaking that focused on terminal disclaimer practice. Under the proposal, a terminal disclaimer would need to include an agreement that the patent in which the disclaimer is filed — or any patent granted on an application in which a terminal disclaimer is filed — would only be enforceable if the patent has never been tied to another patent that has been held to be unpatentable or invalid. As such, if one patent is found to be unpatentable or invalid, then all others that are tied to such patent by way of a filed terminal disclaimer would also be rendered unpatentable or invalid. This is a marked change from the traditional terminal disclaimer practice where tied patents are rendered valid or invalid independently of each other.

Traditionally, the life sciences industry has made frequent use of terminal disclaimers to overcome obviousness-type double patenting rejections. For example, it is not uncommon for life science innovators to: (a) protect a lead therapeutic compound through relatively narrow patent claims in a first patent while (b) simultaneously protect a broader class of therapeutic compounds through relatively broad patent claims in a second, related patent. In such instances, a rejection for obviousness-type double patenting is often issued by the USPTO; under traditional practice before the USPTO, this rejection can be overcome through the filing of a terminal disclaimer. Accordingly, the proposed move by the USPTO to tie patent validity together based on the filing of terminal disclaimers is one that would have a significant impact on how life sciences patents are prosecuted. In an extreme but now plausible scenario, if a single claim in a broad patent focused on an expansive class of therapeutic compounds is held to be invalid due to the identification of relevant prior art, such a finding would render a second patent, focused narrowly on a commercially valuable lead compound, invalid if the second patent and first patent were tied together through the filing of a terminal disclaimer. This type of scenario could have a devastating effect on companies that are logically trying to cover both ends of the patent claim scope spectrum.

To read the full article from *Life Science Leader*, click here.