REPRINT

CD corporate disputes

PHARMACEUTICALS AND BIOTECHNOLOGY PATENT LITIGATION

REPRINTED FROM:
CORPORATE DISPUTES MAGAZINE
JAN-MAR 2023 ISSUE

www.corporatedisputesmagazine.com

Visit the website to request
a free copy of the full e-magazine

CRA Charles River Associates

Published by Financier Worldwide Ltd
corporatedisputes@financierworldwide.com

www.corporatedisputesmagazine.com

HOT TOPIC

PHARMACEUTICALS AND BIOTECHNOLOGY PATENT LITIGATION

PANEL EXPERTS

Sean Sheridan
Principal
Charles River Associates
T: +1 (312) 377 9237
E: ssheridan@crai.com

Sean Sheridan has served as an expert witness in cases brought before federal and state courts, the Patent Trial and Appeal Board, the International Trade Commission, and arbitration tribunals. He has developed numerous damages analyses related to patent infringement, breach of contract and trade secret misappropriation, including analyses quantifying lost profits, reasonable royalties and unjust enrichment. He has also provided financial consulting services for a variety of non-litigation purposes, including transaction due diligence, licence negotiations and strategic decision making.

Christopher Stothers
Partner
Freshfields Bruckhaus Deringer LLP
T: +44 (0)20 7832 7034
E: christopher.stothers@freshfields.com

Christopher Stothers is an experienced patent litigator, managing strategic, cross-border disputes around Europe and beyond, including opposition and appeals before the European Patent Office. He has particular expertise in pharmaceuticals, biotechnology and medical devices, and is well known for his work on the interface between intellectual property, competition and regulatory law. He also helps clients with other IP, antitrust and pharmaceutical regulatory litigation and arbitration. He is a creative problem solver who thinks laterally across the breadth of his practice.

Gabriella Bornstein
Partner
Kirkland & Ellis International LLP
T: +44 (0)20 7953 2707
E: gabriella.bornstein@kirkland.com

Gabriella Bornstein has extensive trial and appellate experience across the IP spectrum with a particular focus on pharmaceutical, biotechnology and high-tech patents. She works on high value, cross-border disputes dealing with complex technical, patent and jurisdictional issues. She is dual qualified in science and law, giving her particular insight into the challenges facing her IP clients.

CD: Reflecting on the last 12-18 months, what do you consider to be the most significant developments shaping patent litigation in the pharma and biotech industries?

Sheridan: One significant development is that the US Food and Drug Administration (FDA) has recently begun publishing patent lists in the 'Purple Book', an online database with information about FDA-licensed biological products. Previously, biosimilar manufacturers had few options to identify the potential patents that might cover a branded biological product. In contrast, manufacturers of small molecule generic drugs have access to the FDA's 'Orange Book' which lists all patents that a branded small molecule drug manufacturer might assert during Hatch-Waxman litigation. The publication of patent information in the Purple Book has now improved access to reliable patent information which should help biosimilar manufacturers evaluate their potential litigation exposure and improve their likelihood of successfully bringing biosimilar products to market.

Bornstein: The increasing complexity of the technologies involved drives shifts in the pharmaceutical and biotech industries and related patent litigation. We have seen an uptick in litigation dealing with complex platform technologies, which dovetails with a reduced frequency of seeking injunctions. The wide application of platform technologies in particular leads to increased awareness and consideration of public interest factors when contemplating whether to seek or whether the court is willing to grant a preliminary injunction. The shift in the true heart of the invention, for example a highly effective delivery vector instead of a new active pharmaceutical ingredient (API), also changes the way companies can prepare for and conduct patent litigation, as claim language becomes increasingly complicated. Over the last year, we have also seen high-stakes and topical

> **"Innovators should build and maintain a broad and robust portfolio protecting their innovation concepts. Proper registration and protection of rights is critical."**
>
> *Gabriella Bornstein, Kirkland & Ellis International LLP*

litigation related to vaccines and clustered regularly interspaced short palindromic repeats (CRISPR)-related technologies, which look set to continue as these technologies mature.

