



Litigation Excellence in the Life Science Industry

Supporting Legal Disputes and Damage
Claims with Industry Specific Expertise





Life Science Industry Litigation Cases are on the rise

Life Sciences Industry Litigation Cases continue to **rise**, accounting for **more than 25% of all filings in 2021** in the United States across all industries. The **top 10 Litigation Cases** summed up to **more than 50% of the consolidated settlement value** amount with **Life Science Industry cases contributing 3 out of the top 10 agreements**. Litigation in the **Life Science** is anticipated to **grow further** throughout the near future.

Litigation involving pharmaceutical and medical device companies includes **various types of underlying causality**. Most common reasons for Litigation in the Life Sciences Industry refer to:

OVERVIEW UNDERLAYING CASUALTIES OF LIFE SCIENCE LITIGATIONS

Figure 1



Both the volume and the diversity of cases are driven by the **complexity of the industry itself**, as well as by the **regulatory frameworks** and doctrinal rules. More generally, an **increase of B2B disputes** in the industry – e.g., **between innovators and generic entrants** or from **regulators against originators** – around the globe can be observed.

Furthermore, **Life Science** companies today are **interdependent** on each other in a way that was not the case years ago, which again, offers **plenty of room for Litigation**.

Additional reasoning for the **growing momentum** can also be found in an **increase of licensing and co-promotion agreements**. This leads to **unlocking of the product-value chain** resulting in a **subsequent uptake in business disputes**, particularly in international arbitrations.

As always, **the best offense is a good defense**. To analyze and address potential **Litigation** issues, companies should have **early case assessment** processes in place.

Such **early case (risk) assessment programs** may allow for **informed and profound decision making** at the **early stages** of a **potential dispute**.

The **sooner** stakeholders can **identify, face, and tackle** the **circumstances** of an **upcoming dispute**, the less likely it is that the dispute will lead into in a “full-blown” crisis.

Pharmaceutical Litigation Cases have reached dizzying heights

A pharmaceutical lawsuit case can arise in many various forms and types including the forementioned “full-blown” crisis with tremendously deviating amounts of disputes. The **top 10 Life Science lawsuit cases** in the last 15+ years reached a combined **approximate \$ 50 billion** of settlement value.

OVERVIEW TOP 10 LARGEST LIFE SCIENCE LITIGATION CASE SETTLEMENTS

Figure 2

Year	Defendant	Product(s)	Prosecution(s)	Settlement
2021	McKesson <small>Contract Sales Ambulatory Care</small>	Opioids	Marketing and selling dangerous opioids to healthcare providers with knowledge of diversion to abusers	\$26 bn
2020	Purdue	OxyContin Butrans Hysingla	facilitating dispensing of opioids without a legitimate medical purpose/Kickback payments	\$8.34 bn
2012	GSK	Avandia, Wellbutrin, Paxil, etc.	Off-label promotion and Kickback payments Failure to disclose safety data	\$3 bn
2009	Pfizer	Bextra, Geodon, Zyprexa, Lyrica	Off-label promotion Kickback payments	\$2.3 bn
2013	Johnson & Johnson	Risperdal, Invega, Nescintide	Off-label promotion Kickback payments	\$2.2 bn
2013	Wyeth	Protonix	Patent litigation	\$2.15 bn
2010	Boston Scientific	Coronary stents	Patent litigation	\$1.73 bn
2012	Abbott	Depakote	Off-label promotion	\$1.5 bn
2009	Lilly	Zyprexa	Off-label promotion	\$1.4 bn
2005	Medtronic	Spinal implants	Patent litigation	\$1.35 bn

While some **Litigation Cases** receive great public attention others do not. However, all **Litigation Cases have in common** that the drawing of a **comprehensive situational picture** is required.

Often **relevant facts** and **figures** are rather simple to collect, while other cases are **comparably more complex** and must be **approached differently capitalizing on in-depth market knowledge**.

Such complex cases can usually be found in the sphere of **patent infringement** and may require complex market dynamic analysis e.g., including considering different **submarkets**, resulting **price erosions**, **tenders** triggered by the infringement, the impact of **re-launches**. All resulting in a necessity to build various **hypothetical market scenarios** and to anticipate the market development which would have taken place without infringement. Such consideration will ultimately have to be translated into a **financial model** based on deeply rooted market understanding.

