Patent paradigm

From *Regeneron v Kymab* to *Unwired Planet v Huawei Technologies*, **Baker Mckenzie** outline some crucial UK and CJEU patent litigation cases passed down this year

In this article, we round up some of the key cases and legal developments that have hit the UK patents courts in 2020. The Supreme Court delivered two landmark judgments: its long-awaited ruling on the determination of fair, reasonable and non-discriminatory (FRAND) terms for the licensing of standard essential patents (SEPs), and its judgment in *Regeneron v Kymab* on insufficiency and specifically the requirement for enablement across the full breadth of the claim. In what may be the last year of its jurisdiction in relation to UK SPCs, the Court of Justice of the European Union (CJEU) continued to wrestle with the interpretation of the SPC Regulation by national courts.

Turning to relief, 2020 saw the rare refusal of an interim injunction against a generic pharmaceutical manufacturer, and the consideration of public interest arguments in relation to the grant of a final injunction and the Crown use defence to infringement – particularly timely cases, as the Covid-19 pandemic shines a light on compulsory licensing. Finally, the courts – and court users – adapted well to the challenges of remote working, which may lead to a longer-term trend towards virtual hearings.

Insufficiency

The Supreme Court has this year continued its foray into substantive patents law, this time considering the principles around insufficiency – and specifically the requirement for enablement across the full breadth of the claim – in *Regeneron v Kymab*.[1] As emphasised by the Supreme Court, the essence of the bargain between the patentee and the public in the context of sufficiency is that the patentee's disclosure must afford the public the ability to "work the invention" after expiry of the patent monopoly across the full range of products claimed.

In this case it was accepted that the patents enabled some, but not all, types of mouse within the claimed range to be made. The Court of Appeal (CoA) had, nonetheless, held the patents sufficient as the claimed invention amounted to an "inventive, indeed ground-breaking, general principle" and that every mouse with the specified characteristics would display the invention's benefits, if and when they could be made, such that the invention was sufficiently enabled in a way that matched the patentee's technical contribution.

The majority in the Supreme Court (save for Lady Black) disagreed, holding that the CoA had not correctly applied the law and that its approach was not a legitimate development of the law. Importantly the Supreme Court held that in the case of product claims the patentee's contribution is the ability to make the product itself rather than (if different) the invention: "patents are about products and processes, not pure ideas". Accordingly, as the product could not be made across the whole of the relevant range, the patents were insufficient.

The Supreme Court's decision has affirmed, therefore, a strict approach to sufficiency. For a patent that covers a range/class of products to be sufficient it must: a) work across the scope of the claim, and b) be possible to make or otherwise obtain the product across all relevant ranges (ie, those that significantly affect the value/utility of the product) without undue burden.

Litigating and licensing standard essential patents

The Supreme Court delivered a second landmark judgment,[2] dealing with the framework for licensing SEPs: can a national court determine FRAND terms on a global basis, what does the "non-discriminatory" element of FRAND mean in practice, and how should SEP owners act in FRAND litigation to preserve their right to an injunction?

The Supreme Court held that the English courts have jurisdiction to determine royalty rates and other terms for a global FRAND licence, and to grant an injunction restraining infringement in the UK if the implementer refuses to take a global FRAND licence. The Supreme Court's reasoning was based on the interpretation of the FRAND obligation as a contractual agreement, and the impracticality of negotiating or litigating country by country, patent by patent. While no other court has, as yet, determined FRAND licence terms on a global basis, the Supreme Court noted that no other court had expressly rejected the possibility of making a global FRAND determination. The Supreme Court also noted the risk of forum shopping, conflicting judgments and applications for anti-suit injunctions, but held that was the inevitable consequence of standard setting organisations having provided for the possibility of worldwide FRAND licences, without providing for an international forum for determining the terms of such licences. The Supreme Court's judgment confirms the position of the English courts as an attractive venue for the enforcement of SEPs; it will be interesting to watch how other jurisdictions react.

The Supreme Court also held that:

- England, rather than China, was the appropriate forum for the determination of this litigation, because it's not clear that the Chinese courts have jurisdiction to determine the terms of a global FRAND licence.
- The "non-discriminatory" element of the FRAND obligation does not amount to a "most-favourable licence" obligation.
- An SEP owner must give notice or "consult" with an implementer before seeking an injunction.
- It was not appropriate to grant damages in lieu of a final injunction.

Supplementary protection certificates

The CJEU continued to wrestle with uncertainty around national courts' interpretation of the SPC Regulation, delivering two judgments in which it applied a narrow view of the

circumstances in which SPC protection may be afforded.

In *Santen*,[3] the CJEU overturned its previous judgment in *Neurim*[4] to find that a marketing authorisation (MA) cannot be considered to be the first MA for the purposes of Article 3(d) of the SPC Regulation where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, which has already been subject of an MA for a different therapeutic application. The CJEU held that the intention behind the SPC regime is to protect only research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product.