Stothers: I would highlight three developments: the start of the anticipated messenger RNA (mRNA) disputes, increasing challenges to breadth of patents, particularly early-stage filings, and the rise of patent licence disputes. The first of these is largely a question of timing of the response to coronavirus (COVID-19), with the initial rollout of the vaccine in richer nations evolving into booster programmes. The second and third are more a consequence of the challenges of early-stage research, both for biotechs and more established pharma, which can impact on decisions made both for patent prosecution and licensing. The third is also a response to the initial belt-tightening in response to the pandemic, as dealmaking slowed and the importance of collecting debts, including unpaid royalties, increased for many in the sector.

CD: To what extent are you seeing an increase in the number of patent disputes across these sectors? Are there any recurring themes?

Bornstein: The number of patent disputes in the pharma and biotech sectors has remained steady but the disputes are increasingly complex and high stakes, and are often fought in parallel across multiple jurisdictions. We are also seeing the continued increase of 'innovator-on-innovator' disputes. Biologics have come to the forefront as the basis of current generation of blockbuster drugs which changes who the consistent players are in large scale patent litigation. There is also a lesser propensity for seeking and being granted injunctions at the earliest stage. The ability to obtain a preliminary injunction to prevent the launch of a generic or biosimilar medicine is an all-important consideration in any business or legal strategy to protect the exclusivity of an originator product.

> **"The wildcard that is the UPC is going to be important, both with game-playing in the short term and with the opportunity to reduce the cost of multijurisdictional litigation in the longer term."**
>
> *Christopher Stothers, Freshfields Bruckhaus Deringer LLP*

Stothers: It is difficult to judge if there has been an increase in the number of patent disputes as they are so global in scope in this sector, and the venues of choice can shift over time, that it can be difficult to read overall trends, particularly when accounting for arbitration and the less transparent jurisdictions. We certainly have not seen the same boom in patent litigation as in the tech sector with the standard essential patent (SEP) and fair, reasonable and non-discriminatory (FRAND) cases. We have seen some of the preliminary injunction changes in recent years settling down, leading to a slightly more predictable sector, but still a highly litigious one.

Sheridan: Stability would be the primary theme with respect to the number of patent disputes in the biotech and pharma sectors. We have not seen any material change in non-abbreviated new drug application (ANDA) patent infringement cases, and new ANDA case filings, which had been declining over the past few years, stabilised in 2022. At the Patent Trial and Appeal Board (PTAB), it continues to be the case that only a small portion of petitions relate to pharma and biotech. However, these petitions are more likely to be instituted compared to petitions involving other technology areas. With respect to litigation at the International Trade Commission (ITC) relating to pharmaceuticals and medical devices, these cases have accounted for about 10-15 percent of ITC cases over the past few years and, based on current data, this ratio appears to apply to cases in 2022 as well.

CD: Could you highlight any recent cases with important implications for patent litigation going forward? What insights can we draw from their outcome?

Sheridan: One case with important implications for the pharmaceutical industry is the ongoing dispute between GSK and Teva that relates to 'skinny labelling'. Skinny labelling refers to generic drug labels that exclude, or carve out, uses of a drug that remain protected by the branded drug manufacturer's patents. Teva has asked the US Supreme Court to overturn its $235m loss to GSK which was based in part on the finding that Teva's skinny label for its generic drug still induced doctors to infringe GSK's patent. The Supreme Court has yet to decide whether to hear the case. This case is particularly important because generic drugs are often launched with skinny labels and a decision in GSK's favour, or a decision not to hear the case, would suggest that generic companies may need to be very careful when marketing skinny labelled drugs to avoid allegations of inducing infringement.

Stothers: The G2/21 referral to the Enlarged Board of Appeal, on so-called 'plausibility', is being carefully watched and for good reason. Although

the questions asked seem very narrow and technical, it is a good indication of the breadth of protection problem, which we have equally seen coming through in national courts, such as the Lyrica case which ended up in the UK Supreme Court. The recent non-binding opinion suggests that we may end up with a fudged decision, which is not particularly surprising, but we can expect the decision to be cited repeatedly in subsequent national litigation on the issue.

