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# LITIGATION IN THE PHARMACEUTICAL AND MEDICAL DEVICE SECTOR

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CRA Charles River Associates

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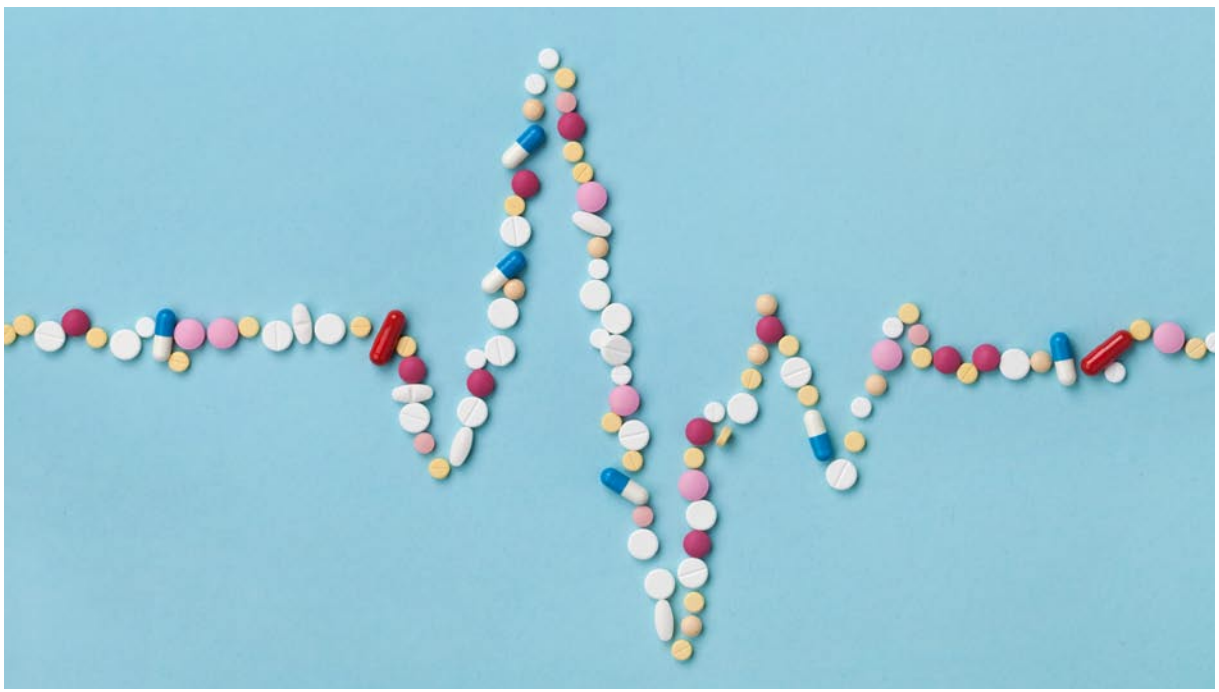
HOT TOPIC

# LITIGATION IN THE PHARMACEUTICAL AND MEDICAL DEVICE SECTOR



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**CD: How would you characterise recent litigation activity involving companies operating in the pharmaceutical and medical device sector? What types of dispute are common and what factors are driving them?**

**Bell:** In the US, we are seeing an upswing in litigation across multiple jurisdictions and involving multiple parties in the industry that is reminiscent in scope of the AWP cases of years past. A prominent example is the wide-ranging opioid litigation against drug manufacturers, distributors and retailers. In these cases, governments and other parties are accusing the defendants of contributing to the overuse of opioids by allegedly engaging in marketing that downplayed the risk of addiction and failing to report suspicious orders. Another significant case is the multidistrict generic price-fixing litigation, in which government entities and private parties allege that companies conspired to fix the prices of certain generic drugs. In essence, the plaintiffs are claiming that alleged price increases for the drugs in question result from a collusive agreement among the defendants as opposed to changes in market conditions that the defendants responded to unilaterally.