MANIFOLD CHALLENGES ALONGSIDE THE PROCESS

A **Litigation Case** tends to be a **complex** and **lengthy process** and companies involved are **facing many challenges** along the way. One key complexity is to **identify** which **personnel** offer the **best sources** to gather the required key **information**, be it as potential **fact-witness** or just as **custodians** who should be consulted to gain a more **complete understanding** of the relevant circumstances.

External and internal corporate counsels may experience difficulties identifying the right employees within the company to collect the manifold facts, data, and documents. **The larger an involved organization is the more often this becomes a bottleneck**. The reasons are diverse, mainly it is because legal departments usually have little to no interaction with marketing and sales departments, which in parallel can interact - **driven by increasing compliance requirements and rules** - only to a very limited extent with medical departments.

Thus, involving an External Expert early - supporting both involved Life Science companies and mandated **Law Firms** - in the Litigation Process will help identify the right functions, as well as responsible employees, to facilitate immediate data collection and exchange of fundamental facts, as well as build a systematic methodology to approach the case.

EXTERNAL EXPERTS HELP PROVIDE CRITICAL INDUSTRY KNOWLEDGE

External Experts contributing with **deep industry knowledge** and expertise play an important role, bringing numerous benefits to all types of Litigation Processes. **Methodology development, document collection, data compiling and analysis, information consolidation, hypothesis creation, conclusion drawing, and result/outcome documentation** typically can add up to be very lengthy time-consuming process for employees of the company.

Throughout the aforementioned Litigation Case process, the Expert will **not only support** and **exchange regularly** with the involved Life Science company, but even more importantly **closely collaborate** with the **mandated Lawyers and Law Firms**.

Representing an important part of the Litigation Team, such **Experts** contribute not only with the existing deep industry knowledge and **insights into the relevant Indication or Therapeutic Area**, but also via engaging with the relevant company management. Thereby, causing chaos and putting unnecessary additional workload as well as burden on corporate daily operations and resources will be avoided. They will provide such benefits in affirmative as well as in defensive positions

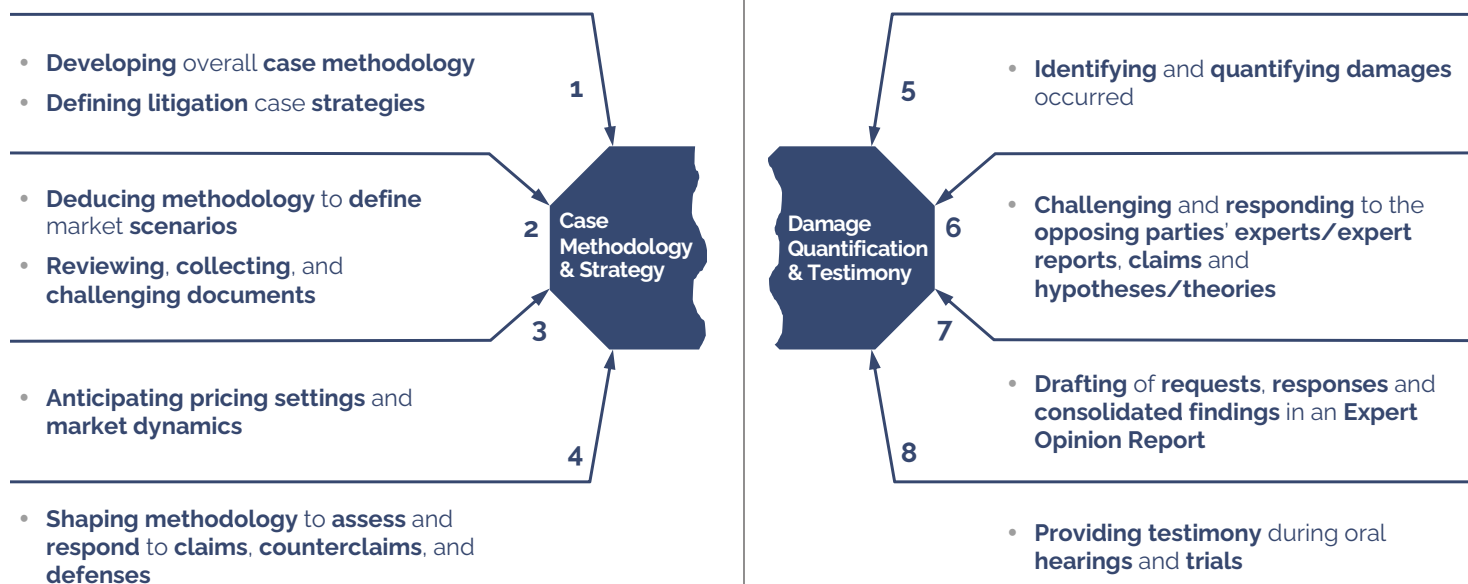
An additional benefit is that External Experts may act as an **unbiased and independent sounding board** providing an ideal sparring partner to challenge any upcoming issues. Evaluating information provided by parties and serving as an orchestrator of employees who possess case relevant knowledge is an indispensable support to internal corporate and external counsels.