Bornstein: Two key cases this year are *Novartis v. Teva*, involving fingolimod, and *Neurim v. Teva*, regarding melatonin, both of which are decisions in which the English court denied injunctive relief sought by a patentee to prevent the launch of a generic version of a blockbuster small molecule drug. In each case the court found that damages would be an adequate remedy for any harm suffered by the patentee absent an injunction. Essentially, the court found that there was no irreparable harm, despite the respective patentees usual and often previously successful arguments regarding the downward price spiral upon generic launch. In *Novartis*, the court also offered as obiter that where a patentee has engaged in repeated divisional filings and amendments to prolong the patenting process, with the consequence

that generics cannot effectively seek to clear the way, this is relevant as a factor against the grant of interim relief. These decisions mark a distinct trend in the recent UK case law, where the English court appears less willing than in the past to grant preliminary injunctions sought by pharma or biotech patentees and is applying increasingly close scrutiny to patentees' claims to irreparable harm.

CD: What initial steps should a biotech or pharma company take if it detects suspected or actual patent infringement?

Stothers: Our experience is that these companies are very advanced and are thinking about identifying potential infringement long before the launch of generic or biosimilar products. The key steps are to instruct counsel in the relevant jurisdictions, take initial advice on preliminary injunctions, for example, and consider how to manage the multijurisdictional litigation, whether in-house or relying on external counsel. Innovator-innovator litigation is a bit different, can be detected later and may be even more strategic, but can be resolved more sensibly between the parties directly depending on existing relationships.

Bornstein: Suspected patent infringement should be treated with both urgency and caution, and patentees should seek proactive advice on protective strategies. The best approach depends heavily on the specifics of the technology and the complexity of the claims at issue. For a 'basic' compound patent or second medical use claim, it is relatively easy to monitor and prepare for expected launch. For a method claim, or functionally limited claim, prospective infringement can be more complicated. In all cases, patentees need to do their homework to ensure they do not risk making unjustified threats. For method or complex claims, patentees should consider whether pre-action disclosure is required. Patentees should also keep in mind what remedy they are after, be it an injunction or a revenue stream, as this will drive strategy.

Sheridan: For many companies, the first inclination may be to file a lawsuit against the infringer to try to recover damages or to force the infringer out of the market. However, this approach does not always make sense from a business perspective. One of the first steps that a company should take when it suspects patent infringement is to understand the costs and benefits of any potential litigation. This includes, but is not limited to, defining the business goals of the litigation, estimating the time and cost of the litigation, and understanding the risks faced by the patent owner, such as the potential for the patents to be invalidated or for the infringer to file counterclaims.

CD: What advice would you offer to companies on preparing for patent litigation, to maximise their chances of a successful outcome?

Bornstein: Innovators should build and maintain a broad and robust portfolio protecting their innovation concepts. Proper registration and protection of rights is critical. They should also ensure strong competitive intelligence and monitor regulatory filings and other pre-launch activity. Both sides should proactively seek to retain their first-choice counsel in all important regions and ensure there is a coordinating team to oversee the global dispute. The pre-dispute time should be used to actively develop the prospective case theory, which should be flexible enough to account for jurisdictional differences. Generics and biosimilars should also consider whether to 'clear the way' first and, if so, which patents to attack and where.

Sheridan: Companies that are considering or preparing for patent litigation should assess the potential financial impact of the litigation as early as possible. If the case involves a damages claim, the company may want to estimate the potential damages, adjusted for the probability of winning or losing the case. If the case involves the potential launch of a generic product, the company may want to analyse the financial impact of the loss of exclusivity for the branded product and the value of 180-day generic drug exclusivity for the first generic applicant. If the case addresses other economic issues, such as the evaluation of commercial success or domestic industry, the company should gather the relevant financial data as early as possible and perform a preliminary analysis to gain a better understanding of the strengths and weaknesses of the case.

