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REPORT

United Kingdom Patent Decisions 2022

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Abstract This report highlights a selection of the most important UK patent decisions from 2022, including: five Court of Appeal judgments (one relating to determining what constitutes an exclusive licensee, two dealing with permission to appeal and the appeal of a divisional patent validity challenge, one dealing with *Arrow* declaratory relief, and one dealing with the appropriate relief after a finding of standard essential patent (SEP) validity and infringement), and seven High Court judgments (one concerning a preliminary issues trial, one concerning divisional patent validity, one concerning plausibility, one considering an application for interim injunctive relief, one considering an application for *Arrow* declaratory relief, one looking at unjustified threats, and one looking at an expedition application relating to an infringement trial).

Keywords *Arrow* declaration · Exclusive licensee · Expedition application · FRAND · Interim injunction · Plausibility · SEPs · Unjustified threats

Cases *Abbott v. Dexcom* [2021] EWHC 2246 (Pat); [2021] 8 WLUK 32; *American Cyanamid Co v. Ethicon Ltd* [1975] AC 396; [1975] 2 WLR 316; *Arrow Generics Ltd v. Merck & Co Inc* [2007] EWHC 1900 (Pat); [2008] Bus LR 487; *FibroGen Inc v. Akebia Therapeutics* [2021] EWCA Civ 1279; [2021] 8 WLUK 161; *Fujifilm Kyowa Kirin Biologics Co Ltd v. AbbVie Biotechnology Limited* [2017] EWCA Civ 1; [2018] Bus LR 228; *Lisa Dräxlmaier GmbH v. Bos GmbH & Co. Kg* [2022] EWHC 1642 (Pat); [2022] 6 WLUK 629; *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd & Anor* [2020] EWHC 3270 (Pat); [2020] 12 WLUK 84;

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Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd & Anor (Rev1) [2022] EWCA Civ 359; [2022] 3 WLUK 415; *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd & Anor (Rev2)* [2022] EWCA Civ 370; [2022] 3 WLUK 423; *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd & Anor* [2022] EWCA Civ 699; [2022] 5 WLUK 323; *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd (t/a Viatris) & Anor* [2022] EWHC 109 (Pat); [2022] 1 WLUK 236; *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd (t/a Viatris)* [2022] EWHC 272 (Pat); [2022] 2 WLUK 265; *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics (UK) Ltd (t/a Viatris) & Anor* [2022] EWHC 512 (Pat); [2022] 3 WLUK 414; *Novartis AG & Anor v. Teva UK Ltd & Ors* [2022] EWCA Civ 775; [2022] 5 WLUK 576; *Novartis AG v. Teva UK Ltd* [2022] EWHC 959 (Ch); [2022] Bus LR 888; *Novartis AG and Anor v. Teva UK Ltd and Ors* [2022] EWHC 2779 (Ch); [2022] 10 WLUK 455; *Optis Cellular Technology LLC & Ors v. Apple Retail UK Ltd & Ors* [2021] EWHC 2564 (Pat); [2021] 9 WLUK 276; *Optis Cellular Technology LLC & Ors v. Apple Retail UK Ltd & Ors* [2022] EWCA Civ 1411; [2022] 10 WLUK 342; *Sandoz Ltd v. Teva Pharmaceutical Industries Ltd* [2022] EWHC 822 (Pat); [2022] 4 WLUK 81; *Shenzhen Carku Technology Co. Ltd v. The Noco Company* [2022] EWHC 2034 (Pat); [2022] 8 WLUK 10; T 939/92 Agrevo/Triazoles; *Teva UK Ltd & Anor v. Novartis AG* [2022] EWCA Civ 1617; [2022] 12 WLUK 74; *Thaler v. Comptroller General of Patents, Trade Marks and Designs* [2021] EWCA Civ 1374; [2022] Bus LR 375; *Warner-Lambert Co LLC v. Generics (UK) Ltd (t/a Mylan)* [2018] UKSC 56; [2019] 3 All ER 95

Legislation Patents Act 1977; Senior Courts Act 1981

Other Intellectual Property Rights Policy; European Patent Convention

The Patents Court was slightly quieter in 2022 than the previous year but a number of appeals have been heard by the Court of Appeal. No patent disputes were heard by the Supreme Court in 2022. As ever, a wide range of topics were litigated, with telecoms and life sciences continuing to have a dominant presence. This review article will focus on a selection of some of the most notable decisions from the Court of Appeal and Patents Court over the past twelve months.

