2021 Life Sciences UK Patent Case Review

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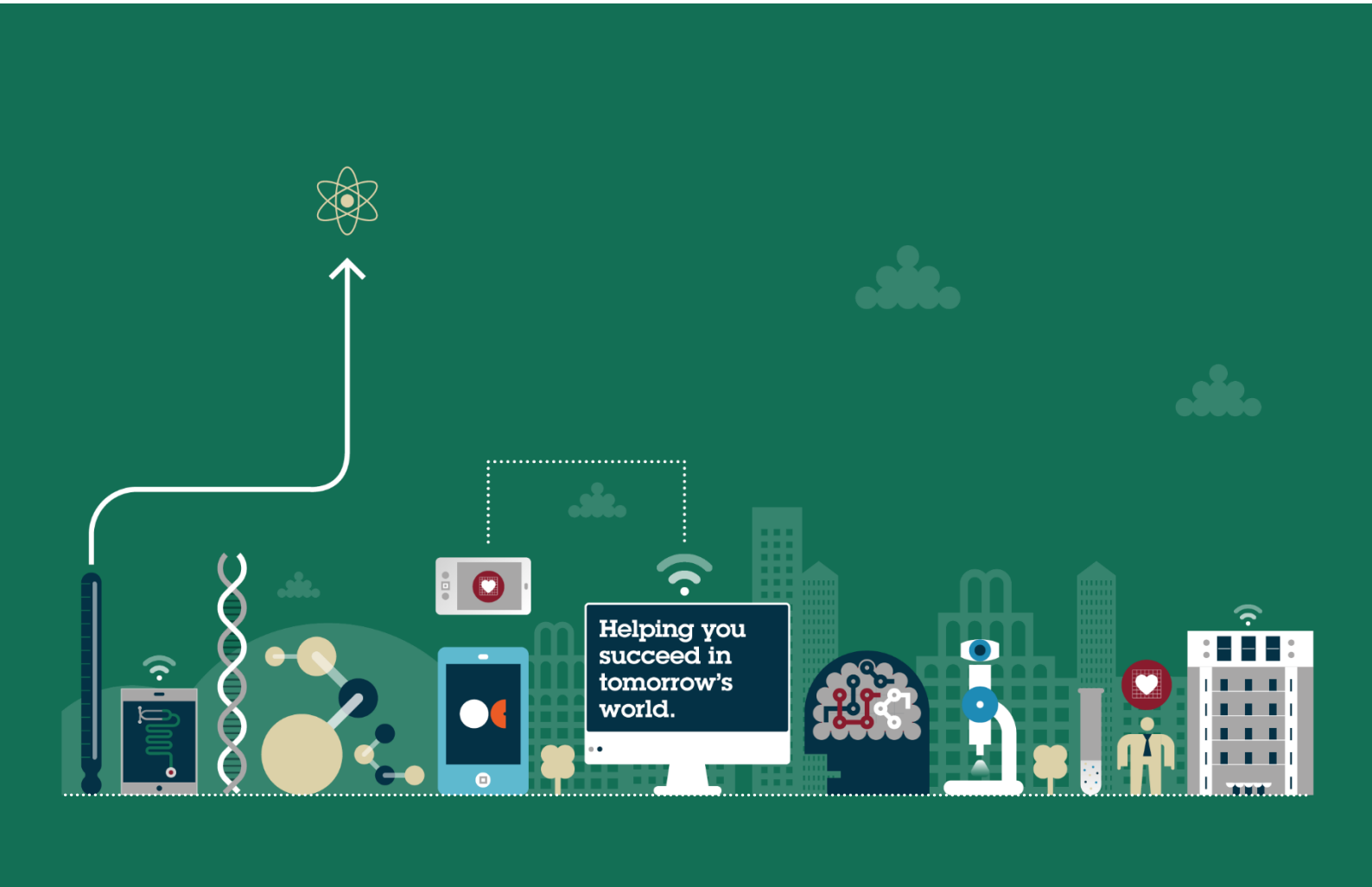


In 2021 the life sciences once again took centre stage in UK patent litigation, with the UK courts having an active year despite the global pandemic. Adaptation and flexibility have been reoccurring topics in these ever-changing circumstances with some trials being heard fully remotely, others entirely in person again, and a hybrid format for others.

A wide range of subjects have been litigated and in this case review Osborne Clarke's patent team pick out both those judgments from 2021 of direct relevance to the life sciences sector, as well as the key patent decisions outside this area that are nevertheless important to practitioners in this field.

We first review the Supreme Court judgment *Secretary of State for Health & Anor v Servier Laboratories Ltd & Ors* [2021] UKSC 24. This focussed on the economic tort of unlawful means, but was of significance to all those litigating patents in the UK – albeit that, as a result, the status quo was maintained.

Four Court of Appeal decisions are also considered: three relating to patent validity (one in which the appeal was allowed, overturning the invalidity finding below (*FibroGen Inc v Akebia Therapeutics Inc* [2021] EWCA Civ 1279), and two dismissing the appeal, upholding the lower court's validity and invalidity findings (*Illumina Cambridge Ltd v Latvia MGI Tech SIA & Ors* [2021] EWCA Civ 1924; and *Wyeth LLC v Merck Sharp & Dohme (UK) Ltd* [2021] EWCA Civ 1099) and the final one relating to an injunction application (*Autostore Technology AS v Ocado Group Plc & Ors* [2021] EWCA Civ 1003)).

This review then summarises the key points from 16 decisions of the Patents Court that deal with a range of topics:

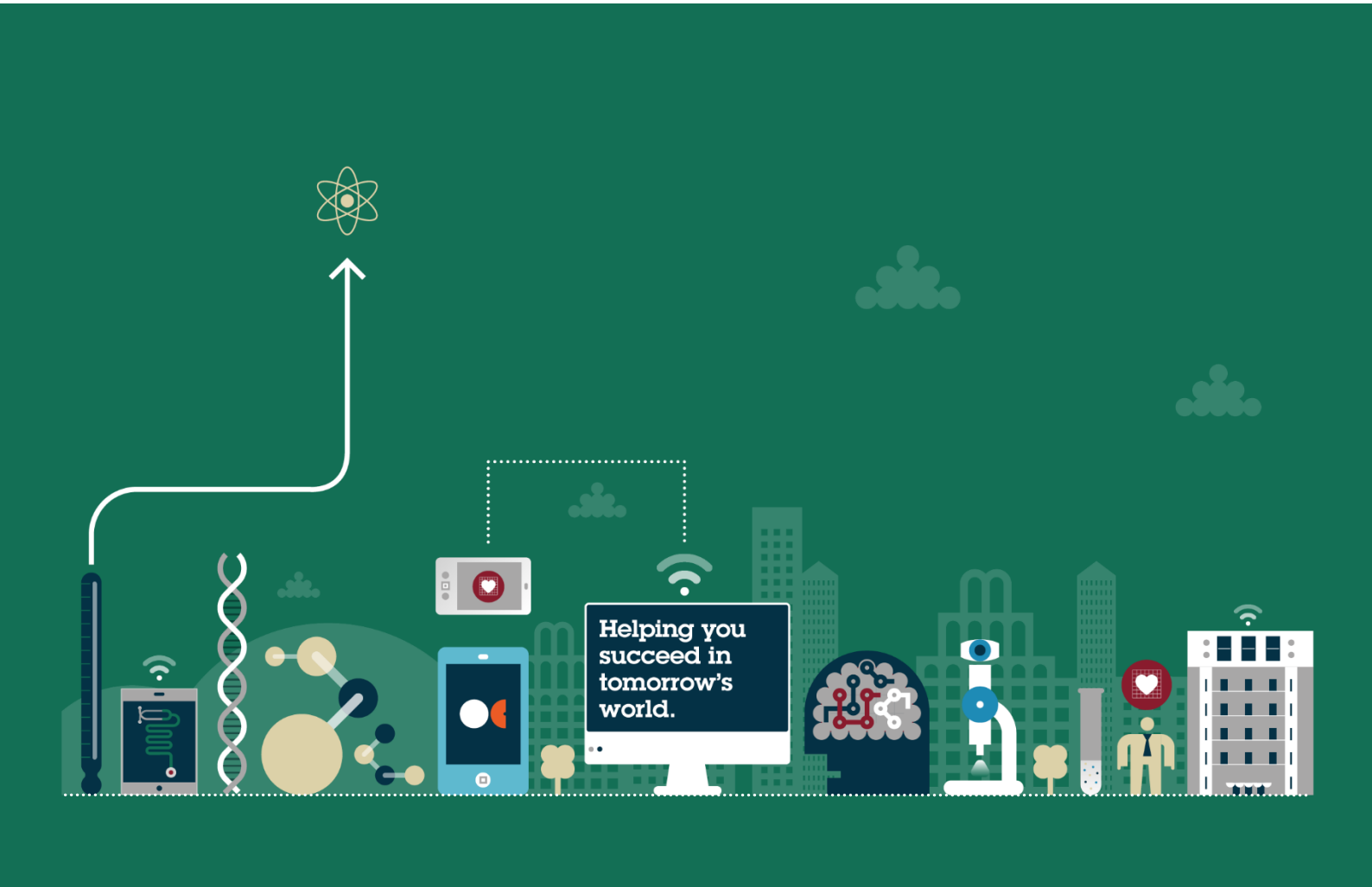
- three with a finding of invalidity (*Coloplast A/S v Salts Healthcare* [2021] EWHC 3 (Pat); *Insulet Corporation v Roche Diabetes Care Ltd* [2021] EWHC 1933 (Pat); and *Teva Pharmaceutical Industries Ltd & Anor v Bayer Healthcare LLC* [2021] EWHC 2690 (Pat));
- two with a finding of validity (*Illumina Cambridge Ltd v Latvia MGI* Tech SIA & Ors [2021] EWHC 57 (Pat); and *Alcon Research LLC & Anor v Actavis Group PTC EHF & Ors* [2021] EWHC 1026 (Pat));
- one relating to the German interpretation of European Patent Convention (EPC) 2000 claims in a royalty dispute (*Royalty Pharma Collection Trust v Boehringer Ingelheim GmbH* [2021] EWHC 2692 (Pat));
- one relating to counterfactuals for a damages inquiry (*Dr Reddy's Laboratories (UK Limited) & Ors v Warner-Lambert Company LLC & Anor* [2021] EWHC 2182 (Ch));

- four relating to applications for expedition of proceedings (*Teva Pharmaceutical Industries Ltd and Anor v Janssen Pharmaceutica NV* [2021] EWHC 1922 (Pat); *Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd (t/a Mylan) & Anor* [2021] EWHC 2198 (Pat); *Abbott Laboratories Ltd v Dexcom Incorporated* [2021] EWHC 2246 (Pat); and *Advanced Bionics AG & Anor v MED-El Elektromedizinische Gerate GmbH* [2021] EWHC 2415 (Pat));
- one concerning an application for a stay of UK proceedings pending European Patent Office opposition (*Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd (t/a Viatris) & Anor* [2021] EWHC 2897 (Pat));
- one relating to an application to limit the number of independently valid claims relied upon by a patentee (*Sandoz Ltd v Bristol-Meyers Squibb Holdings Ireland Unlimited Company & Ors* [2021] EWHC 1123 (Pat));
- one giving *obiter* guidance on the *Formstein* defence in cases of infringement by equivalents (*Facebook Ireland Ltd v Voxer IP LLC* [2021] EWHC 1377 (Pat));
- one relating to anticipation by equivalence and how such claims should be pleaded (*Optis Cellular Technology LLC and Ors v Apple Retail UK Limited and Ors* [2021] EWHC 1739 (Pat)); and
- one concerning the refusal of an application for injunction (*Autostore Technology AS v Ocado Group Plc & Ors* [2021] EWHC 1614 (Pat)).