**Greenblatt:** Litigation remains frequent in this sector. Common litigation involving pharmaceutical and medical device companies includes everything from Hatch-Waxman patent infringement disputes between innovators and would-be generic entrants, to antitrust lawsuits based on brand manufacturer decisions that may alter the timing of generic competition, to mass tort product liability actions involving negligence or strict liability personal injury claims. Both the volume and diversity of cases is driven by the complexity of the business, as well as the specialised regulatory and doctrinal rules in place. Further, consolidated multidistrict litigations have expanded to make up nearly 40 percent of federal court civil actions, a large number of which involve pharmaceutical or medical device companies.

**Torregrossa:** In the US, there has been a shift away from the class action vehicle. That shift is partly a result of two Supreme Court decisions – *Wal-Mart v. Dukes* and *Comcast v. Behrend* – addressing the requirements for meeting class certification generally. It is also the result of a series of decisions in pharmaceutical class action cases finding a lack of causation because the aggrieved parties did not change their use or reimbursement of the product as a result of the alleged misconduct. That shift away from class actions has led to increased filings and focus on individual actions, mass tort actions and multi district litigation (MDLs). More generally, there are increased business-to-business disputes around the world. Increasingly, healthcare companies are interdependent on each other in a way that was

not the case 30 or 40 years ago. This increase in licensing, co-promotion agreements, joint ventures and more has led to a corresponding increase in business disputes, particularly international arbitrations.

**CD: Could you outline any key legal and regulatory developments that are influencing litigation activity?**

**Greenblatt:** Over the past few years, disputes involving personal jurisdiction have become increasingly common, given the US Supreme Court's decisions significantly limiting both general and specific personal jurisdiction over out-of-state defendants. Lower courts continue to address the boundaries of federal pre-emption doctrines set by the Supreme Court, from deciding when a claim states a parallel requirement claim against a medical device manufacturer of a pre-market approved product, to what counts as clear evidence the FDA would refuse to approve the warnings forming a claim against a pharmaceutical company.

**Torregrossa:** It will be interesting to see how the significant changes in the discovery rules in the US federal courts impact litigation activity. Almost every litigator is familiar with the old standard that a party could obtain discovery from another party if it was "reasonably calculated to lead to the discovery of admissible evidence". That broad standard has been replaced with a 'proportionality' standard, based on several factors, including the amount at stake, the resources of the parties, the burden of collecting the information and more. Currently, many cases are resolved because the risks and the costs outweigh the benefit of proceeding to a full trial. This has led some to pronounce the 'death of the trial' because so few cases are tried anymore. There is a lot of litigation around what this new proportionality standard means, but if it results in significantly reduced discovery demands, which, in turn, reduces case expense, it is certainly possible that defendants will begin to try more cases to verdict. If that is the case, it could be an even more exciting time to be a litigator.

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> *Jennifer L. Greenblatt, Goldman Ismail Tomaselli Brennan & Baum*

**Bell:** A growing number of intellectual property cases have now reached the courts that originated with the implementation of the Biologics Price Competition and Innovation Act of 2009. The BPCIA was meant to enable the approval of 'biosimilar' biologic products by, among other things, providing a framework for parties to address patents relating to a reference biologic product. It has taken a while for these cases to progress, but there are a number of interesting issues here. The patent estate on an innovator reference product can include a large number of formulation and process patents, many of which may be asserted in the case at issue. Needless to say, this raises challenges for the parties in addressing patent infringement, validity and enforceability; it also poses interesting issues from a damages perspective, particularly in terms of assessing the relevance and impact of non-infringing alternatives to the patents in suit.