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

There have been a number of decisions this year relating to an ongoing dispute between Neurim and Flynn (together referred to as Neurim in this report) and Mylan concerning a parent and a divisional patent relating to the use of melatonin in treating a certain kind of insomnia. These will be considered together in chronological order.

1.1 Patents Court – Preliminary Issues Trial

The year kicked off with a previously expedited trial of preliminary issues relating to Neurim's divisional patent.[1] The preliminary issues to be determined were: (i) whether Mylan was issue-estopped from challenging the validity of Neurim's divisional patent in light of the successful 2020 UK proceedings against the parent patent;[2] (ii) whether Neurim's conduct in amending the divisional patent to have substantially the same claims as the parent patent was an abuse; and (iii) whether Neurim's conduct amounted to an abuse of a dominant position.[3]

Dealing first with the issue estoppel argument, the basic principles of issue estoppel were not in dispute. Rather, the disagreement focused on the proper approach to be taken in a situation where an estoppel is alleged against the "winner" of earlier litigation, especially if they could not appeal.[4]

Meade J concluded that there was no issue estoppel on the basis that the reasons and findings of the main judgment dealing with the validity of the parent patent were not fundamental to the overall, eventual result of the litigation. An EPO Technical Board of Appeal (TBA) hearing, that took place shortly after the parent patent validity judgment, revoked the patent and therefore eventually "trumped" Marcus Smith J's decision.[5]

As Mylan could not appeal Marcus Smith J's judgment at the relevant time (after the TBA revocation), the general rule was that there could not be issue estoppel and Meade J saw no reason not to apply that general rule.[6] It was held that issue estoppel requires a level of finality, which was found lacking here as the Orders made with respect to the 2020 litigation were "provisional" prior to the TBA decision and it was anticipated that they might change in light of the TBA hearing.[7]

Next, turning to the abuse argument, Mylan argued that Neurim's application to unconditionally amend its divisional patent was an abuse of process.[8] Mylan's argument in this regard was held to be "developed only very thinly in its written and oral arguments at trial".[9] The argument essentially challenged the strategy of using divisionals as backups in case of failure of the parent.[10] On this point, the judge said:

[1] [2022] EWHC 109 (Pat); [2022] 1 WLUK 236. This preliminary issues trial had been expedited last year, *see*: [2021] EWHC 2198 (Pat); [2021] 8 WLUK 1. *See* last year's case summary for further details. IIC 53:377–395 (2022), https://doi.org/10.1007/s40319-022-01161-2.

[2] The parent patent had been found to be valid and infringed: [2020] EWHC 3270 (Pat); [2020] 12 WLUK 84. The patent was later revoked by the European Patent Office.

[3] *Supra* note 1, [15].

[4] *Supra* note 1, [103].

[5] *Supra* note 1, [145]–[153].

[6] *Supra* note 1, [150].

[7] *Supra* note 1, [153].

[8] *Supra* note 1, [156].

[9] Supra note 1, [158].

[10] *Supra* note 1, [159].

> The use of divisionals as backups is a well-established practice that is widely used. It can raise serious problems, which the UK Courts have sought to address, including by the availability of Arrow declarations where appropriate, and by case management. An argument that the practice amounts to an abuse of process would be an important and complex one, and I do not think it is covered by Mylan's pleading, or fair for it to be raised without a pleading…[11]

Furthermore, the judge noted that Neurim was not using a divisional to "have another bite of the cherry".[12] It had won in the UK before Marcus Smith J and was using the divisional because "it came to grief in the EPO".[13] Mylan's abuse argument was ultimately rejected.[14]