We also include a summary table at the back of this booklet, which gives a brief overview of these decisions setting out the main legal issues considered and their outcomes.

Finally, we look ahead at 2022 and highlight some of the life sciences cases to look out for over the next twelve months.

The Supreme Court



1. *Secretary of State for Health & Anor v Servier Laboratories Ltd & Ors*

The Supreme Court upheld the dealing requirement as an essential component of unlawful means economic tort claims, leaving intact the current system for litigating patents in the UK.

This case concerned an appeal brought by the secretary of state for health and the NHS Business Services Authority (the appellants) against Servier. The appellants fund the cost of medicines dispensed by the NHS in England. Servier developed and manufactured a drug for the treatment of cardiovascular disease marketed as "Coversyl".

In 2001, Servier applied to the European Patent Office (EPO) for a patent, which was granted, including a UK designation, in 2004. Opposition proceedings were brought against the patent, which was upheld by the EPO's Opposition Division in 2006.

Servier sought to enforce the UK designation in the English courts and obtained preliminary injunctions against competitors who wanted to launch generic versions of its drug. The generics counterclaimed that the patent was invalid and they were successful at trial in 2007. The invalidity decision was upheld by the Court of Appeal in 2008 and in 2009 the EPO's Technical Board of Appeal revoked the patent. The appellants had not been involved in the proceedings at the EPO or the English courts.

The appellants contended that in obtaining, defending, and enforcing the UK patent, Servier had practised deceit on the EPO and/or the English courts (the third parties) with the intention of profiting at the appellants' expense.

The appellants maintained that as a consequence of this alleged deceit, generic versions of the drug did not enter the market as early as they otherwise would have, which caused drug prices to be higher. This deceit formed the basis of the appellants' claim for an unlawful means tort and they sought damages and interest in excess of £200m.

In August 2017, the High Court struck out the appellants' claim. The appellants appealed the decision and, in July 2019, the Court of Appeal dismissed their appeal. The High Court and the Court of Appeal held that the House of Lords, in its decision of *OBG Ltd v Allan* [2007] UKHL 21, had concluded that an essential element of the tort of causing loss by unlawful means was that the unlawful act intended to cause loss to the claimant by interfering with the freedom of a third party in a way that was unlawful and that affected the third party's freedom to deal with the claimant.

Therefore, the High Court and the Court of Appeal decided that *OBG* determined that a *"dealing requirement"* was a necessary component of the tort, and they were bound to follow that precedent.

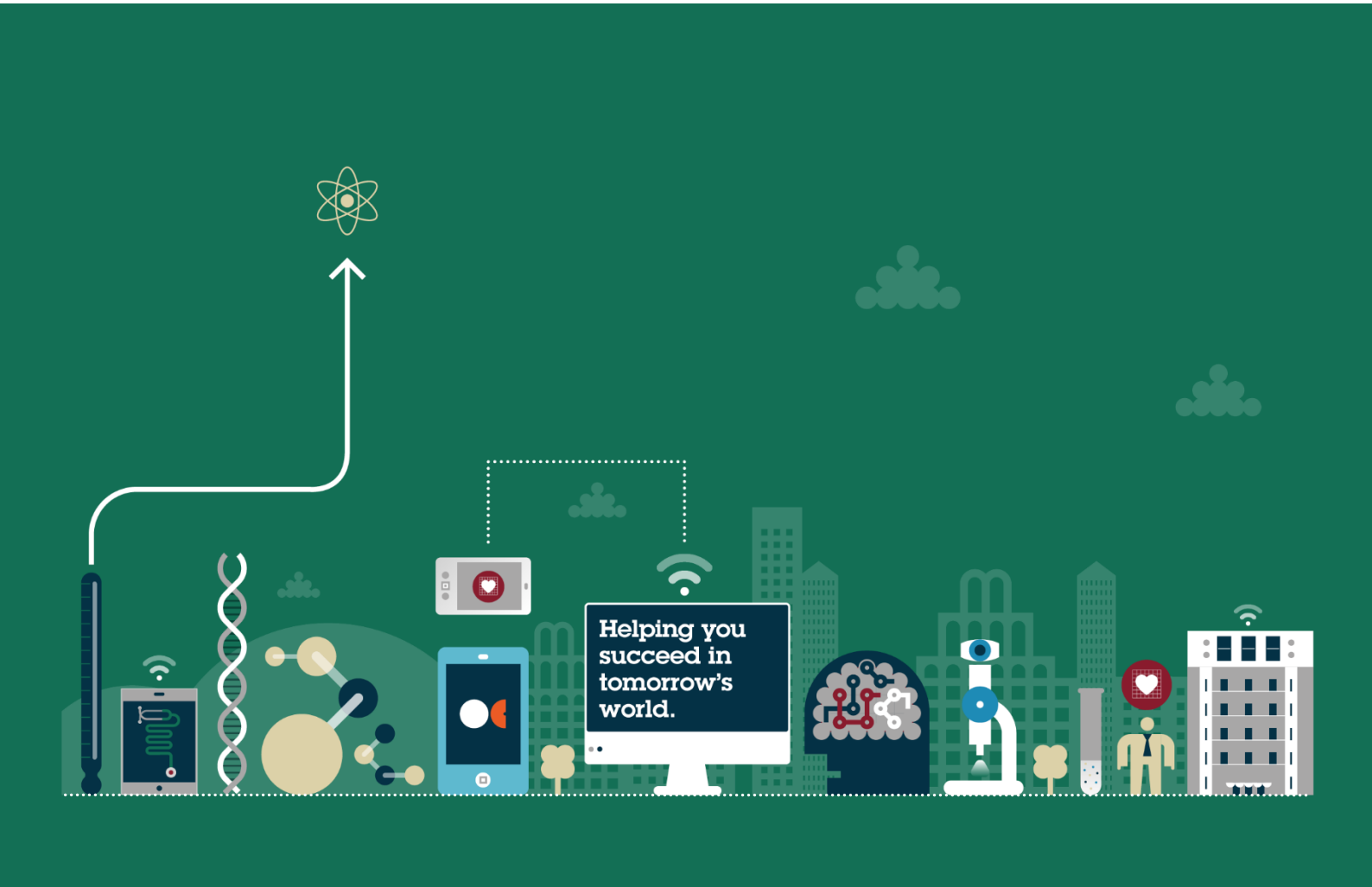
Before the Supreme Court, the appellants contended that the dealing requirement should not be a necessary element of the tort as it didn't form part of the *ratio* of the *OBG* decision or, alternatively, the Supreme Court should depart from *OBG* and remove the dealing requirement.

The Supreme Court unanimously agreed with the lower courts that the dealing requirement did form part of the *ratio* of *OBG*. Lord Hamblen noted the policy issues considered by Lord Hoffmann in *OBG*, including the rationale of the tort being to preserve a person's liberty to deal with others and the concern that the tort should not be too expansive.

As such, the Supreme Court ruled that by defending and enforcing a patent that was later determined to be invalid, Servier did not commit the tort of causing loss by unlawful means.

This decision saw an attempt to bring allegations of fraud on the patent office that exist in other jurisdictions (for example, the USA) within the tort of unlawful means rejected. The patentee, therefore, avoided liability for the economic loss suffered, in this case by the NHS, because generics were only able to enter the market later than if the patent had not been in force. This closes off the opportunity to seek redress by parties tangentially related to patent validity proceedings but who are financially impacted by a finding that a patent is invalid.

The Court of Appeal



2. *FibroGen Inc v Akebia Therapeutics Inc*

The Court of Appeal overturned a first instance judgment from Arnold LJ relating to the sufficiency of claims with structural features and functional requirements.

This judgment concerned an appeal of a first instance decision from Arnold LJ (sitting as High Court Judge) relating to six patents belonging to FibroGen (exclusively licensed to Astellas). The patents formed two families (A and B) relating to claims for the treatment of certain types of anaemia using compounds defined in structural and functional terms.

At first instance, Arnold LJ held that the patent was implicitly promising that substantially all of the compounds that satisfied the structural definitions in the claims would have the claimed therapeutic effect.

As such, he held that the claims were insufficient because: i) it was not plausible that substantially all of the compounds covered by the structural definition in the claims would have the claimed therapeutic effect; and ii) it would be a substantial research project to identify any compounds other than those specifically identified in the specification; therefore, the invention could not be performed across the scope of the claims without undue burden.

The Court of Appeal (the leading judgment was given by Birss LJ, with additional comments on sufficiency from Sir Christopher Floyd) overturned the first instance decision. Birss LJ set out a new three-step structured approach for considering the sufficiency of claims with structural and functional features.

Firstly, one must identify what falls within the scope of the claimed class. Secondly, one must determine what it means to say that the invention works – that is, what is the invention for? With respect to these first two steps, Birss LJ said that it is necessary to distinguish between two types of functional limitations: i) those limiting the claimed class of compounds (Birss LJ gave an example from *Regeneron v Genentech* [2013] EWCA Civ 93 of VEGF (vascular endothelial growth factor) antagonism); and ii) those relating to the desired effect (such as treating the relevant disease).