Moreover, all cases, in which the final outcome heavily depends on **the strength of medical science or commercial methodology**, gain by engaging Industry Experts from the beginning; thereby resulting in better scoping of the case and shaping of the arguments to define a potential **Damage Claim**.

In summary, Experts will **not only serve as Industry Expert-Witness** but also **provide essential support** during a **Litigation, defense, or plaintiff**, alongside the preparation of any legal action taken by the Law Firms.

OVERVIEW OF EXTERNAL SERVICES AND POTENTIAL METHODOLOGIES

Figure 3



The **need** of external Experts can **evolve over the full life cycle** of a case; thus, it is highly recommended to retain an Expert as early as possible for **early sparring** and **joint development** of the **overall case strategy** and desired outcome.

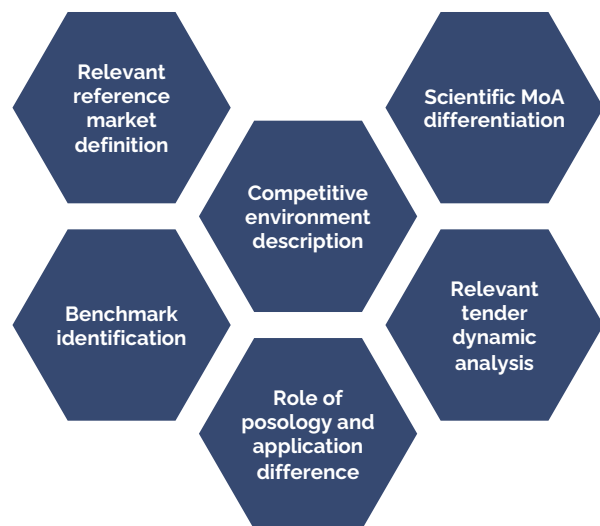
Industry Expert Opinion Reports, the backbone of all legal argumentation

Usually, the purpose of an **Expert Report** is outlining the Expert's Opinion on matters within his expertise and defined scope of the case.

A **profound Expert Opinion Report** has to lay-out systematically all components required to build a qualified opinion on the matter of Litigation. In the case of patent infringement for example they must include:

OVERVIEW OF EXPERT OPINION REPORT COMPONENTS

Figure 4



Running a litigation Case requires building a sound **Business Case** demonstrating the hypothetical overall market development. Market shares will have to be modelled de-facto, as well as, for one or several hypothetical scenarios. Building and deducing the overall Business Case often even requires the Industry Expert to **involve** additional **KOLs or Medical Practitioners** in interviews to deduce the appropriate hypothesis.

All such relevant and complex aspects and levers will have to be formulated in a coherent, transparent, logical, plausible, and structured **Expert Opinion Report**.

The format and scope will be aligned to local legal requirements and applicable jurisdiction in close cooperation with the mandated **Law Firm**.

The ultimate purpose of such an **Expert Opinion Report** is to inform the court on matters outside its expertise on which it must take a decision in order to resolve the dispute. In addition to the court's use, the expert report will also inform the involved company and its counsels on technical matters enabling them to determine the **power** of the **Litigation Case**.



In the preparation for the hearing, during which a **settlement** is usually strived for, most **findings** often will be discussed with the **counterparty** in the dispute. In case counterparties engage their own Expert, a copy of their Expert's Report will be made available at the same time and needs to be critically reviewed for all embedded facts and arguments.

During the Litigation Process, each party involved will grant the opportunity to **respond**, **comment**, and **prepare counter arguments** to any **pleadings** (initial Report, Replication, Triplication) submitted.

Usually, both parties would strive for a **friendly out-of-court-solution**. In the event that a **Litigation settlement** is not reached, the **case will be negotiated** before a **court of first instance**. Oral hearings can be supported in the **preparational process** e.g., identifying the right (counter)arguments and/or appointing the previously involved Expert as a Witness.