As for the competition issues Mylan raised, these were dealt with relatively quickly. Meade J held that the competition issues were not suitable to be decided at a preliminary stage given how matters unfolded, noting that his factual findings on estoppel covered all of the competition law issues raised.[15]

Interestingly, Meade J lamented the timing of the UK parent patent trial in relation to the parallel proceedings in the EPO.[16] He stated that it was "unfortunate" that "so much complexity and confusion ha[d] arisen and so much resource used up" that could have been avoided if the original UK parent patent trial had been scheduled later than the TBA hearing. The judge said that undoubtedly the parties would have had their own strategic reasons for wanting to keep the UK trial date once they knew when the TBA hearing would be but that they "should have kept the Court actively and fully informed" so that the court could have made its own decision as to timing.[17]

Ultimately, the judge ordered for the case to be remitted to Marcus Smith J to consider Mylan's "lay-patient argument", which he said was:

> uncomfortably half way between the basis for an appeal against the decision of Marcus Smith J in the Main Judgment (which is not a function for another judge to undertake) and arguing for a fresh assessment of what was before him, including an assessment of the evidence of Professor Morgan, whom Marcus Smith J criticised in strong terms.[18]

[11] *Supra* note 1, [160].

[12] *Supra* note 1, [161].

[13] *Supra* note 1, [161].

[14] *Supra* note 1, [166].

[15] *Supra* note 1, [168], [180].

[16] *Supra* note 1, [181].

[17] *Ibid.*

[18] *Supra* note 1, [182]–[191], particularly [186].

1.2 Patents Court – Marcus Smith J's Provisional and Non-Provisional Finding on Divisional Validity and Infringement

Following the remittance of the case from Meade J to Marcus Smith J, Marcus Smith J made a provisional finding on the papers.[19] He had to reconsider his judgment from the parent patent proceedings and assess its applicability in the instant case because the divisional was "'patentably indistinct', i.e. indistinguishable" from the parent patent.[20]

In reconsidering his previous judgment, the judge noted that he was operating under some constraints: (i) it would have been inappropriate to rely on new evidence not before him in the previous trial;[21] (ii) given the volume of the documentation before him at the earlier trial, he needed to avoid a re-run of the trial using documents and materials that were before the court but that were not deployed at all or were not deployed to make a particular point;[22] (iii) new points not pleaded at the earlier trial could not be taken into account; and (iv) crucially, he needed to avoid new formulations and new arguments being run that were open to Mylan at the trial but which it did not pursue in the parent patent trial.[23]

In approaching the matter with these constraints in mind, Marcus Smith J held that the earlier judgment was not wrong, even in light of additional submissions from Mylan.[24] The judge noted that it would be an error for him to expand on that earlier judgment to explain why he was satisfied that the judgment and outcome applied to these proceedings.[25] As such he concluded: "I stand by the Main Judgment, for the reasons set out therein. I find the Divisional to be valid and infringed; and, for the reasons I gave at the time of the Main Judgment, I refuse permission to appeal".[26]

As a reminder, in the earlier validity judgment the judge had found Neurim's patent valid, rejecting validity challenges from Mylan on the basis of lack of novelty, obviousness, insufficiency (excessive claim breadth, uncertainty, lack of plausibility) and, provided there was a finding of validity, Mylan admitted infringement.[27]

The judge did, however, state that his decision here was provisional only because he had come to the decision on the papers. As such, he left open the opportunity for him to "resile" from it if necessary.[28] However, the judge did not do this and upheld his provisional finding following an oral hearing.[29] He rejected Mylan's lay-patient

[19] [2022] EWHC 272 (Pat); [2022] 2 WLUK 265 and [2022] EWHC 512 (Pat); [2022] 3 WLUK 414, respectively.

[20] [2022] EWHC 272 (Pat); [2022] 2 WLUK 265, [7].

[21] *Ibid*, [8].

[22] *Supra* note 20, [8].

[23] *Supra* note *20*, [8].

[24] *Supra* note 20, [12].

[25] *Supra* note 20, [12].

[26] *Supra* note 20, [13].

[27] *Supra* note 2.

[28] *Supra* note 20, [14].

