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Patent Litigation

UK

Trends and Developments

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Trends and Developments

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Despite the political upheaval and uncertainty that plagued the UK in 2019, patent litigation remained very active, buoyed in particular by a steady stream of standard essential patent cases on the back of the Unwired Planet decisions in 2017 and 2018. The year ahead promises to be even busier, with no sign of the influx of SEP claims letting up on the tech side (subject to the outcome of the eagerly anticipated Supreme Court appeals from the Unwired Planet and Conversant decisions), and the stage primed for more blockbuster biosimilar litigation in the life sciences field. We visit each of those topics in further detail below, but first touch on some of the key developments to look out for in the courts.

UK Court Developments

Regeneron v Kymab in the Supreme Court

After a few years in which the UK Supreme Court, unusually, heard multiple patent cases, 2020 brings a return to the mean, with just the one patent case scheduled. In February, the Supreme Court will hear Regeneron v Kymab, a case recently hailed by one retired patents judge as the "most interesting biotech case of the last 20 years", and one which will have wide-ranging consequences for companies in all fields. The judges of the Supreme Court will be called upon to decide on a question that is fundamental to the very patent system itself: what is the scope of the monopoly to which a patentee should be entitled in light of its inventive contribution to the field? This question is of particular relevance to patentees of "big inventions", which might be considered to embody principles of general application, and who accordingly seek broad protection in their patent claims. The outcome will shape the law significantly and is certain to influence the patent strategies of innovative companies with big ideas.

New faces expected in the High Court

Meanwhile, at first instance level, the strain placed on the judicial resources of the High Court by a combination of the high influx of new cases and the current dearth of specialist, full-time patents judges still awaits resolution. New judicial appointments are expected in 2020 to help spread the load but for the moment the gap is being filled by a combination of Deputy High Court Judges, HHJ Hacon and Arnold LJ sitting in the High Court (stepping up and stepping down, respectively, to do so), and the judges of the Patents Court who are not normally assigned to hear higher technical difficulty rating cases sitting more often. The present situation has introduced additional complications in effective case management and the listing of hearings, and UK practitioners and court users will be keenly awaiting the announcement of judicial reinforcements and a return to normal operating procedures in the High Court.

Proportionality of injunctive relief to remain a hot topic

2019 saw the question of the proportionality of injunctive relief in the spotlight across Europe, with a series of high-profile conferences and panels, involving leading jurists from across the continent, focused on the question. The UK has a well-deserved reputation as a jurisdiction in which judges are prepared to be flexible and creative in tailoring injunctive relief as appropriate for the case in hand. The best recent example of this was in the 2018 Edwards Lifesciences v Boston Scientific decision in relation to transcatheter heart valves, in which Arnold J (as he was then) found the patent to be valid and infringed, but ordered: (1) a 12-month stay of the injunction to allow clinicians to be retrained on the patentee device; and (2) a carve out from the injunction to allow the infringing device to be used in a limited set of cases where the patentee device was not approved and the infringing device was the only available therapeutic option. In that case, the public interest in ensuring the continued availability of a potentially life-saving product was considered sufficient justification for the judge to deviate from what some might consider to be the default position of simply ordering a final (unqualified) injunction where a patent has been found to be valid and infringed. Whilst such a public interest-based defence against injunctive relief has thus far been mostly discussed in a life sciences setting where patient health is potentially at issue, in principle there is no reason why such arguments should be so limited and could not be made in other settings, particularly where safety may be a factor. In any event, the debate is set to continue in 2020 and we expect to see the development of further public interest arguments in the UK building on this jurisprudence.

Tech Trends and Developments – the SEP and FRAND Bandwagon Rolls On

Introduction to FRAND litigation in the UK

The English courts have continued to take global centre stage in standard essential patent (SEP) litigation, following Mr Justice Birss' landmark decision in Unwired Planet v Huawei in 2017 (which was subsequently upheld by the Court of Appeal in 2018). Following a finding that two of Unwired Planet's UK patents were valid and infringed, the Court concluded that a

fair, reasonable and non-discriminatory (FRAND) licence was, in the circumstances, a worldwide licence of the relevant multinational SEP portfolio, rather than a licence limited to the UK patents in the portfolio. This finding was made in circumstances where the majority of Huawei's relevant mobile phone sales took place in China, and only a negligible proportion took place in the UK. Notably, the royalty rates that were determined by Birss J were substantially higher than those that have since been awarded in other jurisdictions.

Since Unwired Planet, the UK has become a "go-to" forum for SEP holders seeking to obtain a global FRAND licence, potentially on the basis of a single infringed UK SEP from a worldwide portfolio. Many such entities are (like Unwired Planet) non-practising entities (NPEs) that have acquired all or part of a patent portfolio from another entity, often a large telecommunications company seeking to monetise its portfolio.