**CD: Have any recent, high-profile litigation cases gained your attention? What lessons can the pharmaceutical and medical device sector learn from their outcome?**

**Torregrossa:** The recent California Supreme Court decision in *T.H., et al. v. Novartis Pharmaceuticals Corporation* is a very notable decision. While the vast majority of courts reject brand-name manufacturers, owing a duty of reasonable care to ensuring that product labelling includes adequate warnings on generic versions, the court found that brand name manufacturers can be liable for their competitors' generic products. Even further, the court found that this liability might exist even after the brand name manufacturer sold the product and stopped selling the drug. The concept of foreseeability is being stretched so far under the law that every company, not just the companies in the pharma and medical device sector, should stand up and take notice.

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*Brennan Torregrossa, GSK*

**Bell:** Recent US cases are bringing an antitrust focus to the common US practice of manufacturers contracting with third-party payors, such as managed

care organisations. One example is Pfizer alleging that Johnson & Johnson engaged in anticompetitive contracts with payors to disadvantage Pfizer's biosimilar version of J&J's Remicade. In addition to exposing contracting practices to antitrust scrutiny, the Remicade case is also likely to illuminate some of the challenges faced by biosimilar manufacturers attempting to dislodge established incumbents.

**Greenblatt:** Personal jurisdiction is a topic that has received increased attention lately following the Supreme Court's decision in *Bristol-Myers Squibb Co. v. Superior Court of California*, which held due process did not allow non-California residents' claims without a connection to California to proceed against a foreign pharmaceutical manufacturer. In *Bristol-Myers Squibb*, like many other cases pending across the country, the out-of-state plaintiffs had joined in complaints filed by California residents. In addition to sorting out the impact on pending cases, some in the midst of trial, *Bristol-Myers Squibb* has quickly altered the course of initial dispositive motions as defendants challenge filings in venues with little to no connection to the defendants' actions.

**CD: What advice would you offer to companies on preparing for litigation in this sector? Are there any pre-emptive steps they should take based on current disputes dominating the sector?**

**Greenblatt:** On the product liability defence side, litigation is often reactive. However, trying to avoid internal correspondence that can be misread in the context of litigation can go a long way toward keeping lawsuits focused on the merits. Regular training could especially benefit those who do not frequently interact with legal disputes and therefore may not appreciate the implications imprecise written communications may have in defending a company. On patent and antitrust issues, key court decisions have driven major changes in procedure, for example patent venue, and substance, for example, 'product hopping' Sherman Act liability, requiring a fresh perspective on litigation strategies to employ. On the business side, it is also worth reviewing contracts across stakeholders to ensure that key trends, for instance courts upholding class action waivers, are considered and incorporated as appropriate.

**Torregrossa:** Without question, the best offence is a good defence. In our experience, these companies should have a world class early case assessment programme to proactively analyse and address potential litigation issues. These programmes should be designed to facilitate more informed and expedited decision making at the early stages of a dispute. The days of first learning of a dispute when you get the court-filed complaint should be over. One needs to attack these issues early and often. The earlier in the dispute that one can address it, the less

likely it is that the dispute will turn into a full-blown crisis.

**CD: What are the main issues and challenges that typically face pharmaceutical and medical device companies during the litigation process? How might they go about addressing these issues?**

**Greenblatt:** The disparity in discovery burdens is a challenge. For instance, the typical product liability plaintiff may only have a handful of medical records and other documents to produce, but may demand millions of pages of product development and safety information in return, complete with extensive ESI. These issues may be further exacerbated by court-specific expedited timelines, for instance the Mandatory Initial Discovery Pilot Programme recently launched in the Northern District of Illinois and the District of Arizona. Among other tools available in federal cases, moving to dismiss insufficiently pled claims under the US Supreme Court's standards in *Bell Atlantic Corp. v. Twombly,* and *Ashcroft v. Iqbal,* may cabin the material that is relevant to the claims or defences.

**Torregrossa:** The greatest challenge is to explain to the decision maker that the company is more than a corporate entity, but rather an organisation made up of people trying to improve the lives and health of others. If you can tell that human story, it goes a long way to reaching a good outcome.