[29] [2022] EWHC 512 (Pat); [2022] 3 WLUK 414.

argument, holding that no further evidence (beyond that which was before him in the validity trial of the parent patent) was needed to decide the point.[30] Marcus Smith J also refused permission to appeal,[31] granted an injunction and refused a stay of that injunction.[32]

1.3 Court of Appeal – Is Flynn an Exclusive Licensee?

This appeal was brought by Neurim and Flynn against Marcus Smith J's finding in the parent patent proceedings. Neurim is the proprietor of the parent patent and Flynn markets the Circadin product pursuant to a licence granted by Neurim.[33] Marcus Smith J had found that the licence between Neurim and Flynn made no provision for Flynn to have independent enforcement rights and therefore Flynn could not be held to be an exclusive licensee and had no right to bring the infringement proceedings against Mylan.[34]

Although this appeal concerned the parent patent, which was revoked by the EPO after Marcus Smith J's decision below, Arnold LJ (who gave the leading judgment, with Birss and Newey LJJ in agreement) noted that this issue was not purely academic in light of the revocation because of the subsequent proceedings between the same parties in relation to the divisional patent.[35]

Section 67 Patents Act 1977 (PA 1977) states that an exclusive licensee under a patent has the same right as the proprietor to bring infringement proceedings after the date of the licence. Section 130(1) PA 1977 defines an exclusive licensee as "a licence from the proprietor of or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application relates".

Arnold LJ found that Marcus Smith J had made four errors,[36] which included that nothing in Sec. 67(1) PA 1977 requires an exclusive licensee to be able to take action independently of the patentee, nor does it require the licence to provide for this.[37] He noted that Sec. 67(3) PA 1977 contradicts such a reading of Sec. 67(1) PA 1977 because it requires the proprietor to be joined as a party if proceedings are taken by an exclusive licensee.[38] In light of this finding, the Court of Appeal overturned Marcus Smith J's finding that Flynn was not an exclusive licensee and ordered Mylan to pay costs relating to this issue.[39]

[30] *Ibid*, [13], [17].

[31] *Supra* note 29, [18]–[26].

[32] *Supra* note 29, [27]–[44].

[33] [2022] EWCA Civ 359; [2022] 3 WLUK 415.

[34] *Supra* note 2, [120]–[147], particularly [146].

[35] *Supra* note 33, [3].

[36] *Supra* note 33, [18]–[22].

[37] *Supra* note 33, [21].

[38] *Ibid*.

[39] *Supra* note 33, [73].

1.4 Court of Appeal – Permission to Appeal Divisional Validity Finding

Following Marcus Smith J's judgment[40] finding Neurim's divisional valid,[41] the Court of Appeal granted Mylan leave to appeal on the basis that its lay-patient argument had a real prospect of success.[42]

The leading judgment was given by Arnold LJ, with additional small judgments from Birss and Newey LJJ. The judges were quite critical of Marcus Smith below. For example, Arnold LJ commented that it would have been better for Marcus Smith J to have had an oral hearing first off rather than initially making a decision as to validity on the papers.[43]

As discussed above, Marcus Smith J had rejected Mylan's lay-patient argument on the papers and granted Neurim an injunction to restrain Mylan from infringing the divisional. The judge refused an application by Mylan for a stay of the injunction pending determination of an application to appeal to the Court of Appeal. Arnold LJ noted that he was "surprised that the judge did not see fit to grant Mylan a stay of, say, 14 or 21 days …".[44]

Given that the Court of Appeal granted permission to appeal the decision on the divisional's validity and expedited that appeal, the issue was whether a stay should be granted for a period of two to three months.[45] The first question to be approached was whether Neurim and Flynn would be adequately compensated by an award of damages in the event that Mylan's appeal was dismissed.[46]

Neurim and Flynn argued that damages would not be an adequate remedy because the grant of stay "would be a green light" to other generics to enter the market, causing a downward price spiral and therefore unquantifiable damage.[47] Arnold LJ concluded that this submission was not supported by evidence.[48] It was noted that the status quo was that there was one generic on the market (Mylan), which had been on the market for approximately 18 months and had not caused a "price war".[49]

However, Teva had also obtained UK marketing authorisation and Neurim and Flynn had commenced proceedings against Teva. On this, Arnold LJ said: "[j]ust as preservation of the status quo favours a stay of the injunction against Mylan, it

[40] [2022] EWCA Civ 370; [2022] 3 WLUK 423.

