



Legal Ethics in Life Sciences IP: Managing Conflicts, Confidentiality, and Compliance

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Agenda

Conflicts

- Managing Conflicts of Interest
- Navigating Waivers

Confidentiality

- Protecting Confidential Information and Complying with NDAs
- Best Practices for Handling Trade Secret Issues

Compliance

- The Duty of Candor in Patent Prosecution
- Meeting Disclosure Obligations

CONFLICTS

Conflicts

Rule 1.7: Conflict of Interest: Current Clients

- (a) Except as provided in paragraph (b), a lawyer **shall not** represent a client if the representation involves a **concurrent conflict of interest**. A concurrent conflict of interest exists if:
- (1) the representation of one client will be directly adverse to another client; or
 - (2) there is a **significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to another client**, a former client or a third person or by a personal interest of the lawyer.

Conflicts

Rule 1.7: Conflict of Interest: Current Clients (continued)

(b) Notwithstanding the existence of a concurrent conflict of interest under paragraph (a), a lawyer may represent a client if:

- (1) the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;
- (2) the representation is not prohibited by law;
- (3) the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and
- (4) each affected client gives **informed consent, confirmed in writing**.

Conflicts

Hypo: Client offers an equity stake in their early-stage startup in exchange for ongoing IP counsel?

Rule 1.8: Current Clients: Client-Lawyer Relationship

(a) A lawyer shall not enter into a business transaction with a client or knowingly acquire an ownership, possessory, security or other pecuniary interest adverse to a client unless:

- (1) the transaction and terms on which the lawyer acquires the interest are fair and reasonable to the client and are fully disclosed and transmitted in writing in a manner that can be reasonably understood by the client;
- (2) the client is advised in writing of the desirability of seeking and is given a reasonable opportunity to seek the advice of independent legal counsel on the transaction; and
- (3) the client gives informed consent, in a writing signed by the client, to the essential terms of the transaction and the lawyer's role in the transaction, including whether the lawyer is representing the client in the transaction.

But, keep in mind the potential for a material limitation on the representation.

CONFIDENTIALITY

Confidentiality

Rule 1.13: Organization as Client

(a) A lawyer employed or retained by an organization **represents the organization acting through its duly authorized constituents.**

(b) If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, **intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization**, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then **the lawyer shall proceed as is reasonably necessary in the best interest of the organization**. Unless the lawyer reasonably believes that it is not necessary in the best interest of the organization to do so, the lawyer shall refer the matter to higher authority in the organization, including, if warranted by the circumstances to the highest authority that can act on behalf of the organization as determined by applicable law.

COMPLIANCE

Interaction Between State Rules of Professional Conduct and USPTO Rules

37 C.F.R. Part 11, Subpart D governs the ethical behavior of attorneys and agents practicing before the USPTO.

Rules are modeled on and largely mirror the ABA Model Rules.

Key Differences:

- Duty of disclosure and candor in patent prosecution (distinct from ABA Rules).
- USPTO includes explicit exceptions for limited disclosure of client information in connection with lateral movement.
- Discipline is handled by the Office of Enrollment and Discipline (reciprocal discipline is possible).

Interaction Between State Rules of Professional Conduct and USPTO Rules

The USPTO Rule is closely modeled after ABA Model Rule 1.6, but includes:

- **Mandatory Disclosure Exception:** Under **37 CFR § 11.106(c)**, a practitioner **must** reveal information if required by other USPTO rules, which includes the duty of candor under §1.56.
- **Permissive Prevention of Inequitable Conduct:** Under **37 CFR §11.106(b)(2)**, a practitioner **may** reveal information to prevent a client from engaging in "inequitable conduct" before the Office.
- **No “Walling Off”:** The USPTO prohibits deliberate schemes to “wall off” practitioners from information to avoid disclosure obligations. For example, a company cannot ethically hide material FDA submissions from its patent attorney to claim ignorance of that information.

Compliance

37 C.F.R § 1.56 Duty to disclose information material to patentability

“Each individual associated with the filing and prosecution of a patent application **has a duty of candor and good faith in dealing with the Office**, which includes a **duty to disclose** to the Office **all information known to that individual to be material to patentability** as defined in this section. The duty to disclose information exists with respect to each pending claim **until the claim is cancelled or withdrawn** from consideration, or the application becomes abandoned.”

Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each **inventor** named in the application;
- (2) Each **attorney or agent** who prepares or prosecutes the application; and
- (3) Every other person who is **substantively involved in the preparation or prosecution of the application** and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

<https://www.federalregister.gov/documents/2022/07/29/2022-16299/duties-of-disclosure-and-reasonable-inquiry-during-examination-reexamination-and-reissue-and-for>

Compliance

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

- Chief Science Officer provided different information to the USPTO and FDA
- From his dealings with the FDA, CSO knew that company had described the claimed pH range as “old” and that they switched from a lower pH range at least in part to expedite FDA approval
- When dealing with the patent office, the CSO “used emphatic language to argue that the claimed pH range of 2.8 to 3.3 was a “critical” innovation.”
- The district court found it implausible that the CSO withheld the information from the USPTO because it was irrelevant
- The Federal Circuit affirmed a finding of inequitable conduct rendering the patent unenforceable

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

- Prior art submitted to the FDA was not submitted to the USPTO, despite concurrent proceedings
- Patentee did not provide “a credible explanation for the nondisclosure
- “[I]n the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.”

Questions?

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