Independent of any **court of first instance decision taken**, clients might want to and/or will be forced by the counterparty to **file or prepare for an appeal**. The potential impact and outcome of an appeal will be analyzed considering the court of first-instance decision, initial assumptions, hypotheses, financial damage calculated, actual market developments, etc.. The **appeal procedures** can either be supported by **ad-hoc support** (e.g., argumentation analysis and challenge) and/or result in an additional written **Expert Opinion Report consolidating previous facts and judgement** and even **refining the damage calculation** based on the **first instance findings**.

stradoo® OFFERS EXPERT SUPPORT ACROSS THE WHOLE VALUE CHAIN OF LITIGATION

OVERVIEW OF MODULES TO SUPPORT A LITIGATION CASE

Figure 5

Out-Of-Court Settlement ¹⁾		
Damage Quantification	Expert Opinion Report	Replication Report(s)
4-6 weeks	2-4 weeks	Up to 3 months
<ul style="list-style-type: none"> Identify facts and base information from the client's perspective Define overall litigation case strategy Develop case specific methodologies Build quantification model and calculate damage from the client's perspective and simulate, market development considering various scenarios 	<ul style="list-style-type: none"> Seek friendly dialogue (if not already done previously) Define requirements (e.g., particular format obligatory by the respective jurisdiction) for a potential court submission with client Compile expert opinion and findings in a structured, comprehensive report based on previous findings 	<ul style="list-style-type: none"> Submit expert opinion report to counterparty Assess and evaluate counterparty's pleading and potential own expert report considering specific claims and facts Prepare counterarguments Prepare replication report answering/ commenting on to counterparties arguments and facts

In recent years, **stradoo®** has supported **numerous Life Science Litigation Cases** for our clients in the pharmaceuticals, medical device, and biotech industry always in perfect **alliance with the respective Law Firm supporting the case**.

We provide professional Expert Litigation support ranging from (early stage) **Damage Quantification**, written **Expert Opinion Reports** (for various stages), providing **Testimony** during Hearings and Trials up to services in the **Appeal Proceedings**. Expertise from **more than 25 years of professional experience** in **Litigation** and our **Senior Partner's network** throughout the industry can ensure that our clients will maximize the value of each Litigation Case.

Why stradoo® ?

stradoo® Life Science Litigation support for both **plaintiff** and **defense** are grounded in a comprehensive understanding of pharmaceuticals, biotechnology, medical devices, and diagnostics industry.

For more **many years** our Partners and Consultants have collaborated globally with major **Life Science companies, Law Firms, and regulatory authorities**.

First Instance Decision ¹⁾	
Court Hearing & Trial	Appeal Proceedings
1-2 weeks	1-6 months
<ul style="list-style-type: none"> Negotiation of the case in court of first instance if friendly litigation settlement failed Support of oral hearing either in preparation and sparring of argumentation or appointing the previously involved expert as a witness (to bear testimony) 	<ul style="list-style-type: none"> Analyze court of first instance judgement considering client's expectation, counterparty's arguments, etc. Identify relevant facts to assess the potential impact and success of filing an appeal Provide client with ad-hoc support e.g., argumentation sparring, further analyses and/or another full written expert opinion report

¹⁾ stradoo would engage in Plaintiff or Defense support (not both)



stradoo® provides its clients with the crucial industry expertise to address multifaceted issues accompanied by extensive analytical experience in working with complex data including private and statutory health insurance data, pharmaceutical sales data and market research to answer questions of wrongful conduct, causation and damages.

About **stradoo®**

stradoo® is a globally acting Strategy Consulting and M&A Advisory firm focusing exclusively on the Life Science Industry.

Many years ago, we set out to create innovative management tools that would transform the way organizations define and execute their strategies. Today, many of our tools are deployed in most top healthcare companies and institutions in the world to solve problems. On the back of this experience, track record and network in the industry we are able to scale our services with an integrated Damage Claim and Litigation Advisory function serving Pharmaceutical Corporates and Law Firms alike.

stradoo® works in small teams consisting of senior executives with many years of experience.

stradoo® work is consistently founded on deep industry knowledge, innovative analytics, and data-driven algorithms.

stradoo® solutions follow a range of proprietary project methodologies developed over many years and customized to client needs.

stradoo® solutions cover the whole industry value chain.

stradoo® is committed and used to implementing strategies together with its clients, thus ensuring long-term success.

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