[41] *Supra* note 19.

[42] *Supra* note 40, [1].

[43] *Supra* note 40, [19].

[44] *Supra* note 40, [20].

[45] *Supra* note 40, [24].

[46] *Supra* note 40, [26].

[47] *Supra* note 40, [28].

[48] *Ibid.*

[49] *Supra* note 40, [30].

favours the grant of an interim injunction against Teva. In saying that, I am not intending to pre-judge the outcome of that application".[50]

Even if Neurim and Flynn would suffer damage that could not adequately be compensated by damages, it was still necessary to consider whether Mylan would be adequately compensated by damages pursuant to the cross-undertaking offered by Neurim and Flynn if the appeal was successful.[51] Arnold LJ held that Mylan's damage would be difficult to quantify and adequately compensate because of the loss of their first mover advantage:

> Mylan have an advantage upon expiry of EP443 because they will have a right of first refusal of future contracts to supply pharmacies. Not only would they lose that advantage if a stay were refused, but also they would be faced with trying to re-establish their foothold in the market after having been forcibly removed from it.[52]

In any event, Arnold LJ held that even if both sides were equally likely to suffer damage that could not be adequately compensated, then it would still be "prudent" to preserve the status quo pending the appeal.[53]

Both Birss and Newey LJJ gave short judgments putting different emphases on the issue to Arnold LJ – both held that damages would not necessarily be an adequate remedy for Neurim and Flynn either but agreed that the status quo should be preserved.[54]

Birss LJ also noted that just because a numerical figure for damages can be ascertained, it does not mean that damages are an adequate remedy.[55] This picked up on a point raised by Marcus Smith J that harm resulting from an exclusion from a market is "prima facie quantifiable" (he came to this conclusion by reference to competition cases involving anti-competitive conduct).[56]

Thus, Mylan was granted leave to appeal the divisional validity finding in an expedited hearing in May 2022 and the injunction granted by Marcus Smith J was stayed pending the outcome of that appeal.

1.5 Court of Appeal – Divisional Validity Appeal

Following on from the above, the Court of Appeal (Arnold LJ giving the leading judgment)[57] considered Mylan's lay-patient argument (the argument that the Court had found to have a real prospect of success in granting leave to appeal).[58]

[50] *Supra* note 40, [30].

[51] *Supra* note 40, [32].

[52] *Supra* note 40, [33].

[53] *Supra* note 40, [34].

[54] *Supra* note 40, [37]–[38].

[55] *Supra* note 40, [37].

[56] *Supra* note 29, [36].

[57] [2022] EWCA Civ 699; [2022] 5 WLUK 323.

[58] *Ibid*, [32] *et seq*.

Mylan argued that the data in the patent could only render the claimed effect plausible if it was common general knowledge (CGK) that patients were instructed in the relevant studies (as described in Examples 2 and 3) to interpret the "quality of sleep" question as specifically referring to non-restorative sleep (NRS).[59] Mylan noted that the judge had made no such CGK finding nor was there any evidence to that effect.

Arnold LJ held that Marcus Smith J's decision that the patent plausibly disclosed the claimed effect was an "evaluative assessment" and therefore Mylan had to establish that the judge made an error of principle.[60] To which, Arnold LJ stated: "[t]he only error suggested is that the judge was wrong to reject the lay-patient argument".[61]

Arnold LJ rejected various criticisms raised by Mylan, noting that with respect to Mylan's "best point" (regarding an "apparent contradiction" between a claim in the patent and the description of Examples 2 and 3), it failed to either adduce evidence from its expert or put the point to Neurim's expert and, as such, it was now not open to Mylan to rely on this point.[62]

This case highlights an important point about advancing arguments in the appropriate amount of detail in evidence and during trial. The Court of Appeal initially saw at least some potential in Mylan's lay-patient argument, hence giving leave to appeal. However, the argument was then rejected upon seeing the trial evidence (or lack thereof) at the appeal hearing. Arnold LJ particularly noted that the lay-patient argument "was not articulated very clearly by Mylan at trial" and its "best point" was not even advanced at trial.[63] Ultimately, Marcus Smith J's decision finding Neurim's divisional patent valid was upheld.