Once these stages have been determined, one can move on to the crucial third stage of answering the question: whether it is possible to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim. The judge stated that he preferred the language of *"reasonable prediction"* rather than *"plausibility"* but that it is *"the same principle".*

Moving on to the issue of undue burden, Birss LJ also disagreed with Arnold LJ below, holding that the appropriate question is whether it is possible to perform the invention across the scope of the claim without undue burden (rather than requiring the skilled person to identify substantially all compounds covered by the claim without undue burden).

For claims like those in this case, the judge held that this question has two elements. Firstly, it must be possible for the skilled person to identify some other compounds, beyond those named in the patent, that are within the claimed class and are therefore likely to have therapeutic efficacy.

Secondly, separately, it must also be possible for the skilled person to work substantially anywhere within the whole claim. Birss LJ said that this would involve the skilled person, when given a sensible compound within the structural class (or substantially any), being able to apply the tests without undue burden and work out if it is a claimed compound.

Beyond Birss LJ's leading judgment, Sir Christopher also gave a short judgment on the issue of sufficiency because *"we are differing from a patent judge of enormous experience and distinction…".*

Sir Christopher held that functional requirements of claims would be *"otiose"* if only compliance with structural formula was all that was necessary to achieve the therapeutic effect. Thus, it is only compounds that meet the particular functional requirements of a claim that the skilled person would understand to have the predicted therapeutic effect.

The judge also commented that Arnold LJ's approach to claim construction below meant that his conclusion on plausibility was *"inevitable".* But on the correct construction of the claims, that is, they are limited by both the structural and functional features, *"the question of plausibility answered itself".*

As such, the appeal on the sufficiency of the Family A patents (both on the breadth of claim and uncertainty) was allowed, at least in relation to one particular patent. That patent was held to be valid and would be infringed by Akebia's product. Even though the sufficiency findings also applied to the Family B patents, the finding of obviousness with respect to those patents was upheld and therefore they remained invalid.

This decision was certainly a more patentee friendly one than the first instance decision, reinstating the limiting effect of functional requirements. Birss LJ's structured approach to considering the sufficiency of claims with structural and functional features provides a new, more practical way of dealing with such issues.

While Birss LJ's approach to undue burden leaves open the question of what amounts to *"some"* compounds within the claimed class beyond those identified in the patent, it sets in a place a lower standard for undue burden than had previously been determined by Arnold LJ below.

3. *Illumina Cambridge Ltd v Latvia MGI Tech SIA & Ors*

The Court of Appeal upheld Birss J's (as he then was) first instance decision that four patents owned by Illumina were valid and infringed by MGI (a fifth patent was held to be invalid at first instance but this was not subject to the appeal).

The patents subject to the appeal fell into two groups: i) three patents known as the "Modified Nucleotide Patents", which claimed priority from a British application referred to as "P2"; and ii) the 415 Patent.

MGI contended that the Modified Nucleotide Patents could not be both non-obvious over prior art, known as "Zavgorodny", and entitled to priority from P2. At the trial, MGI's primary case was that the Modified Nucleotide Patents were obvious and priority was run as a squeeze. MGI's primary case on appeal was that the Birss J's reasoning on priority was inconsistent with his reasoning on obviousness and that he ought to have concluded that the patents were not entitled to priority. Or, alternatively, if the judge was right on priority then he was wrong on obviousness.

MGI's appeal relating to the Modified Nucleotide Patents was rejected. Arnold LJ, who gave the leading judgment, agreed with Birss J below that there was no squeeze between obviousness and priority in this case. He further held that even though MGI pleaded a case of *AgrEvo* obviousness, the case it ran and the case on appeal was a conventional case of obviousness over Zavgorodny, which it was held did not point the skilled team towards the claimed inventions.

Lastly, Arnold LJ stated that MGI did not clearly argue that the Modified Nucleotide Patents were not entitled to priority because P2 did not make it plausible that the claimed compounds would have the claimed utility. But, even if it had made this argument more clearly, Birss J would have been correct to reject it.

With respect to the 415 Patent, Birss J had found that Claim 1 combined two elements that when taken on their own were obvious but when combined were not obvious. However, he said that if this was a collocation then it would be invalid.

Arnold LJ provided an extensive review of the law on collocation and the EPO Examination Guidelines on this issue. He held that MGI's appeal on this issue should also be dismissed, stating: *"I agree with the judge that, even assuming that the collocation principle is applicable to an invention consisting of a class of molecules, the application of the principle must take account of that technical context."* He concluded that the 415 Patent claimed a single invention that made a technical contribution to the art.

As such, the Court of Appeal rejected MGI's appeal in its entirety and upheld the first instance validity finding of the four patents subject to the appeal. A fifth patent had been held invalid at first instance but this finding was not appealed.

(See case summary 9 below for the first instance decision.)

4. *Wyeth LLC v Merck Sharp & Dohme (UK) Ltd*

The Court of Appeal upheld the decision that Wyeth's vaccine formulation patent was invalid for obviousness over a prior art paper.

Wyeth appealed the judgment of Meade J, which held that Wyeth's vaccine formulation patent was invalid on the basis of obviousness over a prior art research paper and, in any event, Merck Sharp & Dohme's (MSD) vaccine would not infringe any claim of Wyeth's patent even if valid.

Arnold LJ reminded that obviousness assessments involve a multi-factorial evaluation; therefore, the Court of Appeal is not justified in intervening with the decision in the absence of an error of law or principle on the part of the trial judge.

Wyeth had argued that Meade J had erred in principle because he misinterpreted the prior art research paper. Arnold LJ held that the judge had not made any material errors in this regard and he was correct in holding that the claims were obvious.

Sir Christopher Floyd agreed with Arnold LJ, adding that obviousness cases can be rejected on the basis that, with the passing of time, a prior art document becomes a *"dead end as opposed to a useful starting point for further development".* Such treatment of a prior art document must be supported by evidence that this is how the skilled person would treat the document in question based on their common general knowledge.

Wyeth had argued that as the relevant prior art had been published in 2004, two years before the patent's priority date, the relevant question for the judge was what would the reaction of the skilled person have been at the priority date, in light of the common general knowledge as it stood at that time. Wyeth pointed to failures in Phase III clinical trials by two other commercial undertakings as evidence that the disclosure in the prior art would not be worth progressing.

However, Sir Christopher noted that Meade J below had found the difficulties encountered by these other undertakings were specific to those companies and not innate to the task at hand. These difficulties therefore, would not have provided a reasoned disincentive to progress the vaccine disclosed in the prior art, which was disclosed to be in advanced studies by Wyeth.

Absent any evidence that that Wyeth had encountered similar difficulties with respect to its vaccine, the skilled person would be entitled to assume that Wyeth was still actively pursuing its vaccine at the priority date in 2006, as it had said it was doing in 2004. Unless the common general knowledge supported the idea that Wyeth's vaccine had innate problems, which it was found it did not, the prior art would still have given the skilled person sufficient motivation to progress making a formulation falling within the scope of the patent.

5. *Autostore Technology AS v Ocado Group Plc & Ors*

The Court of Appeal by majority upheld the first instance decision that an injunction should not be granted to prevent disclosure of information to the US International Trade Commission; Nugee LJ dissented.

Sir Geoffrey Vos MR (with whom Nicola Davies LJ agreed) held that in light of the parties agreeing that discussions about US matters in the relevant settlement negotiations were to be governed by US rules of evidence, there was, as HHJ Hacon found at first instance, an analogy with anti-suit injunctions. As such, the anti-suit injunction test was rightly applied.

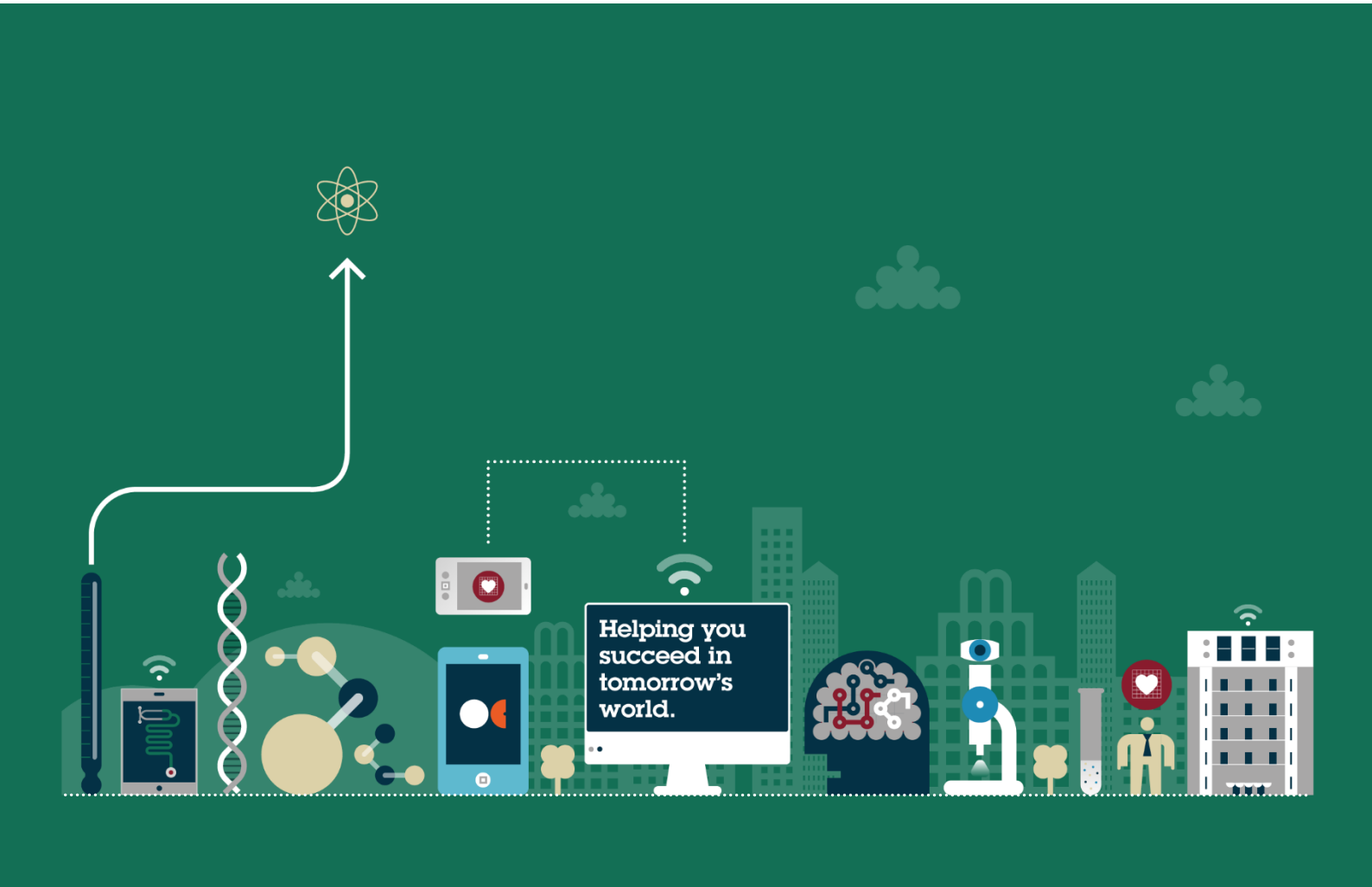
In considering the application of the test, Sir Geoffrey held that he was in agreement with the judge in the first instance decision that Ocado had not shown it would have had a high probability of success of establishing its case at trial, namely: it did not have a high probability of success of showing that the question of whether the document was admissible in the ITC was governed by English law without prejudice principles.

