



CASE STUDY

Industry: Pharmaceutical

Navigating the Patent Dance Streamlining Biosimilar Patent Litigation

The Biologics Price Competition and Innovation Act (BPCIA) established a complex legal framework, often referred to as the “patent dance,” for resolving patent disputes between reference product sponsors (RPS) and biosimilar applicants. This case study details how our client, an RPS, successfully navigated this intricate process when a biosimilar applicant initiated the patent dance following FDA acceptance of their application.

The Challenge: High-Stakes, High-Volume, High-Pressure Litigation

Our client faced a multifaceted challenge, typical of BPCIA litigation, with significant eDiscovery complexities:

- **Commercially Sensitive Information:** As direct competitors, both parties possessed highly sensitive commercial data, necessitating meticulous redaction of non-relevant information across vast document productions.
- **Private Health Information (PHI) Redaction:** Clinical data production required the redaction of PHI from over 12,000 documents, demanding precision and adherence to privacy regulations.
- **Short Message Data Complexity:** The matter involved a substantial volume of short message data from diverse platforms (Zoom, Teams, SMS), requiring strategic review due to the informal and context-dependent nature of such communications.
- **Aggressive Deadlines:** The BPCIA encourages swift resolution, imposing stringent deadlines that demanded rapid and efficient eDiscovery workflows.

Strategic Implementation: Technology-Driven Efficiency and Expertise

To overcome these challenges, Trustpoint deployed a team of experienced review managers and AI consultants, implementing a technology-centric approach and strategic workflows:

Leveraging Technology:

- **Strategic Batching:** Excel files and other document types were strategically batched and assigned to specific reviewers, ensuring consistency and efficiency.
- **Duplicate/Near-Duplicate Detection:** AI algorithms identified and clustered duplicate and near-duplicate documents, enabling efficient application of coding and redactions across related files.
- **Automated Redaction:** Advanced tools automated the redaction of recurring non-responsive terms and PHI within PDFs and Excel files, significantly reducing manual effort.
- **Predictive Coding (RAL) Models:** Search terms and Relativity Active Learning (RAL) models were employed to pinpoint documents requiring redaction, both for initial identification and quality control. RAL was also used to prioritize document review, ensuring critical information was reviewed early.
- **Foreign Language Detection:** Automated language detection tools identified foreign language documents, enabling their swift isolation and review by a specialized, multilingual team.

Strategic Workflow Optimization:

- **Dedicated Redaction Team:** A specialized redaction team was formed in parallel with the review team, accelerating the redaction process after initial document prioritization.
- **Strategic Batching:** Excel files and other document types were strategically batched and assigned to specific reviewers, ensuring consistency and efficiency.

Delivery & Results: Exceeding Expectations in a High-Pressure Environment

Trustpoint successfully processed over 400,000 documents, redacting 23,000 documents across three languages within a demanding three-month timeframe, achieving the following results:

- **Meeting Strict Deadlines:** All deadlines were met, demonstrating the team's ability to operate effectively under pressure.
- **Significant Cost Savings:** Automated redactions saved the client over \$35,000, showcasing the efficiency of technology-driven solutions.
- **Accurate and Consistent Productions:** The team delivered accurate and uniform document productions, minimizing the risk of errors and disputes.
- **Deposition Support:** The review manager provided expert assistance in preparing deposition binders, enhancing the case team's effectiveness.