2 *Sandoz Ltd & Anor v. Bristol-Myers Squibb Holdings Ireland Unlimited Company*

Leaving aside Neurim and Mylan's dispute, next came a trial of two actions in which Sandoz and Teva (the Claimants)[64] sought the revocation of BMS's patent, and corresponding SPC, relating to the compound apixaban. BMS also counter-claimed for infringement, which the Claimants admitted in the event that the patent was valid.[65]

This case is particularly interesting because of Meade J's findings on plausibility. Apixaban's use in therapy relies on it being a factor Xa inhibitor. There was no dispute that apixaban had been proven to be a potent factor Xa inhibitor and a useful therapeutic. Rather, the central attack on the patent was that it did not make

[59] *Supra* note 57, [32]–[40].

[60] *Supra* note 57, [44].

[61] *Ibid*.

[62] *Supra* note 57, [45]–[56], particularly [56].

[63] *Supra* note 57, [41], [56].

[64] [2022] EWHC 822 (Pat); [2022] 4 WLUK 81.

[65] *Ibid*, [1]–[4].

plausible that apixaban would have any useful factor Xa inhibitory activity, or be useful in therapy, or for any other purpose.[66]

Meade J acknowledged that "lack of plausibility" is not a ground for revocation itself, rather it arises in obviousness under Art. 56 European Patent Convention (EPC) (inventive step) and Art. 83 EPC (sufficiency), and is carried into the PA 1977 as conditions for grant and revocation under Sec. 72. Here, the Claimants ran the point as both *Agrevo* obviousness and insufficiency attacks. The Claimants maintained that it did not make any difference which head of invalidity was applied and the judge agreed in light of *Warner-Lambert Co LLC v. Generics (UK) Ltd (t/a Mylan)*[67] and *FibroGen Inc v. Akebia Therapeutics*.[68] He therefore unusually just referred to lack of plausibility on its own, perhaps opening the door for this to be done in other circumstances as well?[69]

When setting out the applicable legal principles on plausibility, the judge referred to what he called the three "central" cases: *Agrevo*,[70] *Warner-Lambert*[71] and *FibroGen*.[72] Importantly, Meade J stated that although *FibroGen* represents significant recent guidance from the Court of Appeal on plausibility, the context of that case was very different from the instant case (i.e. it was a lot simpler than this case).[73] Here, he said that there was no useful analogy to step one and step two functional features.[74] Nevertheless, he still noted that he had in mind the three-step *FibroGen* approach.[75]

Taking the second step of the *FibroGen* approach – that is, what does it mean to say that an invention works – Meade J concluded that this must be determined from the specification where the claim is not explicit but the patentee is not restricted to the "most ambitious assertion made".[76] Thus, sometimes a patentee can rely on a more limited contribution but this is fact-dependent and must still have a basis in the specification.[77]

The judge accepted BMS' argument that there is no requirement to file data in an application in order to establish plausibility, for example, the effect may be made credible from the structure of a compound.[78] The Claimants met this structural argument on the facts. Meade J concluded that "no prediction based on structure

[66] *Supra* note 64, [7].

[67] [2018] UKSC 56; [2019] 3 All ER 95. Covered previously in the 2018 United Kingdom Patent Decisions Overview, IIC 50:331–351 (2019), https://doi.org/10.1007/s40319-019-00796-y.

[68] [2021] EWCA Civ 1279; [2021] 8 WLUK 161. Covered previously in last year's edition of this review, IIC 53:377–395 (2022), https://doi.org/10.1007/s40319-022-01161-2.

[69] *Supra* note 64, [10.2], [24].

[70] T 939/92 *Agrevo/Triazoles*.