In light of this finding, Sir Geoffrey stated that it was unnecessary to go on to consider the balance of convenience or the balance of irreparable harm. But, in any event, felt that the balance fell *"squarely"* in favour of refusing the injunction. The appeal was dismissed.

Nugee LJ gave a dissenting judgment and would have allowed the appeal. He preferred the argument that the US law discussions and the relevant document were subject to the contractual agreement between the parties; therefore, English law without prejudice principles would have applied. Thus, he held that the anti-suit injunction test should not apply. Instead, he maintained that it was enough for Ocado to establish a sufficient case on the merits, which, even if that was a test of high probability, Nugee LJ felt Ocado would have satisfied.

(See case summary 18 below for the first instance decision.)

Patents Court



Validity (patents invalid)

6. *Coloplast A/S v Salts Healthcare*

For obviousness assessments, it is enough to show that the invention would have occurred to the skilled person: it is not necessary to show they would have actually implemented it.

Coloplast commenced infringement proceedings against Salts with respect to Salts' range of ostomy bags. Ostomy bags are small, waterproof pouches that collect waste from people with stomas. Ostomy bags typically have two layers of barrier film and an additional layer, known as the comfort layer.

The comfort layer can be removeable or non-removeable. As at the priority date, the judge held that only integrated comfort layers made of non-woven materials were available. Coloplast's invention claimed a new collecting bag – an ostomy bag with an accompanying comfort layer made of a partially woven textile material.

Salts counterclaimed that Coloplast's patent was invalid for a number of reasons, including that the claims were obvious over the common general knowledge and five pieces of prior art.

In assessing obviousness, the judge applied the well-known structured approach set out in *Windsurfing/Pozzoli*. He ultimately concluded that the inventive concept relied on by Coloplast – the use of woven material to make an integrated comfort layer with improved properties – was not inventive.

The judge held that the reason woven materials had not previously been used was of a commercial rather than technical nature. It was common general knowledge that woven materials could be used but they had not been pursued because of higher costs and environmental concerns.

The fact that the idea had not been implemented or there was a delay in its implementation was not proof of inventiveness. The courts had previously pointed out that there may be a number of non-inventive reasons why an alleged inventive step was not taken.

When assessing whether a technical step requires a degree of inventiveness, one must consider whether the step adds something to the existing knowledge. Here, it was held that the skilled person, subject to minor adjustments, would have been able to use the same commonly known techniques used in respect of the non-woven comfort layer for the woven layer. At the priority date the skilled person would have known that it was possible to integrate a woven layer, they just had no desire to do so.

This decision served as a reminder that invalidity arguments based on commercial factors will usually have limited impact and should not be dressed up as obviousness attacks. What is central to determining obviousness is whether the relevant step requires a degree of invention. Non-implementation or a delay in implementation are not necessarily proof of inventiveness.

7. *Insulet Corporation v Roche Diabetes Care Ltd*

Patent for insulin pump found invalid for lack of novelty and obviousness over an international patent application and for added matter.

Insulet claimed that Roche had either directly infringed its patent with the manufacture and sale of its "Solo" micropump and related components, infringed by equivalents, or infringed indirectly by supplying consumable Solo components. Roche denied infringement and counterclaimed for revocation, citing lack of novelty, obviousness, and added matter.

The judge, Ms Pat Treacy, first dealt with the infringement issues, finding that Roche's device did not infringe directly on a normal interpretation, by equivalents, or indirectly. She then moved onto validity, first considering novelty. The judge concluded that all of the disputed aspects of the relevant claim had been disclosed by the prior art.

In assessing obviousness, the judge applied the *Pozzoli* analysis and concluded that the teachings in the patent would have been obvious in light of the prior art. As for added matter, Ms Treacy held that the patent as granted provided the skilled person with information about the invention that was not derivable directly and unambiguously from the original disclosure in the patent application as filed and therefore was invalid for added matter.

It is interesting to note that this case operated under the Shorter Trials Scheme, which aims to limit the length of trials so that they can be heard more quickly and more cost effectively. Despite this, the judgment ran to nearly 600 paragraphs and covered a wide range of issues. Indeed, the judge admitted that the complexity of the issues and the number of areas of dispute *"tested the outer limits of the time and procedures available under the Shorter Trial Scheme".*

8. *Teva Pharmaceutical Industries Ltd & Anor v Bayer Healthcare LLC*

Mellor J confirmed that the previous approaches to obviousness adopted by the courts are fact specific and therefore are not inconsistent, the relevance and applicability of each test will depend on the facts of the case.

This case concerned a claim in a patent owned by Bayer, which claimed the tosylate salt of sorafenib. Teva alleged that this claim was invalid, as they sought to clear the way for their own sorafenib tosylate product.

There were originally a number of validity attacks pleaded by Teva, including a novelty attack, which Bayer had responded to with a conditional amendment to the claim to claim sorafenib tosylate "for oral administration". This attack was withdrawn the weekend before the trial and as such Bayer agreed not to pursue its conditional amendment.

The judge noted that Bayer fought its case at trial at least partially on its proposed amended claim, that is, on the basis that Teva would have to prove not only that it was obvious to make sorafenib tosylate but also that it had to establish that the skilled team could have, without invention, progressed on to formulating sorafenib tosylate for oral administration. But, in construing the claim, the judge found it related to just the compound per se.

By the time of closing arguments in the trial, the obviousness attack was limited to a single piece of prior art but common general knowledge (CGK) was also relevant.

In considering the law of obviousness, the judge cited Arnold J (as he then was) in *Allergan Inc and Anor v Aspire Pharma Ltd* [2019] EWHC 1085 (Pat) where he considered that the "overall tenor" of the Supreme Court's review of the law of obviousness in *Actavis v ICOS* [2019] UKSC 15 as confirming the approach previously taken by the courts.

The judge noted that the parties placed much emphasis on Lord Hodge's "could/would" distinction in *Actavis v ICOS*. Bayer accused Teva of relying on Birss J's approach in *Hospira v Genentech* [2014] EWHC 3857 (Pat) as a way to *"distance itself"* from what Bayer called "*the standard could/would approach*". Bayer argued that this could not trump Lord Hodge's statement from *Actavis* or the European Patent Office (EPO) approach, which distinguishes between what a skilled person could do from what they would do.

Mellor J stated that he did not see a conflict between *Hospira* and *Actavis* or the EPO approach because each case turned on its own facts. The judge said that some of the arguments from *Hospira* reflected some of the points in this case.

Bayer argued that this was a CGK-only case because the cited prior art did not give any directions to use tosylate. But, the judge held that it was not and that the starting point was the cited prior art, which provided the skilled team with a *"strong (but not irresistible) motivation to investigate"* sorafenib.

Thus, the judge said that the case really turned on whether it was obvious to include the tosylate salt in a salt screen. If it was, the judge held that the skilled formulator would ask the medicinal chemist to make it and they would be able to make tosylate sorafenib that falls within the claim.

Ultimately, the judge concluded that the claim was obvious. The judge noted that most skilled teams would have selected the tosylate salt in their salt screens and such inclusion would have been the result of standard and routine considerations.

This case reiterates the approaches to obviousness previously taken by the courts and underscores the fact-specific nature of obviousness assessments. This emphasis on the facts of each case allowed the judge to conclude that the different approaches to assessing obviousness are not inconsistent but that their relevance and applicability may change depending on the facts.

Validity (patents valid)

9. *Illumina Cambridge Ltd v Latvia MGI Tech SIA & Ors*

The judgment offers clarity on the application of the insufficiency principles laid down by the Supreme Court in *Regeneron v Kymab* [2020] UKSC 27, in particular on the "Regeneron ranges".

This case concerned DNA sequencing technology, with Illumina holding five patents (three of which were divisionals of each other) relating to this technology. MGI raised invalidity attacks against Illumina's patents on the basis of obviousness, lack of technical contribution, and insufficiency (amongst others).

Focussing on the insufficiency arguments, MGI asserted that the patents were insufficient in two respects: "*read length*" and "*impractical linkers*". With respect to "*read length*", MGI maintained that the claim covered unspecified read lengths but there was nothing in the patent to suggest that anything beyond what was known in the prior art could be achieved. On the "*impractical linkers*" point, MGI submitted

that the skilled person would not be able to perform the claimed sequencing method across the breath of the claim without undue burden.

Despite extensive attack, four of Illumina's five patents were held to be valid in some form.

Birss J (as he then was) reviewed the insufficiency principles set out by Lord Briggs in *Regeneron* and noted that although those principles had been laid down in the context of product claims, they were also applicable to process claims (as in the current case). But, care needed to be taken in applying the principles to different circumstances. Thus, Birss J altered the wording of principles (v) to (viii) to reflect the statutory language that process claims are performed and not made.

At principle (viii) in *Regeneron*, Lord Briggs was clear that sufficiency wouldn't be negated by a wholly irrelevant factor. Thus, the requirement to show that an invention is enabled across the scope of the claim applies only to a *relevant* range. There, a relevant range was held to be a variable that significantly affected the value or utility of the product in achieving the purpose for which it was made.

In this case, Birss J held that being relevant in a Regeneron sense was dependent on all the circumstances, not just the claim as drafted but also *"the essence or core of the invention (closely related to the technical contribution and/or inventive concept)".* Birss J applied this test to the Illumina patents, first setting out what he considered to be the essence of the invention.

