What USPTO's Disclosure Duties Notice Says And Doesn't Say

By **Ben Katzenellenbogen and Paul Stewart** (September 29, 2022)

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The director of the U.S. Patent and Trademark Office recently published a notice in the Federal Register: "Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board."[1]

The notice states that it "clarifies" the duty of disclosure for parties appearing before the USPTO who receive information from, or make representations to, other federal agencies.

Stakeholders from various perspectives, including patent practitioners, patent applicants and owners, and patent challengers, may have very different views as to whether the notice "clarifies" existing law. This is because stakeholders may have differing views regarding many of the issues addressed by the notice, especially a duty to investigate, and many of the director's statements are not followed by citation to any authority, or are followed by citations to cases that address potentially distinguishable facts.

To the extent statements in the notice do not reflect existing law, stakeholders are also likely to disagree as to the appropriate weight that should be given to statements of the director in the absence of formal rulemaking.

Patent practitioners and companies that appear before the U.S. Food and Drug Administration and the USPTO may have particularly strong views regarding the portions of the notice that discuss a duty to investigate whether statements to the USPTO are consistent with statements made to other agencies.

The Notice Responds to Political Comments

The notice begins by citing an executive order from President Joe Biden expressing concern that the patent laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, denying Americans access to lower cost drugs.

The notice also cites a letter from Sens. Patrick Leahy, D-Vt., and Thom Tillis, R-N.C., requesting that the USPTO take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the USPTO and other federal agencies. The notice quotes the senators as expressing specific concern about submitting statements to the FDA to secure approval of a product that are directly contradicted by statements made to the USPTO to secure a patent on the product.

The notice states that it is "part of the USPTO's efforts to put into effect the Administration's goals and address the Senators' concerns." The notice asserts that it "clarifies the 'duty of disclosure' and 'duty of reasonable inquiry' owed to the USPTO and American public" and that it "specifically addresses these duties as they relate to information and statements material to patentability including, but not limited to, those received from or submitted to the FDA and other governmental agencies."

The notice does not purport to have been issued pursuant to traditional rulemaking authority, including public notice and an opportunity to comment.

The Notice Addresses the Duty of Candor and Disclosure of Material Information

The notice focuses upon situations where a patent applicant or patentee is communicating with governmental agencies in addition to the USPTO. Where a party to a USPTO proceeding discovers that a position taken in a submission to the USPTO was inconsistent with statements made by the party to other agencies, the notice states that the party must correct the record before the USPTO. The notice specifically calls out statements made in proceedings before the USPTO and FDA:

> This requirement could include statements made or information submitted to other Government agencies such as the FDA. For example, when examining a claim directed to a process of manufacturing a particular drug product that was effectively filed more than one year after FDA approval of the drug product, an examiner may appropriately require an applicant to submit to the USPTO information submitted to the FDA (e.g., in a New Drug Application or Biologics License Application) on how the drug product was manufactured.

The Notice Discusses a Duty of Reasonable Inquiry

Part IV of the notice is titled, "What Is the Duty of Reasonable Inquiry."

The notice states that each party presenting a paper to the USPTO, whether a practitioner or nonpractitioner, has a duty to perform an inquiry that is reasonable under the circumstances and "[t]his reasonable inquiry may comprise reviewing documents that are submitted to or received from other Government agencies, including the FDA."

The notice does not explain the circumstances under which the duty would and would not include reviewing such documents. Nor does the notice provide a supporting citation for the obligation to review documents submitted to or received from other agencies.

Part V of the notice provides the director's views on "when the duties of disclosure and reasonable inquiry arise in dealings with other government agencies." This final part of the notice is likely to be the mostly hotly disputed by those on differing sides of the issue.

The notice states that "[e]ach individual with a duty to disclose, or party with a duty of reasonable inquiry, should ensure that the statements made to the USPTO and other Government agencies, or any statements made on their behalf to other Government agencies regarding the claimed subject matter, are consistent." The notice does not separately discuss how the obligations of individuals with a duty to disclose may differ depending on their knowledge of, or access to, other information.

For example, the notice does not discuss whether an attorney who handles patent prosecution matters for a company would be expected to "ensure" that all statements she makes to the USPTO are "consistent" with company statements to other governmental agencies of which the attorney has no knowledge. Nor does the Notice discuss how an attorney could be expected to do so.