Key developments following Unwired Planet

In 2017, the NPE Conversant brought proceedings against Huawei and ZTE in the UK, seeking a global FRAND determination as well as a "FRAND injunction" in the event that the defendants refused to take a licence on the basis ordered by the English court. Huawei and ZTE subsequently challenged the jurisdiction of the English court on the basis that it lacked jurisdiction to grant a global licence, since this would impermissibly involve assessing the validity of foreign patents in the portfolio and, further, because the UK was not the proper forum to hear this dispute when the vast majority of relevant sales relate to China. This jurisdiction challenge was rejected by the court at first instance, and then again by the Court of Appeal in early 2019. As noted below, this decision has been appealed to the UK Supreme Court.

In 2018, the NPE TQ Delta brought proceedings in the UK against Taiwanese networking device manufacturer ZyXel for infringement of two UK SEPs relating to broadband technology. In early 2019, at first instance Carr J found one of the patents to be valid and essential, and the other patent to be invalid. However, the valid patent was due to expire three months before the RAND trial was due to take place in September 2019. Faced with the prospect of a RAND trial and the determination of a global licence by the Court, at a further hearing before Carr J in March 2019, ZyXel indicated that it was no longer seeking a licence from TQ Delta. As such, Carr J granted an injunction until patent expiry and ordered an enquiry as to damages for infringement, which would take place alongside the RAND trial. He also declined a request from ZyXel to immediately vacate the RAND trial, instead adjourning that question to a later hearing. By that time, TQ Delta had also filed a new claim for infringement of two other patents and declaratory relief, stating that ZyXel were not willing licensees to their patent portfolio and/or that TQ Delta was not obliged to offer a licence on RAND terms.

ZyXel then elected to provide an irrevocable undertaking waiving any and all of its rights to enforce TQ Delta's RAND obligations to license its UK-designated asserted SEPs in the UK. ZyXel also applied to strike out TQ Delta's newly issued claim on the basis of that waiver. This undertaking and the question of vacating the RAND trial was considered at first instance by Birss J, who refused ZyXel's strike-out application and allowed the RAND trial to proceed, inter alia, on the basis that there was still a live dispute between the parties. This was overturned on appeal to the Court of Appeal and the RAND trial was cancelled. The Court of Appeal considered that it was open for ZyXel to no longer rely on any licence to which it was entitled to resist the grant of relief for infringement of the UK patents, and that there would be no utility in allowing the RAND trial to proceed.

Most significantly, at the end of October 2019, a panel of five justices of the UK Supreme Court heard joint appeals brought against the decisions of the Court of Appeal in Unwired Planet and Conversant, and in doing so commented upon the international commercial significance of the issues they raise. These highly anticipated decisions, which are imminent, will determine whether, and the circumstances under which, it is within the power and jurisdiction of the English court, following a finding of infringement of a valid UK SEP, to require a defendant in the UK to take a global FRAND licence upon threat of a UK-wide injunction. At the heart of these cases is the tension between the territoriality of patent rights and national courts, as against the international nature of standards, licensing arrangements and supply chains.

On the one hand, the appellants argued that the English court has exceeded its jurisdiction by determining the licensing terms of portfolios containing mostly foreign patents, the validity (and essentiality) of which has not been assessed by the English court, especially in circumstances where only a small proportion of the products implementing such SEPs are sold in the UK as compared to key commercial centres, such as China. On the other hand, the respondents focused in their arguments on the international nature of the contractual standard-setting organisation regimes governing the licensing of SEPs as distinct from the underlying patents themselves, as well as the impracticality of litigating each SEP in a portfolio on a jurisdiction-by-jurisdiction basis before requiring an implementer to take a FRAND licence.

What's next for FRAND in the UK?

If the UK Supreme Court decides to uphold the decision in Unwired Planet and Conversant, this will cement the UK going

forward as the global centre for FRAND litigation and will no doubt attract more SEP holders to the jurisdiction, drawn by the relatively higher FRAND rates that the English courts have so far granted, compared to other jurisdictions. In such a case, a key issue going forward in SEP litigation will be whether and how any regional FRAND rates set by courts in other jurisdictions will factor into the English court's royalty calculation methodology. Even if the court considers that setting global rates may be appropriate in some instances, it will still need to grapple with the potential for overlap between any global or multinational rates it determines and national rates determined by the relevant national courts.