He held that neither of the ranges that had been put forward by MGI were *"Regeneron ranges".* Accordingly, they did not render the patent insufficient, as they did not go to the essence of the invention. Birss J held that in both cases suitable types could be selected without undue burden, although some skill and routine testing may have been needed. The claims were therefore held to be sufficient.

This decision allayed to some extent the concerns expressed after *Regeneron* that the English courts might be more willing to find patents insufficient. The sufficiency attacks raised in the case underscore the need for patentees to consider the extent to which they are able to future-proof their inventions when drafting patent applications. As such, it is important for patentees to assess whether ranges covered in a claim (whether expressly or impliedly) significantly affect the value or utility of the essence or core of the claimed invention.

Illumina Cambridge Ltd v Latvia MGI Tech SIA & Ors – Court of Appeal

The Court of Appeal upheld the finding that four of five of Illumina's patents are valid but no appeal was made on insufficiency.

The issue of insufficiency was not appealed by MGI and so there was no decision from the Court of Appeal on Birss J's application of "*Regeneron ranges*". The Court of Appeal (Arnold LJ giving the leading judgment) did, however, uphold the first instance finding that four out of Illumina's five patents were valid and infringed. The first instance decision that the fifth patent was invalid had not been appealed.

(See case summary 3 above for a more detailed summary of the appeal judgment.)

10. *Alcon Research LLC & Anor v Actavis Group PTC EHF & Ors*

Alcon's patent relating to the treatment of glaucoma and ocular hypertension was held to be valid, obviousness arguments were rejected.

Alcon's patent and related supplementary protection certificate (SPC) had already expired by the time of the trial, but the trial was necessary to determine whether cross-undertakings in damages given by Alcon when it obtained interim injunctions would take effect. Had the patent been found to be invalid, those cross-undertakings would have come into force.

The patent in suit claimed a 1993 priority date and related to the use of travoprost (an ester prodrug of fluprostenol), a prostaglandin F2α analogue, for the treatment of glaucoma. Validity was attacked primarily on the basis of: novelty over a prior art patent application, EP800; and obviousness over a prior art scientific paper, referred to as Stjernschantz.

Focussing on the judge's assessment of obviousness, Meade J first applied the *Pozzoli* analysis. In doing so, he noted the different characterisations made by the parties of the difference between the prior art and the claims of the patent (the third *Pozzoli* question).

Meade J concluded that this was more than a *"presentational issue"* of the patentee seeking to maximise the number of differences and the defendant trying to minimise them. It was held that the disparity was more substantive and related to the nature of the skilled team and the way they would see the work reported in the prior art. As such, the judge concluded that the defendant's task was to show that it was obvious to use fluprostenol isopropyl ester (FIE), instead of any of the analogues in Stjernschantz, to treat glaucoma.

The judge moved on to considering the obvious to try aspects of the defendants' case, which arose because of the way the defendants considered the skilled team to be made up and the way that skilled team would interpret the prior art. The defendants had argued that Stjernschantz showed that latanoprost bound well to a particular prostaglandin receptor (the FP receptor) and that this binding was responsible for its biological activity (reduced intra-ocular pressure) and side effects were mediated by binding to different prostaglandin receptors.

They further maintained that in light of this the skilled team would then consider other FP receptor agonists for the same purpose and, as travoprost was known to be a potent and selective FP receptor agonist, it would have been obvious to try travoprost for treating glaucoma.

Meade J decided that Stjernschantz was focussed on structure-activity relationships, so its teaching pointed away from trying other structurally different compounds based on activity. It was not argued that using fluprostenol would be consistent with any of the structure-activity work reported in Stjernschantz. Overall, the prospects of using fluprostenol were considered uncertain with merely a hope (rather than a positive expectation) of success.

Meade J emphasised that motivation and expectation of success may be important factors in considering obviousness, with their relative importance depending on the context and the facts in each case, but a hope for a positive result sufficient to justify research being carried out does not necessarily imply an expectation of success.

Although the judge concluded that Alcon's approach to the skilled team better reflected the contents of the prior art, as it is the defendants' task to make out its obviousness argument, the judge proceeded on the basis of the defendants' approach. On this basis, the judge rejected the obviousness attack and noted that the defendants' case would have been even harder to make out on Alcon's approach to the skilled team.

Meade J particularly pointed out that the expert evidence relied on by the defendants was not persuasive. He especially noted that the defendants' pharmacology expert failed to deal with why the skilled team would consider using fluprostenol in the first place, they did not include a proper analysis of the prospect of success, and they did not take account of the nature of the work done and suggestions made in the prior art.

As such, the patent was held to be valid. Infringement had already been admitted by the defendants. The cross-undertakings given by Alcon when it obtained interim injunctions did not take effect.

This decision emphasised the need for experts to address all factors relevant to the obviousness assessment in their evidence. Of particular note was the care taken by Meade J to accurately characterise the practical content of the prior art paper and how the skilled team would realistically implement its teaching. It is welcome to see the court emphasising the practical nature of the task of assessing obviousness.

It is also refreshing to see the court properly engage with the teaching of a prior art citation and how this would have been understood and acted upon by the skilled team at the priority date. This demonstrates that the Patents Court continues to place patents in a real-world practical context and recognises the uncertainties involved in research that may only appear to have been obvious at a later date.

Judgments concerning quantum

11. *Royalty Pharma Collection Trust v Boehringer Ingelheim GmbH*

Boehringer was ordered to pay royalties, under a pharmaceutical licensing agreement governed by German law, to the proprietor of a patent that related to the use of linagliptin for the treatment of diabetes. Liability arose as a result of Boehringer's manufacture of products in which linagliptin was the active pharmaceutical ingredient (API).

In 2005, Boehringer was originally granted a non-exclusive licence in relation to patents and patent licences owned by Prosidion Ltd. The benefit of the agreement was assigned from Prosidion to Royalty Pharma in 2011, and Royalty Pharma and Boehringer negotiated amendments to the agreement in 2015. The licence was governed by German law but with the English courts having jurisdiction over any disputes.

Royalty Pharma issued proceedings claiming outstanding royalties under the 2015 amended licence and Boehringer counterclaimed for repayment of overpaid royalties under the original agreement.

Boehringer sell products used to treat type 2 diabetes, the API in which is linagliptin. The API was manufactured by Boehringer in Germany, with some being formulated into products in Germany and some being exported to other countries.

Royalty Pharma claimed that but for the amended licence, the manufacture of linagliptin in Germany would amount to infringement of the German designation of one of its patents, which contained an European Patent Convention (EPC) 2000 claim for the use of linagliptin to treat type 2 diabetes. Thus, it claimed that Boehringer owed it royalties under the amended licence.

Boehringer counterclaimed that under the original licence only the sale of the product in a territory with an existing licensed claim that covered the sale of the product would result in an obligation to pay royalties. Accordingly, Boehringer claimed that it had overpaid under the original licence as it had calculated the royalties paid on the basis of worldwide sales. This was accepted as common ground by the time of the trial and Boehringer was entitled to recover its overpaid royalties under the original licence.

In finding that Boehringer was obliged to pay Royalty Pharma royalties under the amended licence, HHJ Hacon held that an EPC 2000 claim will be directly infringed if the alleged infringer carries out an act in relation to the product of the claim, where the product is sufficiently tied to the use specified in the claim (such that the requirement of the German doctrine of *sinnfällige Herrichtung* is satisfied).

The judge further held that at the time Boehringer manufactured the linagliptin, including where the product was destined for export, in German law the requirement of *sinnfällige Herrichtung* was satisfied in relation to the purpose specified in the relevant patent.

Thus, HHJ Hacon held that Boehringer's manufacture of linagliptin would have infringed the relevant patent but for the amended licence and the acts of manufacture generated royalties under the amended licence to be paid by reference to sales of products containing linagliptin irrespective of where those sales took place.

12. *Dr Reddy's Laboratories (UK Limited) & Ors v Warner-Lambert Company LLC & Anor*

A decision concerning the "counterfactuals" to be used in a damages inquiry that relates to the pregabalin litigation – where interim injunctions were wrongly granted against a number of defendants – determined that the court will proceed on the basis of a single hypothetical counterfactual.

This judgment related to preliminary issues concerning a damages inquiry that followed the Supreme Court judgment finding that a patent for pregabalin was invalid. The damages inquiry relates to claims brought by a number of generic manufacturers who either had interim injunctions granted against them or who had given undertakings not to infringe the patent, and NHS bodies who had been ordered to issue guidance on prescribing pregabalin.

The inquiry claimants are seeking compensation under the cross-undertakings in damages given in respect of the interim injunctions or contractual undertakings, and for damages in respect of threats of infringement proceedings.

In determining the appropriate "counterfactual" assumptions for the damages inquiry, the judge held that only a single hypothetical "counterfactual" would be used, which assumes that none of the interim injunctions, agreements or threats were made and that the patent was not known to be invalid.

Noteworthy procedural decisions

13. Expedition applications

A spate of expedition applications raised questions as to whether the speeding up of patent proceedings in the UK is becoming more frequent and easier to achieve.

A string of cases this year related to applications to expedite proceedings in the Patents Court. The power to expedite hearings falls within the general powers of case management afforded to courts in the Civil Procedure Rules.

Over time, the courts have laid down factors to be taken into account when considering expedition applications. The Court of Appeal laid down four factors in *WL Gore and Associates GmbH v Geox SpA* [2008] EWCA Civ 622. Three additional points relevant to patent cases were made by Birss J (as he then was) in *Nicoventures v Philip Morris* [2020] EWHC 1594 (Pat), most notably that the desire to avoid the German "injunction gap" is a factor to be taken into account but alone is not enough to warrant expedition.

The German injunction gap arises from the bifurcated system in Germany, where infringement proceedings are held separately to validity proceedings and are often undertaken more quickly – and can be enforced, including by injunction, before a validity finding is made.