In support of the statements regarding the duty to inquire, the notice cites a 2021 U.S. Court of Appeals for the Federal Circuit decision — Belcher Pharmaceuticals LLC v. Hospira

Inc. — that the notice characterizes as affirming a district court's determination of inequitable conduct because the patent owner's chief science officer failed to provide to the USPTO submissions he made to the FDA about the prior art that were inconsistent with positions taken before the USPTO during the prosecution of a pending patent application.[2]

The notice does not explain how a case involving a senior executive who allegedly had actual knowledge that he was personally making inconsistent statements to the USPTO and the FDA relates to a duty to investigate.

The notice also cites the 2005 Federal Circuit decision in Bruno Independent Living Aids Inc. v. Acorn Mobility Services Ltd., which it characterizes as finding inequitable conduct when an official involved in both the FDA and the USPTO submissions chose to disclose material prior art to the FDA but not to the USPTO.[3] Again, the notice does not explain how a case involving a person with actual knowledge of the allegedly material information relates to a duty to investigate.

Pharmaceutical companies may be particularly interested in portions of the notice discussing patents challenged in abbreviated new drug applications. An ANDA applicant typically discloses to the patent owner the basis for any assertion that the patents listed with the FDA as protecting the brand-name drug are invalid, are unenforceable, or will not be infringed by the proposed generic ANDA product. The notice states that entities should review such documents to determine whether any portions are material to the patentability of any pending matters before the USPTO, and submit any material portions to the USPTO.

The notice specifically adds that submitting an FDA-compiled list of patent challenges "does not satisfy the duty of disclosure for any material information" because the FDA's lists "do not include patent numbers, relevant claims, or an explanation of the basis for the certification." The notice does not provide a supporting citation for its statements regarding ANDA challenges.

The notice states that "each individual with a duty to disclose, or 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 USPTO."

Stakeholders may dispute whether the use of "it" means that the notice intends to convey that each individual with a duty to disclose, such as a patent attorney, should review documents the individual receives from other agencies, or that each individual with a duty to disclose should review documents the patent applicant or patentee receives from other agencies.

The notice also states:

> Deliberate schemes or established practices to prevent 37 CFR 1.56(c) individuals from obtaining knowledge of material information is not acting in accordance with candor and good faith under 37 CFR 1.56(a). For example, walling off the patent prosecution practitioners from the attorneys seeking FDA approval, as a way to prevent material information from being exchanged between the practitioners and attorneys, is inappropriate.

In support, the notice states that the U.S. Supreme Court has refused to enforce patents where deliberate steps were taken to suppress material information. The notice cites the 1933 case Keystone Driller Co. v. General Excavator Co., which it characterizes as involving a situation where "the patent owner paid a third party to keep a prior use secret,"[4]

and 1945's Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., "where [the] patent owner actively suppressed evidence of perjury to the USPTO."[5]

The notice does not address whether such deliberate steps to suppress material information are required. Stakeholders may dispute whether the notice intends to address only policies that are designed to segregate knowledge for the purpose of concealing material information from those having a duty to disclose it to the USPTO, or also policies that have another purpose but may result in material information not being known to those with a duty to disclose it.

One situation in which such disputes may arise is with respect to corporate policies designed to comply with patent prosecution bar provisions in litigation protective orders.

Conclusion

The director appears to have issued the notice in response to political attention regarding a small number of seemingly egregious situations in which senior executives were accused of making intentionally inconsistent statements to the FDA and USPTO.

Stakeholders will undoubtedly dispute the extent to which the notice clarifies existing law as well as the authority of the director to clarify or expound upon existing law without formal rulemaking.

At the very least, practitioners and companies may want to consider both the content of the notice, as well as the insight it offers into the current and potential future approach of the USPTO toward such issues.

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[1] See federalregister.gov/d/2022-16299.

[2] See Belcher Pharms., LLC v. Hospira, Inc., 11 F.4th 1345 (Fed. Cir. 2021).

[3] Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348 (Fed. Cir. 2005).

[4] Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240 (1933).

[5] Precision Instruments Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806 (1945).