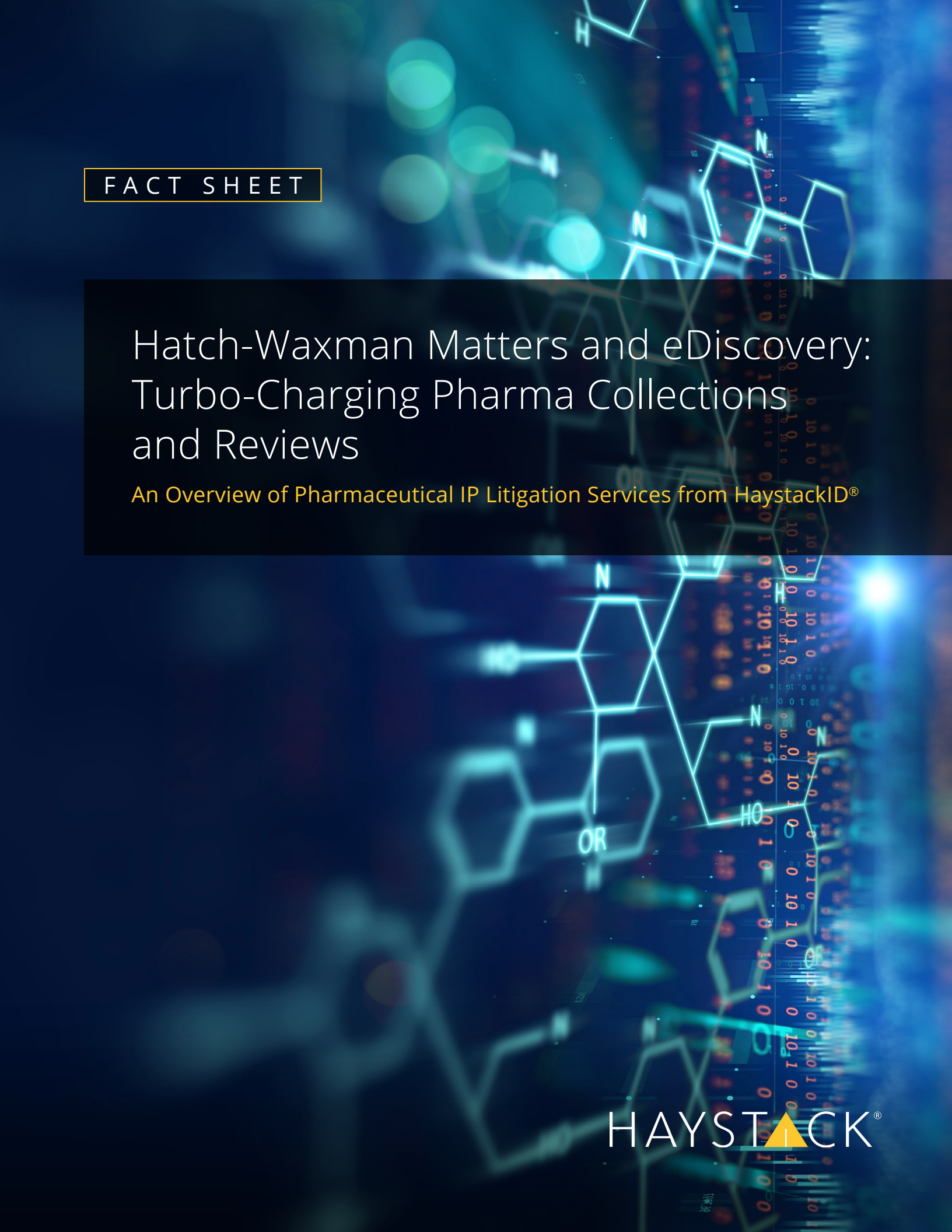

FACT SHEET

Hatch-Waxman Matters and eDiscovery: Turbo-Charging Pharma Collections and Reviews

An Overview of Pharmaceutical IP Litigation Services from HaystackID®

HAYSTACK®

Streamlining Medication Approvals and Ensuring Data Compliance

The Hatch-Waxman Act, implemented in 1984, has simplified the approval process for generic pharmaceuticals and established guidelines for patent litigation in the United States. This legislation has played a significant role in advancing biopharmaceutical research and development in the country.

In seeking approvals and ensuring compliance, pharmaceutical companies regularly engage in complex **data mapping**, **data collection planning**, **document reviews**, Electronic Common Technical Document or **eCTD reviews**, and **compliance monitoring**. This process involves eliminating redundant or irrelevant data, identifying valuable information relevant to certifications, and safeguarding research data by understanding its flow within and outside the company.

HaystackID is an essential partner for manufacturers and legal counsel navigating the intricate and ever-changing landscape guided by the Hatch-Waxman Act. Expedited approvals accomplished through precise data analysis can frequently lead to legal disputes. Given the complexity and dynamic nature of the legislation, collaborating with experienced discovery management and data experts like HaystackID can mean the difference between positive outcomes or unplanned delays.