[71] *Supra* note 67.

[72] *Supra* note 68.

[73] *Supra* note 64, [57].

[74] *Ibid.*

[75] *Supra* note 64, [57].

[76] *Supra* note 64, [68].

[77] *Ibid.*

[78] *Supra* note 64, [73].

could be made from the CGK" and that "apixaban's binding is unexpected and hard to explain", noting that there has to be "some positive reason" from the CGK to suggest that there might be success, which there wasn't.[79] On the level of biological or therapeutic activity required by law to render something plausible, the judge said: "… the law requires a technical contribution of some, even if low, real significance. There is no contribution in disclosing a uselessly low degree of activity so that comparisons can be made with something which is useful".[80]

In the end, Meade J held BMS' patent and related SPC to be invalid for lack of plausibility. This decision is being appealed so plausibility will be back on the agenda in due course.

3 *Novartis AG and Anor v. Teva UK Ltd and Ors*

Next we had a number of applications with respect to a dispute concerning the drug fingolimod between Novartis and a range of generics.[81]

3.1 Novartis' Application for Interim Injunctive Relief

Novartis applied for interim injunctive relief against a range of generics. The application concerned a divisional patent application relating to fingolimod, which is used to treat a certain type of multiple sclerosis.[82] As this application concerned a patent application that was due to grant a couple of months after the application, the application was made by Novartis as a prospective patentee.[83]

Fingolimod has been supplied by Novartis in the UK since 2011 under the brand name Gilenya. However, the drug's regulatory data and market exclusivity was due to expire a few days after the application was heard. The defendants had received marking authorisations for their generic versions of fingolimod and Novartis sought to prevent them from entering the market ahead of its patent being formally granted.[84] The court had to determine whether it had jurisdiction to grant interim relief prior to formal grant of a patent and, if so, whether it should be granted.

On the jurisdiction point, Roth J held that the court did have jurisdiction as Sec. 69 PA 1977 (which deals with infringement of rights conferred by publication of a patent application) should not be interpreted as a statutory bar on the jurisdiction of the court to grant interim relief under Sec. 37 Senior Courts Act 1981.

[79] *Supra* note 64, [214]–[215].

[80] *Supra* note 64, [76].

[81] [2022] EWHC 959 (Ch); [2022] Bus LR 888. Permission to appeal denied in: [2022] EWCA Civ 775; [2022] 5 WLUK 81. *Arrow* declaration sought by Teva and declined in: [2022] EWHC 2779 (Ch); [2022] 10 WLUK 455. Appealed in: [2022] EWCA Civ 1617; [2022] 12 WLUK 74.

[82] *Ibid*, [5].

[83] *Supra* note 81, [14]–[15].

[84] *Supra* note 81, [6]–[7].

After finding this, the judge went on to apply the *American Cyanamid*[85] test to determine whether interim relief should be granted.[86] After this analysis, Novartis' application was refused as damages were held to be an adequate remedy.[87] Novartis sought permission to appeal this judgment from the Court of Appeal and this was denied.[88]

3.2 High Court – Teva's Application for *Arrow* Declaratory Relief

Prior to Novartis' divisional application granting, Novartis de-designated the UK from its application. It also applied to discontinue its infringement action against all of the defendants. As such, when the patent eventually granted at the EPO on 12 October 2022, it did not apply to the UK, which became a generic market. At this point, Novartis either settled or reached agreement in principle with each of the defendants to its infringement action, with the exception of Teva.

Teva maintained and amended its application for *Arrow* declaratory relief.[89] Teva advanced five main arguments – most importantly, that Novartis had aggressively enforced the patent in issue, including obtaining injunctive relief, a declaration would provide certainty to Teva's UK customers (the NHS), it could be useful to German courts in considering whether to grant a preliminary injunction against Teva, and the fact that Teva's supply to the UK transited through the confidential "Country A", such that an injunction in Country A would threaten the UK supply chain.[90]

