

PTO Issues Notice on Duties of Disclosure and Reasonable Inquiry

Article By:

Bernard P. Codd

The US Patent & Trademark Office (PTO) issued a notice on July 29, 2022, titled “[Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board](#).” The notice comes in response to US President Joe Biden’s July 9, 2021, executive order on Promoting Competition in the American Economy, and to a September 9, 2021, letter from Senators Patrick Leahy (D-VT) and Thom Tillis (R-NC), who requested that the PTO “take steps to reduce patent applicants’ making inappropriate conflicting statements in submissions to the [PTO] and other federal agencies.”

PTO Director Vidal explained in the notice that parties involved in proceedings before the PTO should not take a position about the patentability of the claims that is inconsistent with positions taken in submissions to other government agencies regarding the same subject matter. If a party to a PTO proceeding discovers that an earlier position taken in a submission to the PTO or another government agency was incorrect or inconsistent with other statements made by the party, the party must promptly correct the record.

When an examiner has a reasonable basis to conclude that an individual identified under [37 CFR 1.56\(c\)](#) or any assignee has information that would aid in the examination of the application or treatment of some matter, the examiner may require submission of information that is not necessarily material to patentability. This requirement could include statements made or information submitted to other government agencies, such as the US Food & Drug Administration (FDA).

Any party presenting a paper to the PTO has a duty to perform an inquiry that is reasonable under the circumstances. This reasonable inquiry may comprise a review of documents that are submitted to or received from other government agencies, including the FDA. If any reviewed document is material to the patentability of a pending matter before the PTO, the party has a duty to submit the information to the PTO.

Each individual with a duty to disclose, or each party with a duty of reasonable inquiry, should ensure that statements made to the PTO and other government agencies, or any statements made on their behalf to other government agencies regarding the claimed subject matter, are consistent. Providing material information to other government agencies, including the FDA, while simultaneously withholding the same information from the PTO violates those duties.

Further, any individual with a duty to disclose, or any party with a duty of reasonable inquiry, should review documents it receives from other government agencies to determine whether the information should be submitted to the PTO. For example, a party receiving a paragraph IV certification related to a generic drug application (e.g., an Abbreviated New Drug Application (ANDA)) should review such documents to determine whether they are material to the patentability of any pending matters before the PTO. If any information that is part of the ANDA process is deemed material to patentability in a pending PTO matter, then such information must be submitted to the PTO during the pendency of the matter to meet the duties of candor and good faith and disclosure.

According to the notice, schemes or practices that prevent [37 CFR 1.56\(c\)](#) individuals from obtaining knowledge of material information are inconsistent with candor and good faith under [37 CFR 1.56\(a\)](#). For example, walling off the patent prosecution practitioners from the lawyers seeking FDA approval as a way to prevent material information from being exchanged between the practitioners and lawyers is inappropriate.

© 2024 McDermott Will & Emery

National Law Review, Volumess XII, Number 223

Source URL: <https://www.natlawreview.com/article/pto-issues-notice-duties-disclosure-and-reasonable-inquiry>