The Hatch-Waxman Act

Since 1984, the Hatch-Waxman Act has streamlined the process for generic pharmaceutical approvals and created a framework for generic pharmaceutical patent litigation. This act helped the United States become a biopharmaceutical research and development leader.

Under the act, the first filer or FTF (First To File) of an Abbreviated New Drug Application (ANDA) with a Paragraph IV certification is entitled to a 180-day market exclusivity period for the first marketed generic.

Hatch-Waxman created a data-driven fast-paced race to the finish line that typically generates multiple lawsuits. The complexity and evolving nature of the law, coupled with the need for speed, make it essential for the manufacturer and legal counsel to partner with an experienced discovery management and data expert like HaystackID.

Data Mapping

The first step in mitigating compliance risk and ensuring you get the data when needed is to start with data mapping, categorization, migration, and remediation planning. This process will eliminate duplicate, outdated, and trivial data and identify high-value relevant data based on categories that you can use to support your certification.

Using a data map, pharma companies will better understand security risks and safeguard the research data by knowing how data flows within the company and out. The data mapping team will help classify your applicable data by type, sensitivity, risk, and regulatory obligations for retention, data correction, migration, and remediation.

Data Collection Planning

A collection plan is critical since data collection can be challenging and complex because of all the proprietary data and structured data sources used by pharma companies and the need to quickly and accurately convert this proprietary data into a usable production format. The planning requires a complete technology assessment and workflow review to create an operational collection strategy.

A good collection plan ensures that everyone working on a research project is on the same page and that the information is efficiently and correctly channeled to the right people when needed.

Document Review

An efficient Hatch-Waxman review aims to quickly and accurately search for relevant documents from the data set, classify them by issue and category, identify privileged documents for redaction, and promote relevant documents to production in the agreed format. It is recommended that TAR (technology-assisted review) and advanced analytics be considered to speed up the review process.

In Hatch-Waxman litigation, the data set to review will typically include thousands of Excel documents with multiple tabs, columns, and rows with numerous references to responsive data elsewhere. Without using the latest review technology, this can make spreadsheets time-consuming to review, redact, and produce responsive data accurately.

Pharma companies must keep other drugs they are creating a secret (non-responsive). To protect trade secrets, having a list of all drugs/products the company makes is advised. If an inventory is not readily available, reviewers can create a list as they review documents. Once the list is created, it can be used for future reviews.

eCTD Review

The Electronic Common Technical Document (eCTD) is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER).

HaystackID has solved the challenge of eCTD review for legal professionals with our proprietary eCTD Compliance Review Module. This review module is designed to help legal experts tackle the complicated formats of eCTD filings.

HaystackID's eCTD Compliance Review Module provides context and structure around documents in an eCTD submission immediately upon uploading into Relativity, during document review, and through productions to others, standing alone as the only comprehensive solution on the market for eCTD review challenges.

Compliance Monitoring

Recent reports of foreign governments hacking into pharma research facilities and allegations of false claims (unproven statements or misrepresentations) by some pharma companies necessitate pharma companies to have an internal proactive compliance monitoring program.

Monitoring is considered distinct from auditing, which is typically retrospective and often limited by time, frequency, and scope. Monitoring can be executed by using surveillance policies and technology that, in real-time, can monitor common destructive behaviors, including market manipulation, insider trading, bribery, corruption, and more.

Delaying action on suspicious activity – risking an investigation, regulatory inquiry, IP theft, leaks, false claims, litigation, etc. – is not an option when dealing with Hatch-Waxman litigation. Proactive compliance and surveillance workflows should be used to identify the suspicious or inappropriate activity as it's created, so that companies can act on it before it escalates.

Key Benefits of HaystackID's Pharmaceutical IP Litigation Services:

- Pharmaceutical IP Litigation Expertise
- Strong Data Management Policy
- Effective Compliance Monitoring
- Robust Data Collection Planning
- Skilled Legal Review Team
- Latest Technology

Learn More. Today.

Contact us today to learn more how HaystackID's specialized collection and review services can help turbo-charge your pharmaceutical IP litigation.

About HaystackID®

HaystackID is a specialized eDiscovery services firm that supports law firms and corporate legal departments and has increased its offerings and expanded with five acquisitions since 2018. Its core offerings now include Global Advisory, Discovery Intelligence, HaystackID Core™, and artificial intelligence-enhanced Global Managed Review services powered by ReviewRight®. The company has achieved ISO 27001 compliance and completed a SOC 2 Type 2 audit for all five trust principles for the second year in a row. Repeatedly recognized as a trusted service provider by prestigious publishers such as Chambers, Gartner, IDC, and The National Law Journal, HaystackID implements innovative cyber discovery services, enterprise solutions, and legal discovery offerings to leading companies across North America and Europe, all while providing best-in-class customer service and prioritizing security, privacy, and integrity. For more information about its suite of services, including programs and solutions for unique legal enterprise needs, please visit HaystackID.com.