For example, shortly after Conversant commenced proceedings against Huawei in the UK, Huawei commenced proceedings in the Intermediate People's Court of Nanjing in China, in which it sought to invalidate certain of Conversant's Chinese patents, initiated a non-infringement action and requested a FRAND determination in respect of certain patent families in China. In September 2019, following the invalidation of certain of Conversant's Chinese patents, the Nanjing Court set royalty rates that were substantially lower than those awarded in other jurisdictions, including the UK (eg, in Unwired Planet) and the USA (eg, TCL v Ericsson). If maintained, it remains to be seen whether and how such rates might be taken into account in the calculation of any global rates determined by the English court.

Of course, it is also possible that we will see more implementers (particularly those whose current UK operations are marginal) electing to waive their rights to a FRAND licence in the UK (and accordingly submit to an injunction and payment of damages in the UK) in order to avoid a global determination of FRAND terms (as ZyXel did).

Conversely, if the UK Supreme Court overturns these decisions, there may be a shift away from FRAND litigation in the UK toward other markets, with a renewed focus on disputes in key markets or regions, but with no single forum prepared to determine global FRAND without the consent of both parties.

Life Sciences Trends and Developments – Spotlight on Biologics and Biosimilars

Introduction to biologics and biosimilars

Biologic medicines are large, structurally complex molecules created using multi-stage biological processes that usually involve the culturing of cells. The precise molecular structure of a biologic is determined by the (mostly confidential) processes used to manufacture them, and the complexity and importance of such processes has led biologic manufacturers to typically seek to obtain not only product and indication patents to protect their medicines, but also process patents directed to various stages of manufacture.

Unlike small molecule medicines made by simple chemical synthesis, the biological complexity of biologics and the unavoidable variables present in their manufacture mean that it is not possible to perfectly replicate a biological medicine. Accordingly, intended "generic" versions of biologic medicines – which will not be identical to the original medicine – are known instead as "biosimilars". To gain regulatory approval, a biosimilar manufacturer is required to demonstrate that the physicochemical characteristics and clinical efficacy of its product are sufficiently similar to those of the relevant reference product.

Led by the multibillion-dollar mega-blockbuster medicine Humira® (adalimumab), biologics have come to dominate the list of best-selling medicines and the pipelines of pharmaceutical and biotech companies around the world. While this revenue opportunity incentivises biosimilar challengers and government health departments seeking to rationalise their expenditure by supplying cheaper biosimilars, the resource investment in terms of time, money and expertise involved in developing a biosimilar product is an order of magnitude greater than for a small molecule generic. In practice, this narrows the field of potential companies with the capabilities to successfully develop a biosimilar product, and has also meant that the levels of discounting for biosimilars compared to the reference originator biologic are typically much lower than for small molecule generics (often in the order of around 30%, as opposed to 80-90% or higher).

"Innovator v innovator" litigation

Given the level of know-how and capital required to develop and successfully market a biosimilar, it has become increasingly common for traditional "innovator" companies to manufacture biosimilar versions of other innovators' biologics. This has been one of the major factors behind the erosion of the traditional "innovator v generic" dynamic in life sciences patent disputes, such that it is now increasingly common to see disputes between two parties that have traditionally been regarded as notional "innovators". Another major driver of this trend has been the narrowing of innovator pipelines and increasing focus on a more limited number of indications and biological targets (particularly in oncology), which is increasingly bringing innovator companies with competing pipeline candidates (and patent portfolios to boot) into dispute.

Uptake of biosimilar products

While the rate of biosimilar uptake in Europe is increasing, and remains higher than that of the USA, the position varies greatly between product, therapeutic area and country. By way of example, while the average biosimilar market penetration in the case of anti-TNF drugs is ~43%, in Denmark it is ~94% and in the UK it is 69%, whereas in Switzerland it is ~7%. The greater uptake in Europe as compared to the USA is likely attributable to a more developed regulatory framework and greater pressure

for payors (eg, the NHS in the UK) to drive biosimilar uptake and implement cost savings in Europe, as compared to greater reluctance on the part of physicians and patients to switch to biosimilars, as well as protracted patent disputes that have served to delay entry of some biosimilar products in the USA.

Arrow declarations

Given the comparatively higher density of patents protecting biologic medicines (typically including a mixture of product, process and medical use patents), a recent trend has been for biosimilar entrants to seek an "Arrow declaration" from the English Court that a given biosimilar product lacked novelty and/or was obvious at a particular date, such as the priority date of the patent of an innovator biologic manufacturer. Such a declaration, if granted, pre-empts and effectively precludes a patentee's ability to allege that the biosimilar product in question infringes that patent, as bringing such a claim would logically suggest that the patent in question was similarly lacking in novelty and/or was obvious and therefore invalid.