**Bell:** Litigation tends to be a complex and lengthy process, and companies face many challenges along the way. One issue that I frequently confront as an expert witness is identifying which company personnel are the best sources of key pieces of information, whether as potential fact witnesses or just custodians who should be consulted to gain a more complete understanding of the relevant circumstances. Counsel may have difficulty finding the right people within the company to speak to the various facts and documents; this is particularly common in the case of large organisations where,

for example, the legal department may have little interaction with the marketing team, which in turn may have little interaction with clinical personnel. Involving expert witnesses early in the process can help identify those individuals – or roles within the company – that are likely to be important in establishing the basic facts.

**CD: Do expert witnesses play an important role in bringing their knowledge and experience to pharmaceutical and medical device litigation? What are the main benefits of engaging expert witnesses to assist with the process?**

**Torregrossa:** Sometimes, it feels as though pharmaceutical and medical device cases are 90 percent science and 10 percent law. If you work in the industry you will be familiar with the famous court observation that the "law lags science, it does not lead it". That is true of working on these cases as well. One must master the science in order to master what the result under the law should be. The use of expert witnesses is critical in this regard. An expert witness who can act a science teacher for the attorneys, judge and jury can have a profound influence on a case.

**Bell:** Experts can be an important part of the litigation team. A good expert already has knowledge of the industry and can engage with the company personnel involved in the litigation without placing an undue burden on corporate attention and resources.

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*Gregory K. Bell, Charles River Associates*

This can be very important during the process of collecting documents and data to be produced as part of expert discovery, which can sometimes be a lengthy process. Additional benefits include acting as an independent sounding board for issues arising in the case, vetting information produced by the parties, and serving as a gateway to staff who can assist counsel in locating the right people and information.

**Greenblatt:** Expert witnesses remain an important element in almost any pharmaceutical and medical device litigation, both in developing affirmative and defensive positions. By way of example, establishing

that plaintiffs cannot support their theory of causation through admissible expert testimony can spell the end to thousands of MDL cases in a matter of a few motions. In the meantime, experts for the defence can provide helpful context for testing those opinions. In any case where the outcome may hinge on the strength of the medical or scientific theory of the case, promptly engaging experts can help align the early case themes for maximum effect.

**CD: How do you envisage the level of litigation in the pharmaceutical and medical device sector unfolding over the next few years? Are there any particular trends you expect to see?**

**Bell:** There will continue to be high-profile antitrust litigation involving life sciences companies. Some of this will be a continuation of the patent settlement challenges we have seen in prior years – examples include the ongoing Effexor XR and Lipitor cases, which are back before the courts in the US. We will see some new types of claims being brought as well, spurred by the advent of biosimilars in the marketplace. As biosimilar versions of innovator products increase their presence in the marketplace, I expect that these cases will give rise to some interesting damages issues involving analyses of pricing and sales that differ significantly from the types of analyses that have been done in the past with respect to small-molecule products.

**Greenblatt:** Over the next few years, we expect to see many of the current legal trends continue to impact the course of complex pharmaceutical and medical device litigation, including evolving doctrines concerning personal jurisdiction, pre-emption, discovery limits and consolidation. On the product liability side, the recent downward trend in the number of MDL petitions granted has the potential to lower the overall volume of federal cases and shift more cases to state consolidated proceedings in defendants' home states. In the antitrust arena, both the FTC and private litigants continue to challenge settlements of patent litigation in the pharmaceutical industry with new precedents shaping the contours of liability. High-stakes patent disputes are likely to remain a consistent feature in this sector, although venue and challenge procedures are in a state of flux.

**Torregrossa:** The level of litigation should remain somewhat constant in the US. The litigation funding practice, in which a litigant obtains third-party financing, could increase that level of litigation, but that remains to be seen. Despite increased money behind these cases, litigation still requires lawyers, cases and courts to handle that increased volume. The potential for increased litigation capacity is really outside the US. There are a few pockets of the world that are adopting practices that signal the dawn of a US-like litigation environment. CD