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Life Sciences Disputes: Lessons From 2023 And What To Expect In 2024

Insights From Cooley LLP

by **In Vivo Team**

Looking back at the prominent commercial dispute trends in the life sciences industry in 2023 sheds some light on what might be expected in 2024.

Though 2023 did not produce significant surprises, the year did see class actions continue to grow, particularly in the EU as a result of the recent legislative reforms. The widespread expectation remains that we will see more 'US-style' actions within Europe in the future. Connected to that, the sector also saw an increase in product liability cases which is likely to continue into 2024 and increase significantly beyond that.

Finally, the life sciences sector remains a key enforcement focus for antitrust authorities and so we anticipate seeing damages actions being brought in 2024 in relation to various infringement decisions.

Class Actions

Life sciences remains one of the main areas of focus for class actions in Europe. According to some reports, class actions in the consumer products and life sciences sector grew as much as 44% in 2023. The growth was extremely significant and, as the new EU class action mechanism under the Representative Actions Directive only applied from June 2023, we can expect this growth trend to continue.

The new EU rules introduce a full class action procedure for the first time into all member states, which is expected to make the grouping and advancement of large numbers of claims across Europe much easier for plaintiff firms. At the same time, the UK (which has had collective procedures in place for some time), is also seeing significant growth in class actions, with a

reported 10-fold increase in the value of class actions between 2016 to 2022. Whilst markets like the Netherlands, Portugal and Germany are developing, the UK class actions market remains more than four times bigger than any other in Europe.

The growth in the EU and UK class actions markets has not gone unnoticed – with major investments made by litigation funders, as well as an influx of specialist US plaintiff firms into the EU and UK in anticipation of significant shift in the area.

Continuing Effect Of Market Conditions

Many life sciences companies came under increasing strain in 2023 as a result of the continuing difficult market conditions (including the lingering effects of the COVID-19 pandemic). As a result, we saw many disputes arising around unpaid invoices or alleged failures by parties to meet contractual obligations (especially around clinical trials and obligations designed to protect the integrity of trial data, or performance of CDMOs).

The difficulties faced by many has also led to the downsizing of operations and in some cases the closure of sites. While this can bring some relief from short term overheads, it can also cause difficulties in respect of compliance with contractual obligations, as well as causing supply chain and continuity disruptions. Over the last 12 months, we have continued to see commercial disputes created by life sciences companies having to take these measures.

The vast majority of these disputes were resolved either commercially or through other confidential dispute resolution processes, showing a continued desire from life sciences companies to try to avoid full blown litigation where possible and to focus on overcoming the challenging conditions.

Disputes Arising From The COVID-19 Pandemic

While 2023 saw a reduction in the number of disputes relating to failed attempts to develop and commercialise COVID-19 vaccines, some disputes remained to be resolved during the year. Those primarily related to the speculative purchasing of manufacturing space during the previous few years in preparation for approval of vaccines under development, which was then no longer needed. However, most disputes of this nature have been resolved, and we do not expect to see significant new developments in this area.

However, there are ongoing disputes between service providers and their clients in the life sciences sector, particularly in cases where service providers are said to have overpromised and underdelivered, sometimes due to difficulties in sourcing materials and competent staff during the pandemic, sometimes due to their own financial pressures. Other disputes have arisen because the parties entered into rushed contracts and have since discovered that those contracts do not reflect the needs of the parties outside of the unpredictable and more impulsive pandemic environment. We anticipate those types of disputes will continue into 2024 and beyond.

Antitrust Disputes

2023 saw a continuation of the trend of the last few years with global antitrust regulators being increasingly active in taking enforcement action. The European Commission, the Federal Trade Commission Competition in the US and the Competition and Markets Authority in the UK all being particularly active in challenging anti-competitive conduct in life sciences markets. Whilst the focus to date has been scrutinizing anti-competitive agreements, excessive pricing and patent settlement agreements, regulators commenced new cases looking at novel patent misuse and product disparagement allegations.

Trends For 2024

With difficult market conditions expected to persist well into 2024, there will likely be a continuation of the types of disputes relating to those conditions during the course of the year and beyond. Life sciences companies will face increasing pressure on cash flows which will continue to create a natural environment to produce disputes – an absence of funds to pay invoices and increasing difficulty in complying with contractual obligations.

With a number of cases concerning excessive pricing and anti-competitive conduct and agreements concluding, we expect to see damages actions in respect of harm suffered by third parties. But with regulators having a continued focus on anti-competitive conduct in the sector, and seeking to extend enforcement action into novel theories of harm, there is a greater likelihood of parties being emboldened to bring standalone challenges where they perceive anti-competitive conduct is impacting their go-to-market strategies.

We expect 2024 will see a continued increase in the number of European class actions, boosted by the new EU mechanism, increased litigation funding and growth of US plaintiff firms across Europe. The leading European consumer NGO has called this evolution “game changing” for plaintiffs and all life sciences companies selling products in Europe need to be aware of the increasing risks of doing business, and what steps they can take to try to mitigate these risks.

About The Authors

Written by: [Henry Stewart](#), [Sascha Grimm](#), [Caroline Hobson](#), [Ed Turtle](#) and *Emerald Hockley* from law firm Cooley’s life sciences disputes team. As part of Cooley’s global life sciences capabilities, its life sciences disputes team is kept busy resolving issues that arise for life sciences clients whether through formal litigation, arbitration processes or otherwise. A significant amount of Cooley’s time is spent helping life sciences companies avoid disputes so that they can focus on their primary objectives. As such, many of the insights in this article comes from matters that have not been litigated and are not public.

2024 will also be a watershed year for product liability risks. At the end of 2023, the EU Parliament and Council reached provisional agreement on the text for a new product liability regime in Europe, which will enter into force in 2024 and apply in full in 2026. It is a major shakeup, fully revising the EU's already claimant-friendly "no fault" regime for the first time in nearly 40 years.

Amongst other changes, software is brought in scope and data loss and mental health risks will be recoverable. Significantly for life sciences companies, a court will be able to assume defect in certain cases where products are scientifically or technically complex (with examples of pharma and AI given), or if there is an established non-compliance with relevant EU product regulations. The period for claims to be brought is also extended from 10 years to 25 years for claims where symptoms are slow to emerge.

Product liability claims are already the single biggest source of class actions claims in the life sciences sector and a new, more claimant-friendly, product liability regime in Europe has the potential to supercharge this risk. Moreover, the reforms sit alongside parallel policy initiatives – such as the EU's new class action mechanism (mentioned above), new AI regulation and accompanying liability regime, and stricter ESG rules.

While the full effect of these measures may not be felt in 2024, taken together, the reforms are a fundamental shift in the European risk landscape that, undoubtedly, will have a major impact in the next few years for EU-based and international life sciences companies.