Stothers: Companies should plan ahead and get realistic, sensible advice on the strengths and weaknesses of their case. Burying your head in the sand about problems in your case can massively increase your legal spend, while leading to much greater problems when the other side attacks the point. It is also important for realistic business planning – being too optimistic, or even too pessimistic, on prospects can lead to serious misallocation of resource across the business.

CD: How important is it for pharma and biotech companies to retain control of their intellectual property rights with effective protection, monitoring and enforcement strategies? What key steps do they need to take?

Stothers: This sector is one which is often used as the poster child for how intellectual property (IP)

should work – massive R&D costs for the innovator but much lower for follow-on, absent IP rights. Of course, things can go wrong, and innovators can be criticised, but this is a sector which is already finely attuned to its IP need. Hiring great talent, both internally and externally, is key, including the need for team players, as collaboration is very important to successful multijurisdictional patent litigation.

Sheridan: The protection of IP rights is very important to pharma and biotech companies since IP is often the most important asset for companies in these industries. This is because successfully developing a new drug and bringing it to market is a very risky, time consuming and expensive process. Retaining control of their IP rights provides pharma and biotech companies with market exclusivity for their products which, in turn, helps to ensure ongoing investment in drug development. Given that the effective protection, monitoring and enforcement of IP is driven by numerous factors particular to each case, companies should work closely with their in-house and outside counsel to determine what steps they need to take.

Bornstein: IP rights are at the absolute core of the value of pharma and biotech companies, and they need to be closely managed at all stages of the research, development and commercialisation lifecycle. This applies equally whether the business' goal is exclusivity or licensing. At the initial research stages, companies need to educate their workforce, especially researchers and scientists, on the importance of patent and trade secret protection, both to prevent accidental disclosure and to ensure innovations are recognised and captured. Companies also need clear patent filing strategies, ensuring sufficient data and disclosure for full protection of the rights and ensuring registrations in all applicable jurisdictions. In the commercialisation phase, monitoring and competitive intelligence are critical. When faced with prospective infringers, patentees need to be clear about their willingness

"Retaining control of their IP rights provides pharma and biotech companies with market exclusivity for their products which, in turn, helps to ensure ongoing investment in drug development."

Sean Sheridan, Charles River Associates

to enforce – patents are only as valuable as the enforcement mechanisms which sit behind them.

CD: How do you expect disputes in this sector to unfold over the coming months and years? What issues are likely to dominate the arena?

Sheridan: One particularly important issue relates to patents that claim a genus of antibodies based on where the antibodies bind to a particular target protein. This issue will be addressed in the coming months since the US Supreme Court has recently agreed to grant Amgen's petition for certiorari in *Amgen v. Sanofi*. The court will consider whether a patent specification must teach how to make and use the claimed invention or whether it must instead identify and teach how to make all or nearly all embodiments of the invention without the need for substantial additional experimentation. The outcome of this case is particularly important to the pharma and biotech industries given the fact that US sales of antibody-based drugs are in the tens of billions of dollars annually.

Bornstein: We will continue to see increased complexity of technologies, which will drive litigation in a more complex direction. In particular, we expect to see increasing convergence between mindsets across differing technologies, for example the digitalisation of healthcare and pharmaceuticals is likely to lead to an intersection with 'tech' style patent litigation strategies entering the pharma and biotech sphere. The long-awaited Unified Patent Court (UPC) in Europe is now on track for commencement in the second quarter of 2023. This will bring some changes to the litigation landscape in Europe. This new court offers powerful pan-European injunctions on patents and supplementary protection certificates (SPCs), as well as the opportunity for European-wide revocations and will be an important factor to consider in preparing for litigation. Initial points to watch will be how companies treat the opt-out mechanism for existing European patents (EPs) and how the UPC handles procedural disputes – the early cases will be hard fought on these issues as they will all be making new law.

Stothers: This is a mature sector and we do not expect great change. However, the wildcard that is the UPC is going to be important, both with game-playing in the short term and with the opportunity to reduce the cost of multijurisdictional litigation in the longer term. It will be fascinating to see how wholesale the opt-outs are in the sector, and to see how that then impacts on the development of the jurisprudence of the new system. CD