Table 1: FTO Risk Calibration Across the Life Sciences Financing Lifecycle

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

Key Insight: Freedom-to-operate risk does not scale linearly with financing stage. Rather, the character of the risk evolves as a company progresses from scientific concept to commercial enterprise. Effective diligence therefore requires stage-specific FTO objectives and diligence standards.

Financing Stage	Primary FTO Focus	Key Investor Questions	Typical Diligence Expectations	Principal Risks	Common Mitigation Approaches
Pre-Seed	Foundational patent landscape assessment	Have major patent holders and blocking patent families been identified? Does the team understand the competitive patent landscape?	Preliminary landscape review and evidence that the founding team has evaluated patent barriers, not merely scientific feasibility.	Unknown blocking patents; technology development within a crowded patent space.	Early landscape analysis, patent monitoring, and product architecture decisions designed to avoid known barriers.
Seed	Validation of product direction and evolving risk profile	Has the product evolved beyond the original landscape assessment? Have newly published applications introduced new risks?	Focused review of relevant third-party patent families and ongoing monitoring efforts.	Product development creating new infringement vectors; insufficient tracking of emerging patent rights.	Targeted searching, early design-around strategies, and landscape-informed prosecution planning.
Series A	Product-specific diligence and risk management strategy	What specific product was analyzed? Is the analysis current? Has an independent review been conducted? Is there a credible strategy for managing identified risks?	Formal FTO analysis or equivalent diligence, often supplemented by targeted independent review of key patent families.	Stale opinions; mis-scoped analyses; unidentified blocking patents; product evolution not reflected in prior assessments.	Design-arounds, licensing strategies, validity challenges, and prosecution efforts directed toward identified landscape gaps.
Series B	Commercialization and geographic expansion	Has FTO been assessed in key international markets? Are there territorial barriers to partnering, out-licensing, or commercialization?	Jurisdiction-specific review covering major commercial markets, including Europe, China, Japan, and South Korea.	International blocking patents; territorial restrictions; diligence issues identified by prospective partners.	International FTO analyses, regional licensing strategies, and coordinated global patent filing programs.
Series C	Maintaining a current and defensible FTO position	Has the FTO analysis been refreshed recently? Have continuation patents, oppositions, reexaminations, and litigation developments been considered?	Comprehensive and regularly updated FTO review with active monitoring of important third-party patent families.	Newly issued continuation claims; evolving competitor portfolios; overlooked post-grant proceedings.	Periodic FTO updates, portfolio surveillance, and proactive licensing or challenge strategies.
Pre-IPO/Exit	Transaction readiness and external scrutiny	Would acquirers, underwriters, or strategic partners reach the same conclusions? Are material risks understood, documented, and appropriately disclosed?	Portfolio-wide and jurisdiction-wide review capable of withstanding third-party diligence and public-market scrutiny.	Material IP disputes; outdated analyses; incomplete territorial coverage; disclosure vulnerabilities.	Comprehensive updates, disclosure planning, litigation readiness, and active management of high-priority third-party risks.

Contact: Paul A. Calvo, Ph.D., pcalvo@sternekessler.com