These four cases build on this background.

a. Teva Pharmaceutical Industries Ltd and Anor v Janssen Pharmaceutica NV

This short decision concerned an application to expedite a patent trial relating to a then newly granted patent for a dosing regimen for the drug paliperidone. Meade J considered the *Gore* factors and noted that the trial could be expedited to a degree that would bring the timetable in-line with the Patents Court's one-year trial target with "*only minor disruption*". The judge held that Teva had demonstrated a need for commercial certainty that the expedited

proceedings would provide, without prejudice to Janssen. He noted that Janssen was being tactically "*cagey*" about whether it would apply for interim relief, which resulted in him making a decision based on imperfect information. The judge allowed the application and permitted a degree of expedition. In coming to that decision, he stressed that the issue of expedition exists on a "*sliding scale*", with certain reasons justifying a moderate degree of expedition and others supporting a greater degree.

b. *Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd (t/a Mylan) & Anor*

This dispute concerned a divisional patent for the use of melatonin as a treatment for primary insomnia. The expedition application related to various preliminary issues including estoppel. The judge set out four "*special factors*" he had taken into consideration, being that: (i) Neurim had a *prima facie* valid patent; (ii) it appeared that Mylan's marketed product infringed the patent; (iii) the patent was close to expiry and this final period is often particularly valuable for a patentee; and (iv) there were estoppel *"arguments to be had"* against Mylan. These special factors and what the judge called the *"unusual circumstances"* of the case (a preliminary injunction had not been granted despite Mylan having failed to clear the path) meant that *"a moderate degree"* of expedition was granted on the preliminary issues, this being "*the only realistic way in which Neurim can hope to secure injunctive relief before expiry of* [the patent in suit]*"*.

c. *Abbott Laboratories Ltd v Dexcom Incorporated*

This concerned revocation proceedings for four Abbott patents relating to various features of continuous glucose monitoring devices for managing diabetes. Although commercial certainty was an important reason put forward for expedition, the primary reason was held to be to try to avoid the problems caused by the German injunction gap. The former issue was held to be not a *"particularly powerful"* reason for expedition. The latter was a significant factor, but could not alone justify expedition. The fact that there were separate UK proceedings involving eight Dexcom patents and to grant expedition only in respect of the trial involving the Abbott patents would have created a timing asymmetry also appears to have been an important reason for refusing expedition.

d. *Advanced Bionics AG & Anor v MED-El Elektromedizinische Gerate GmbH*

Like *Abbott*, this last judgment was also part of international proceedings involving the US and Germany as well as the UK. It also concerned issues of commercial certainty and the German injunction gap. Interestingly, however, in *Advanced Bionics* the judge decided in favour of expedition. The main reason for the different outcome was that Advanced Bionics was able to demonstrate that the German injunction gap would have an adverse effect on the UK market for cochlear implants, the subject matter of the patent. Other factors that appear to have played an important part in the judge's reasoning are that the case involved a single patent (rather than the four (or arguably eight) in suit in *Abbott*), for technology that the judge considered to be less complex, and there was also only a single prior art citation. Mellor J also found that MED-El would not be adversely affected by the expedition and that the expedited listing ordered could slot into the Patents Court diary without actively displacing any other litigant.

These cases confirm that the question of whether to grant expedition and, if so, the amount of expedition is not a binary one. Rather, these issues exist on a sliding scale and are impacted by external factors, such as the number of other concurrent proceedings and whether other litigants who have already begun proceedings will be actively displaced by the expedition. The state of the Patents Court diary and the desire for speed seem to have been highly relevant factors in these recent decisions, perhaps more so than in the past.

Although the precise impact these decisions will have on the speed of UK patent proceedings is not yet clear, what is certain is that the UK courts are prepared to entertain applications for expedition and remain determined to ensure that patent disputes continue to be heard promptly. But, given the success of a number of these recent expedition applications, it seems likely that more requests that are similar will be made in the future.

14. *Neurim Pharmaceuticals (1991) Ltd & Anor v Generics (UK) Ltd (T/A Viatris) & Anor*

An application for a stay of the trial of preliminary issues expedited by Mellor J was rejected, and Neurim's undertaking to repay damages or profits figured as a weighty factor in the decision to refuse the stay.

This decision followed the judgment of Mellor J to expedite the trial of the preliminary issues in this dispute concerning Neurim's divisional patent for the use of melatonin as a treatment for

primary insomnia. Mellor J had held that the expedited trial of the preliminary issues was the only hope for Neurim to secure injunctive relief before expiry of the patent (see case summary 13b above).

Here, the defendant, Mylan, brought an application for a stay of the expedited proceedings pending the final determination of validity by the European Patent Office (EPO) in opposition proceedings. The judge reminded that the law on stay applications relating to UK proceedings during EPO opposition was set out by the Court of Appeal in *IPCom GmbH v HTC Europe* [2013] EWCA Civ 1496.

In that case, the Court of Appeal set out a number of factors to be considered by a judge when making a decision regarding a stay application in this context and it generally stated that the relevant issues should be considered at a relatively high level of generality.

The judge worked through these factors, giving particular weight to the fact that Neurim had given an undertaking to repay any damages or profits ordered to be paid if the patent is eventually revoked. The judge noted that although the offer of this undertaking came *"late in the day"*, it still dealt with a *"significant"* part of Mylan's argument that it would suffer irrevocable losses if no stay was ordered.

The judge also acknowledged that the final decision from the EPO on validity would not come until after the patent had expired. This emphasised the point that had been made by Mellor J in his expedition judgment that a decision on the preliminary issues was the only way in which Neurim might be able to secure injunctive relief. However, the judge did state that *"Neurim's path to any injunction is not necessarily straightforward"*.

Nevertheless, the judge held that the balance of justice laid in favour of rejecting the stay application and allowing Neurim to follow the course of action ordered by Mellor J (that is, the expedited trial of the preliminary issues). In declining the stay the judge commented that this case was *"most unusual"* but that a decision on the preliminary issues would give the parties some commercial certainty within a relatively short period of time and during the lifetime of the patent.

15. *Sandoz Ltd v Bristol-Meyers Squibb Holdings Ireland Unlimited Company & Ors*

The patentee was limited to identifying no more than 10 independently valid claims within 28 days of service of product or process descriptions.

Teva had argued that the patentee should not be permitted to rely on more than six independently valid claims. BMS offered to identify 15. In considering these offers, Mellor J noted that in most patent actions the number of independently valid claims tends to decrease as the trial approaches; therefore, BMS was unlikely to have 15 independently valid claims at trial.

In light of this, the judge acceded to Teva's application in part by limiting BMS to 10 independently valid claims. The judge emphasised that BMS should expect to limit itself to fewer than these 10 claims by the time of trial, if not by the service of expert reports. Mellor J noted that all parties have the liberty to apply to the court to argue either that 10 independently valid claims is justifiable or that 10 claims remains excessive.

Non-life sciences decisions

16. *Facebook Ireland Ltd v Voxer IP LLC*

***Obiter* guidance was given on the *Formstein* defence when infringement by equivalents at issue.**

Although this dispute arose outside of the life sciences field, Birss LJ's comments on the *Formstein* defence are highly relevant to pharmaceutical and biotech patents.

The Supreme Court decision in *Actavis v Eli Lilly* [2017] UKSC 48 set out how the doctrine of equivalents should be applied in UK law in the infringement context. The case was limited to infringement issues and so questions remain as to how the doctrine of equivalents should properly be applied in the invalidity context.

Formstein was a German case in which equivalents were considered by the infringement court. Rather than finding the patent in suit invalid, the court limited the patent's claim to its normal construction.

The *Formstein* defence effectively applies the well-established *Gillette* defence to infringement to circumstances where the doctrine of equivalents applies. In deploying a *Gillette* defence, an alleged infringer argues that their activities would have lacked novelty or been obvious at the patent in suit's priority date. This has the effect that

either the patent is valid but not infringed or, alternatively, if the alleged infringement falls within the scope of the patent in suit, it must be invalid.

Following *Actavis*, if the court finds that the patent in suit is valid but not infringed on its normal construction, it must go on to consider infringement by equivalents. The question that then arises is what happens if a product is found to infringe only by equivalents but it is also held to be obvious over the prior art.

The UK courts have previously noted this issue and that a *Formstein* defence might apply. Although Birss LJ did not need to decide the issue, he provided obiter guidance. In his view, the correct approach is to confine the patent's claim to its normal construction and hold the claim to be valid but not infringed, rather than infringed but invalid. This was the approach that was taken in *Formstein* itself and has also been followed in the Netherlands and the USA.

The judge considered this to be the correct approach as: i) it would be harsh to invalidate a claim that was valid on a normal construction and it promotes certainty in allowing patentees to write their claims such that they don't cover the prior art on a normal construction; and ii) other EPC countries have adopted that approach and therefore the UK, as another EPC state, should take the same approach.

Although Birss LJ's comments were only *obiter* and are therefore not binding, his deep experience of patents and his elevation to the Court of Appeal mean that they provide a good indication of the approach likely to be taken by the UK courts if a *Formstein* defence does need to be applied.

17. *Optis Cellular Technology LLC and Ors v Apple Retail UK Limited and Ors*

The guidance given on pleading anticipation by equivalence builds on Birss LJ's comments on infringement by equivalence in *Facebook v Voxer*.

Despite this decision arising outside of the life sciences context, Meade J provided some useful guidance on how to plead anticipation by equivalence claims, building on Birss LJ's obiter comments in *Facebook v Voxer* [2021] EWHC 1377 (Pat) concerning the use of the *Formstein* defence in cases where infringement by equivalence is in issue (see case summary 16 above).

In this case, at the beginning of the trial, Meade J gave Apple permission to argue anticipation by equivalence even if there was no anticipation on the ordinary meaning of the claims. In granting this permission the judge made a number of key points, which he reiterated in this judgment.

Firstly, Meade J noted that Birss LJ decided in *Facebook v Voxer* that infringement by equivalence claims must be pleaded. Meade J held it to follow that

anticipation by equivalence must also be pleaded. However, he did state that allowances should be made for the cases where pleadings were submitted prior to the handing down of the judgment in *Facebook v Voxer*.

Meade J stressed that there is a *"big difference"* between cases that make a *"fresh"* pleading of equivalence, which raise for the first time new and potentially disputed features or behaviours of the alleged infringement, and those that seek to characterise matters already in issue as equivalent. The judge held this case to be in the latter category.

Lastly, the judge emphasised that a pleading of equivalence must identify the claim feature(s) to which it is directed and then answer the three relevant *Actavis v Eli Lilly* [2017] UKSC 48 questions by reference to that feature(s). He stated that a general pleading that equivalence will be relied on where a purposive construction fails is *"not good enough".* Indeed, Apple's first draft proposed amendments were rejected on this basis.

In addition to these pleading points, Meade J also noted that this case raised the issue of whether, as a matter of law, the doctrine of equivalence can be used to broaden a claim as a target for an anticipation attack, or whether it should only be applicable with respect to infringement.