The aim of this declaratory relief is to give a biosimilar manufacturer greater commercial certainty prior to launching its product, including outside of the UK, given the influential nature of the English Court's decisions. In the recent Pfizer v Roche case, Pfizer sought a declaration that certain Roche European patent applications relating to the use of bevacizumab (Avastin®) in combination with the relevant other cancer drugs for the treatment of other relevant indications lacked novelty and/or were obvious. Relevantly in this case, shortly before the commencement of proceedings, Roche "de-designated" the UK from the European patents in question. Given that there were no longer any UK patent rights in issue, the English Court at the outset declined to exercise its jurisdiction to grant the requested relief, on the basis that doing so would not serve a "useful purpose " in the circumstances.

Notwithstanding the outcome in this particular case, it remains likely that biosimilar manufacturers will continue to seek Arrow declarations in respect of secondary biologic patents, although, at the same time, patentees may be more willing to embrace UK de-designation of their European patents as an effective countermeasure (albeit one that requires sacrificing their patent protection in the UK). The cases that have come before the English courts so far have tended to be those at the extremes, involving large portfolios of pending divisionals and/or so-called "shielding" tactics at the EPO – accordingly, what still remains to be seen is the extent to which English courts will deign to exercise their discretion to grant Arrow relief in more moderate cases.

Antitrust scrutiny

Recent arrangements between innovator biologic manufacturers and biosimilar manufacturers allowing for biosimilar entry prior to patent expiry in certain jurisdictions in return for not engaging in patent challenges have resulted in increased scrutiny from competition law authorities in the biosimilar space, as have discounting arrangements from innovator biologic manufacturers seeking to retain market share upon biosimilar entry. The scope of permissible conduct in the biosimilar space is likely to be clarified in coming years, including in relation to arrangements involving delayed entry but which do not involve reverse payments.

Bolar exemptions

Under UK law there exists a so-called "Bolar exemption" covering activities conducted for the purpose of obtaining abridged marketing authorisations in the EU, as well as an experimental use exemption for medicinal products, which covers activities conducted for the purpose of a medicinal product assessment, including where they are undertaken in support of regulatory filings outside the EU. In the context of these exemptions, an emerging issue in the context of biologics is the potential for biosimilar companies, under the guise of these exemptions, to manufacture more drug substance than is strictly necessary to fulfil regulatory requirements, as a means of preparing for commercial entry. It remains to be seen how these exemptions are to be construed in the UK in such a scenario, and moreover how patent rights (including in relation to process patents) are to be enforced in circumstances where the biologic manufacture is carried out in relative secrecy.

Brexit

After the recent election of the Conservative Government in the UK, the UK left the EU on 31 January 2020, though will remain in the single market for another 11 months thereafter. Subject to the final Brexit terms and the nature of any transitional arrangements, upon exit the UK will, in essence, adopt or incorporate into its national law the relevant EU law as it exists and applies in the UK on the date of exit. Accordingly, following Brexit, EU law as incorporated into UK domestic law upon exit, as well as the interpretation thereof, is liable to diverge from CJEU case law.

While Brexit is expected to have a relatively negligible impact in the patent space (including in relation to biologics and biosimilars) given that the UK patent regime is governed by domestic law as well as international agreements which are separate from EU agreements, it may nevertheless have an impact (at least in the short term) on the regulation of medicines, including biologics, such as in respect of the procedures for obtaining new marketing authorisations. While existing Supplementary Protection Certificates (SPCs) granted in the UK will remain valid post-Brexit, and existing applications for SPCs and paediatric extensions will be assessed under the existing regime, post-Brexit the procedure for obtaining an SPC is likely to change, and while existing law in respect of SPCs (including CJEU jurisprudence) will be retained, the UK law on SPCs is similarly liable to diverge post-Brexit.

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Kirkland & Ellis International LLP has a patent litigation practice comprised of approximately 200 attorneys in London, Chicago, Los Angeles, New York, Palo Alto, San Francisco and Washington, DC. Nearly 80% of Kirkland's patent litigation attorneys are engineers and scientists, who are trained and experienced in a variety of technical disciplines. With decades of experience, Kirkland's IP litigation attorneys have achieved extraordinary results in patent, copyright, trade mark, trade-secret misappropriation and advertising matters, and they excel in large-scale, bet-the-company cases. They represent clients across a broad range of industries, including life sciences, technology, consumer products manufacturing, financial services, automotive, and food and beverage. Other areas of practice are pharmaceutical and biologics patent litigation, co-ordinating global IP enforcement/defence cases, standard essential patent (SEP) and fair, reasonable and non-discriminatory (FRAND) disputes, post-grant proceedings before the United States Patent and Trademark Office's Patent Trial and Appeal Board, and appeals of high-stakes cases in the US Court of Appeals for the Federal Circuit and the US Supreme Court, as well as the Court of Appeal of England and Wales and the UK Supreme Court.

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