The CJEU in *Royalty Pharma*[5] confirmed and further developed the legal test for determining whether a product is "protected by a basic patent" under Article 3(a) of the SPC Regulation. It held that a product cannot be protected by a basic patent if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing or priority date of the application for the basic patent, following an independent inventive step. The CJEU stated that it would be contrary to the objective of the SPC Regulation to grant an SPC for a product that is not covered by the invention which is the subject of the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent.

Relief – interim and final injunctions

In many patent cases the grant of an injunction is the key remedy sought, and 2020 saw two interesting developments in relation to interim and final injunctions.

In *Neurim v Generics UK* the court (at first instance[6] and on appeal[7]) refused to grant an interim injunction restraining the launch of a generic pharmaceutical: the damage to the patent holder was quantifiable and so damages were an adequate remedy. In the Court of Appeal Floyd LJ was careful to emphasise that the case did not lay down any principle of general application but was decided on its "extremely unusual" facts (only four months to the full trial, one potential generic entrant and detailed sales projections available), but it demonstrates that the availability of an interim injunction should not be taken for granted.

The Patents Court also considered two defences that are of particular interest in light of the Covid-19 pandemic: the Crown use defence against infringement,[8] and the public interest defence against a final injunction.[9] Both judgments provide a summary of the ways in which public interest considerations are built into patent legislation and case law, and in *Evalve v Edwards* the judge expressly noted a special case that could prompt a different answer, and which is now more than a theoretical possibility: "a novel pandemic disease".

Virtual litigation

The patents courts responded swiftly to the shift to virtual working necessitated by the UK lockdown in March 2020: within a few days hearings were being conducted by phone and Skype, and many hearings and full trials have now been held either fully or partly virtually. The arrangements the court can put in place for a "hybrid" in-person and remote hearing were described in detail in *Edwards v Meril*:[10] a relatively limited number of in-person participants in court, remote video access for other participants, remote cross-examination of witnesses, and remote public access on request. As Birss J (as he then was) noted, remote participation in court proceedings is an established practice and promotes access to justice. As in other areas, one longer-term legacy of the Covid-19 pandemic for UK patent litigation may be an increase in the use of technology to streamline proceedings and reduce cost.

"The courts – and court users – adapted well to the challenges of remote working."

Outlook for 2021

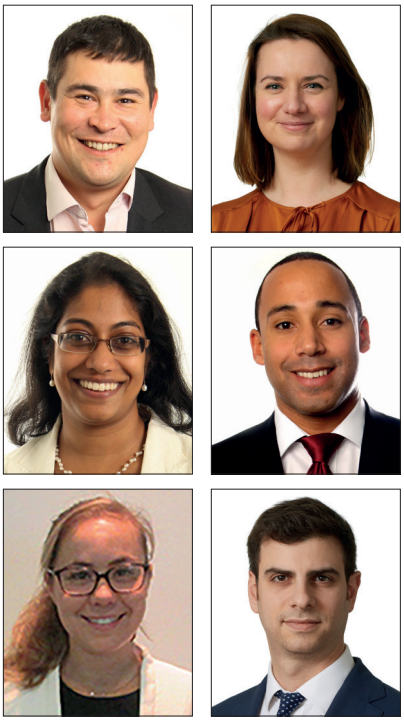
FRAND disputes dominate the Patents Court diary for the next 12 months, and 2021 will bring further developments both in the UK and further afield. We look forward in particular to seeing the courts grapple with the issues raised where multiple jurisdictions are asked to determine FRAND terms for the same portfolio.

While Brexit is expected to have a limited impact on UK patents law in general, it offers one enormously interesting possibility: the possibility for the UK courts to depart from the CJEU case law on SPCs. With the power to depart from existing CJEU case law likely to be extended down to the Court of Appeal, and no detailed guidance currently proposed to help the courts determine when departing from existing CJEU case law might be appropriate, SPC case law may present a tempting testing ground for the UK courts' newfound independence.

Footnotes

1. *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27.
2. *Unwired Planet International Ltd & Anor v Huawei Technologies (UK) Co Ltd & Anor* [2020] UKSC 37.
3. Case C-673/18 *Santen SAS v Directeur général de l'Institut national de la propriété industrielle.*
4. C-130/11 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents.*
5. Case C-650/17 *Royalty Pharma Collection Trust v Deutsches Patent- und Markenamt.*
6. *Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd* (t/a Mylan) & Anor [2020] EWHC 1362 (Pat).
7. *Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd* (t/a Mylan) & Anor [2020] EWCA Civ 793.
8. *IPcom GmbH & Co Kg v Vodafone Group Plc & Ors* [2020] EWHC 132 (Pat).
9. *Evalve Inc & Ors v Edwards Lifesciences Ltd* [2020] EWHC 513 (Pat).
10. *Edwards Lifesciences Corporation & Anor v Meril GmbH & Anor* [2020] EWHC 2562 (Pat).

Authors



Hiroshi Sheraton (top left) is a partner at Baker McKenzie and Kathy Harford (top right) is a knowledge lawyer at the firm.

Tanvi Shah (middle left) and Jason Raeburn (middle right) are senior associates at the firm, and Raeburn is also a deputy master of the High Court.

Alexandra Willis (bottom left) and George Khouri (bottom right) are associates at the firm.