On this point, the judge concluded that *"[i]t seems certain to need the consideration of the Court of Appeal and very probably the Supreme Court".* Moreover, he held that when this issue is first ruled on in a way that is decisive to the result, the anticipation by equivalence case will need to be *"fully argued"*, including with reference to the law of other EPC jurisdictions and with regard to how and whether people can be prevented from practising the prior art, or if not, how and why not.

In this case, the judge held that Apple's late pleading amendment did not give it time to make the kind of *"detailed and demanding"* arguments he had found would be necessary. The parties agreed that the judge should assume that equivalence was not available with respect to anticipation but to make the factual findings necessary to answer the three relevant *Actavis* questions. On this basis, the judge found that the anticipation arguments failed, even if such arguments were available at law.

Ultimately, the judge provided useful guidance on how to plead anticipation by equivalence claims, building on Birss LJ's finding in *Facebook v Voxer* that infringement by equivalence claims must be pleaded, which can be implemented by parties seeking to make such claims going forward. However, it remains to be seen whether anticipation by equivalence arguments are permissible as a matter of law. As the judge

foreshadowed, the importance of this point to patent law means that it will likely require consideration by the Court of Appeal or even the Supreme Court.

18. *Autostore Technology AS v Ocado Group Plc & Ors*

In rejecting an interim injunction application to restrain the disclosure of information to the US International Trade Commission, HHJ Hacon applied the anti-suit injunction threshold test rather than the classic *American Cyanamid* test.

Although this decision arose outside the life sciences field, it is instructive on the approach taken to assessing whether an interim injunction to restrain disclosure of information should be granted.

Ocado sought an injunction to restrain Autostore disclosing to the US International Trade Commission (ITC) a document arising from unsuccessful settlement negotiations that took place in the UK.

Usually the starting point for assessing interim injunction applications is the *American Cyanamid* test of whether there is a serious question to be tried. However, in this case, neither party argued that this usual approach should be applied. Each party argued for a different starting point.

Ocado contended that the court must have regard to the underlying merits of the parties' respective cases. It also asserted that Autostore's actions would amount to breach of a negative covenant (that is, it would do something that it had promised not to do) and therefore special circumstances must be present before the court exercises its discretion to refuse an injunction.

Whereas Autostore, amongst other arguments, maintained that Ocado was seeking an anti-suit injunction because grant of the injunction would effectively restrain proceedings before the ITC.

While the judge favoured the anti-suit injunction approach, he did not entirely agree that the grant of the injunction would restrain foreign proceedings. Instead, he said it would interfere with the conduct of foreign proceedings. This was enough though to convince the judge that he must approach the application with *"circumspection"* and that he should not grant the injunction unless he was *"satisfied that there is a high degree of probability that Ocado would succeed at trial"*.

The judge ultimately concluded that he was not able to say with a high degree of certainty that Ocado would succeed at trial and therefore the threshold for grant was not met.

Despite this finding, the judge still went on to consider the balance of irreparable harm that could be caused if the injunction was granted or not. The judge concluded that the balance of harm *"clearly"* falls in favour of no grant. As such, Ocado's application was dismissed and no injunctive relief was granted.

This case provided a useful example of the circumstances where the classic *American Cyanamid* test will not be applied with respect to interim injunctions. Here, it was clear that the judge felt a higher threshold had to be met if an injunction was to be granted because of the effect the decision would have had on foreign proceedings. Even though the judge noted that Autostore's anti-suit comparison was *"not exact"*, the fact the decision would interfere with foreign proceedings was enough to apply the higher threshold to the assessment of the application.

(See case summary 5 above for the appeal decision.)

Looking ahead…

The UK patent courts are set for another busy year in 2022 . What are the cases to look out for?

The trial in *Alcon Eye Care UK Limited and another v Amo Development LLC* (HP-2020-000028) was heard at the beginning of November 2021. By the time of the trial, Alcon accepted that its LenSx infringed Amo's patent; therefore, the remaining issue concerned the validity of two Amo patents relating to a laser system for cataract surgery and for fragmenting the lens. These patents are alleged to be obvious over a US patent and a Patent Cooperation Treaty application. Alcon also raised a number of insufficiency attacks, maintaining an insufficiency/obviousness squeeze. The judgment should be handed down in early 2022.

The trial of *Sandoz Limited v Bristol-Myers Squibb Holdings Ireland Unlimited* (HP-2020-000042) is listed to be heard towards the end of January 2022. Sandoz is seeking a declaration of invalidity and revocation of a Bristol-Myers Squibb patent and related supplementary protection certificates concerning the compound apixaban (an anticoagulant) and pharmaceutically acceptable salts thereof. This action has been referred to as the "Compound Patent Action" and is the first of two clearing the path actions brought by Sandoz.

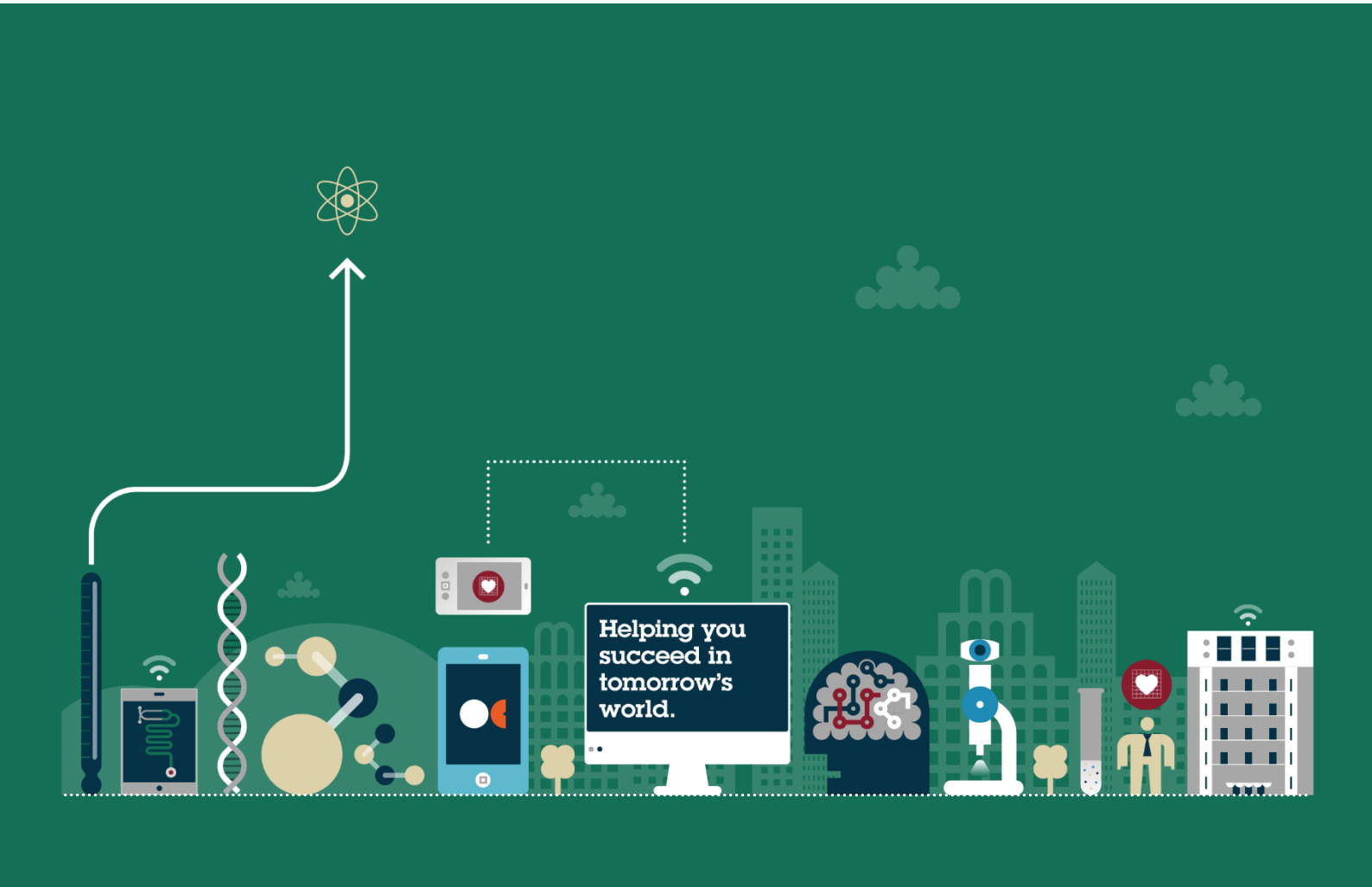
The second action, in which Mellor J handed down a decision to limit the number of independently valid claims BMS can rely upon in *Sandoz Ltd v Bristol-Meyers Squibb Holdings Ireland Unlimited Company & Ors* [2021] EWHC 1123 (Pat) (see case summary 15 above), is due to be heard in April 2022 (HP-2020-000048). These patents again concern apixaban and relate to different features of different formulations of the compound. This action has been referred to as the "Formulation Action".

Two expedited trials will also be heard in the first half of 2022: *Advanced Bionics AG & Anor v MED-El Elektromedizinische Gerate GmbH* [2021] EWHC 2415 (Pat) (see case summary 13d above), is listed for February 2022 (HP-2021-000028) and *Teva Pharmaceutical Industries Ltd and Anor v Janssen Pharmaceutica NV* [2021] EWHC 1922 (Pat) (HP-2021-000013) (see case summary 13a above) is due to be heard in early June. It will be interesting to see how each of these trials plays out following the compressed timetables, and what consequences (if any) will follow.

In separate proceedings, Teva is seeking a declaration of invalidity and revocation of a Janssen Oncology Inc patent relating to the use of abiraterone acetate and prednisone in a method of treating prostate cancer in humans, which is listed for late June 2022 (*Teva Pharmaceutical Industrials Ltd and Anor v Janssen Oncology Inc* (HP-2021-000027)).

In July 2022, we expect to see the trial of *Astellas Pharma Inc v Teva Pharmaceutical Industries Ltd and Ors* (HP-2021-000014). Astellas is seeking a declaration of infringement that actions carried out by Teva and Sandoz would infringe its patent relating to a pharmaceutical composition for modified release, which has no limitations on patient food intake.

Table of Cases



	Case	Court & Judge(s)	Main legal issue(s)	Outcome
SUPREME COURT				
1	*Secretary of State for Health & Anor v Servier Laboratories Ltd & Ors* [2021] UKSC 24 (2 July 2021)	Lord Hamblen (leading judgment), Lord Reed, Lord Hodge, Lord Lloyd-Jones, Lord Briggs, Lord Kitchen Lord Sales	Unlawful means economic tort	Appeal dismissed
COURT OF APPEAL				
2	*FibroGen Inc v Akebia Therapeutics Inc* [2021] EWCA Civ 1279 (24 August 2021)	Phillips LJJ Birss LJJ Sir Christopher Floyd	Sufficiency Obviousness	Appeal on insufficiency of Family A patents allowed – invalidity overturned Appeal on obviousness of Family B patents dismissed
3	*Illumina Cambridge Ltd v Latvia MGI Tech SIA & Ors* [2021] EWCA Civ 1924 (17 December 2021)	Arnold LLJ Nugee LLJ Warby LJJ	Obviousness Priority	Appeal dismissed – validity upheld
4	*Wyeth LLC v Merck Sharp & Dohme (UK) Ltd* [2021] EWCA Civ 1099 (22 July 2021)	Newey LJJ Arnold LJJ Sir Christopher Floyd	Obviousness Sufficiency	Appeal dismissed – invalidity upheld
5	*Autostore Technology AS v Ocado Group Plc & Ors* [2021] EWCA Civ 1003 (7 July 2021)	Sir Geoffrey Vos MR, Nicola Davies LJJ Nugee LJJ	Application for injunction preventing disclosure of information to US ITC	Appeal dismissed (Nugee LJ dissenting) – rejection of injunction application upheld

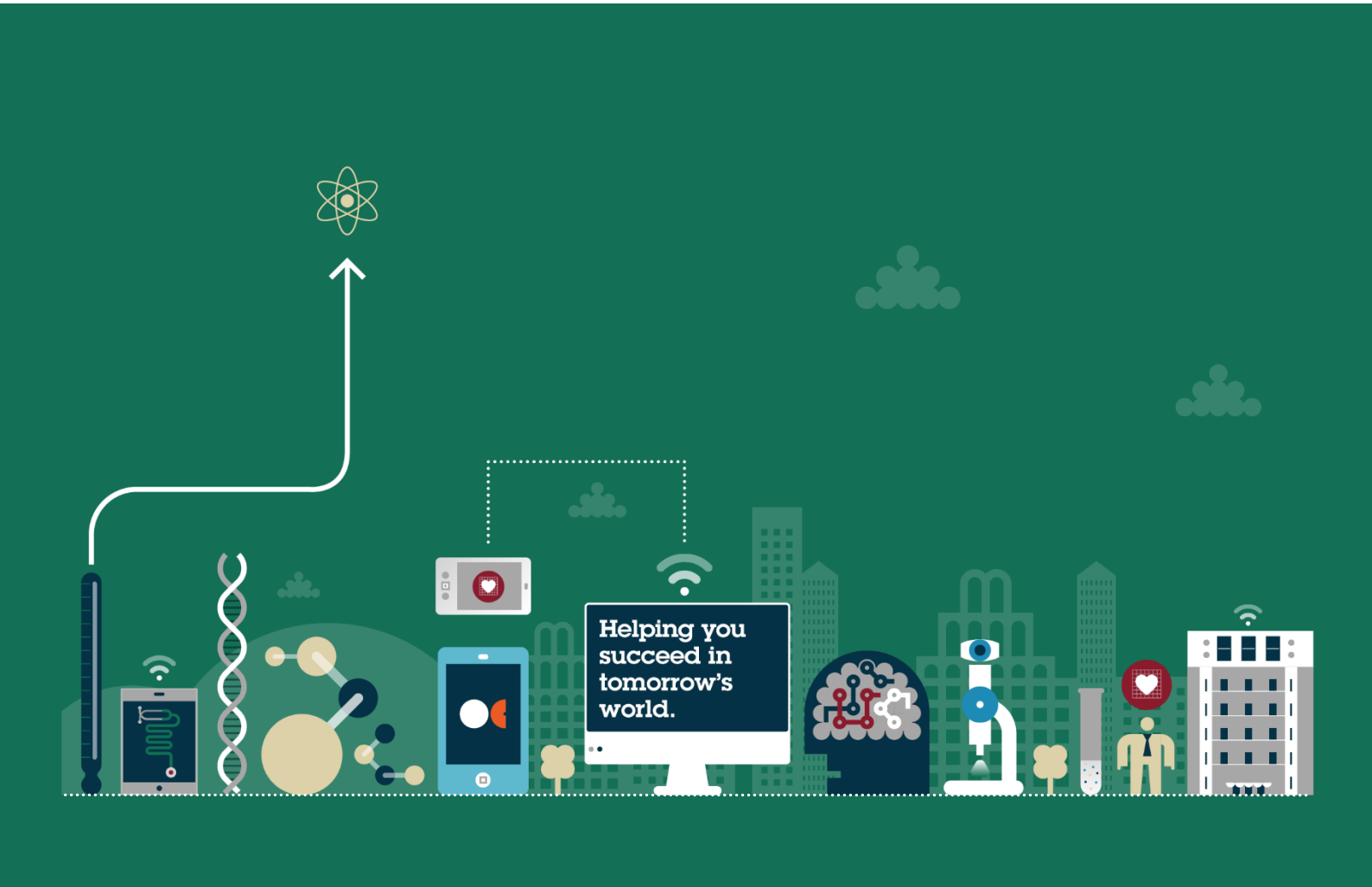
	Case	Court & Judge(s)	Main legal issue(s)	Outcome
PATENTS COURT				
Invalid				
6	*Coloplast A/S v Salts Healthcare* [2021] EWHC 3 (Pat) (18 January 2021)	Nicholas Caddick QC (sitting as Deputy High Court Judge)	Obviousness	Patent invalid for obviousness
7	*Insulet Corporation v Roche Diabetes Care Ltd* [2021] EWHC 1933 (Pat) (9 July 2021)	Pat Treacy (sitting as a Judge of the Chancery Division)	Novelty Obviousness	Patent invalid and not infringed
8	*Teva Pharmaceutical Industries Ltd & Anor v Bayer Healthcare LLC* [2021] EWHC 2690 (Pat) (08 October 2021)	Mellor J	Obviousness	Patent invalid for obviousness
Valid				
9	*Illumina Cambridge Ltd v Latvia MGI Tech SIA & Ors* [2021] EWHC 57 (Pat) (20 January 2021)	Birss J (as he then was)	Sufficiency Obviousness	4 patents valid and infringed 1 patent invalid for obviousness
10	*Alcon Research LLC & Anor v Actavis Group PTC EHF & Ors* [2021] EWHC 1026 (Pat) (23 April 2021)	Meade J	Novelty Obviousness Obviousness / insufficiency squeeze	Patent valid

	Case	Court & Judge(s)	Main legal issue(s)	Outcome
PATENTS COURT				
Judgments concerning quantum				
11	*Royalty Pharma Collection Trust v Boehringer Ingelheim GmbH* [2021] EWHC 2692 (Pat) (8 October 2021)	HHJ Hacon (sitting as Judge of the High Court)	Royalty dispute – EPC 2000 claims	Unpaid royalties due
12	*Dr Reddy's Laboratories (UK Limited) & Ors v Warner-Lambert Company LLC & Anor* [2021] EWHC 2182 (Ch) (30 July 2021)	Zacaroli J	Counterfactual assumptions in damages inquiry	Court to proceed on the basis of a single hypothetical counterfactual
Noteworthy procedural decisions				
13a	*Teva Pharmaceutical Industries Ltd and Anor v Janssen Pharmaceutica NV* [2021] EWHC 1922 (Pat) (8 July 2021)	Meade J	Expedition application	Expedition granted
b	*Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd (t/a Mylan) & Anor* [2021] EWHC 2198 (Pat) (02 August 2021)	Mellor J	Expedition application	Expedition granted

	Case	Court & Judge(s)	Main legal issue(s)	Outcome
PATENTS COURT				
Noteworthy procedural decisions (continued)				
c	*Abbott Laboratories Ltd v Dexcom Incorporated* [2021] EWHC 2246 (Pat) (06 August 2021)	Mellor J	Expedition application	Expedition refused
d.	*Advanced Bionics AG & Anor v MED-El Elektromedizinische Gerate GmbH* [2021] EWHC 2415 (Pat) (31 August 2021)	Mellor J	Expedition application	Expedition granted
14	*Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd (t/a Viatris) & Anor* [2021] EWHC 2897 (Pat) (29 October 2021)	Ian Karet (sitting as Deputy High Court Judge)	Application for stay of UK proceedings pending EPO opposition	Stay refused
15	*Sandoz Ltd v Bristol-Meyers Squibb Holdings Ireland Unlimited Company & Ors* 2021] EWHC 1123 (Pat) (23 April 2021)	Mellor J	Limitation on the number of independentl y valid claims	Number of independently valid claims limited to no more than ten

	Case	Court & Judge(s)	Main legal issue(s)	Outcome
PATENTS COURT				
Relevant non-life sciences decisions				
16	*Facebook Ireland Ltd v Voxer IP LLC* [2021] EWHC 1377 (Pat) (26 May 2021)	Birss LJ (sitting as Judge of the High Court)	*Formstein* defence when infringement by equivalents is at issue	*Obiter* guidance that a patent's claim should be limited to its normal construction and should be held valid but not infringed
17	*Optis Cellular Technology LLC and Ors v Apple Retail UK Limited and Ors* [2021] EWHC 1739 (Pat)	Meade J	Anticipation by equivalence	General guidance on pleading anticipation by equivalence, including building on Birss LJ comments in *Facebook v Voxer*
18	*Autostore Technology AS v Ocado Group Plc & Ors* [2021] EWHC 1614 (Pat) (11 June 2021)	HHJ Hacon (sitting as Judge of the High Court)	Application for injunction preventing disclosure of information to US ITC	Application rejected – anti-suit injunction threshold test applied rather than the classic *American Cyanamid* test

Contacts



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About Osborne Clarke

Osborne Clarke is an international legal practice with over 270 expert Partners and more than 925 talented lawyers in 25 locations*.

Our sector-based approach enables us to help our clients tackle the issues they are facing today, and prepare for the ones that they will face tomorrow. Advising them both comprehensively and commercially. We love working closely with our clients on new deals, products and solutions which will transform their businesses, markets and even sectors.

We have always been happy to embrace change and the opportunities it creates – because it's those opportunities which enable us to help our clients succeed.

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