With respect to Novartis' enforcement conduct, Bacon J dismissed the idea that an *Arrow* declaration could be used as some form of censure or to discourage such conduct.[91] Instead, the case law indicated that party conduct was considered because it "created and perpetuated commercial uncertainty in the UK" and therefore it could be considered with the other factors Teva relied upon.[92] As for Teva's argument that a declaration would provide certainty for the NHS, the judge found that there was no such confusion on the part of the NHS.[93]

Taking Teva's last two main arguments – Bacon J was clear that the case law established that if the "only or predominant purpose of the declaration sought is to use the judgment for a foreign court" then the court will have to carefully consider the justification for the declaration.[94] To this end, Teva relied on its supply chain

[85] [1975] AC 396; [1975] 2 WLR 316.

[86] *Supra* note 81, [40]–[80].

[87] *Supra* note 81, [71].

[88] *Supra* note 81.

[89] This form of negative declaratory relief originates from *Arrow Generics Ltd v. Merck & Co Inc* [2007] EWHC 1900 (Pat); [2008] Bus LR 487 and is a declaration that a product or process was obvious at a particular date (in *Arrow*, this was the priority date of a pending divisional patent application).

[90] *Supra* note 81, [34].

[91] *Supra* note 81, [43].

[92] *Supra* note 81, [43].

[93] *Supra* note 81, [44].

[94] *Supra* note 81, [61].

argument – it argued that the effect of the declaration would be felt in the UK because its supply chain to the UK involves transit through Country A. It maintained that if an injunction was granted in Country A then it would seek to rely on the UK declaration to resist an injunction because it would be time-consuming and expensive to re-route its supply chain.[95]

Although the judge accepted that a UK *Arrow* declaration may impact Teva's supply chain, the question to answer was whether that was reason enough to grant a declaration.[96] In answer, the judge held it was not "… the fact that a decision in Country A will therefore affect the UK market indirectly by having an impact on Teva's supply route to the UK does not change the fact that the purpose of an Arrow declaration in this jurisdiction will be to use it in the courts of Country A and other countries, rather than to obtain or enforce any right in the UK".[97] Bacon J continued that there was "nothing unusual" in that global supply chains would be affected by a decision in one country and, unlike in other cases,[98] Novartis' conduct did not result in continued uncertainty on the UK market.[99] As such, the judge declined to grant an *Arrow* declaration.

3.3 Court of Appeal – Teva's *Arrow* Declaration Appeal

Then, towards the end of the year, Teva appealed Bacon J's decision to refuse *Arrow* declaratory relief.[100] Arnold LJ (giving the leading judgment) noted that the judge's decision below involved an exercise of discretion and the Court was only entitled to interfere with it if she erred in law or principle.[101] Teva maintained that she did.[102]

This judgment helpfully set out a reminder of the legal principles relating to *Arrow* declarations and their "spin-off value" versus using declaratory relief to aid foreign proceedings.[103] Crucially, Arnold LJ stated:

> [i]t is one thing for a party to rely upon the "spin-off value" of a judgment of the Patents Court concerning a patent or patent application designating the UK. It is quite another for a claimant to seek a declaration from the Patents Court for the sole purpose of influencing a foreign court applying its own law to an issue before it (as opposed to the Patents Court itself deciding the issue applying the foreign law)[104]

[95] *Supra* note 81, [63].

[96] *Supra* note 81, [70]–[71].

[97] *Supra* note 81, [71].

[98] *Fujifilm Kyowa Kirin Biologics Co Ltd v. AbbVie Biotechnology Limited* [2017] EWCA Civ 1; [2018] Bus LR 228.

[99] *Supra* note 81, [76].

[100] *Supra* note 81.

[101] *Supra* note 81, [62].

[102] *Supra* note 81, [63].

[103] *Supra* note 81, [15]–[52].

[104] *Supra* note 81, [35].

This led to the conclusion that "assisting a foreign court to decide an issue under its own law is not a legitimate reason for the grant of declaratory relief".[105] Thus, the judge below had been correct to dismiss Teva's claim. Arnold LJ agreed with the judge below for rejecting Teva's supply chain argument, adding that any effect on the UK market would simply be a "knock-on consequence of the courts of Country A applying their own law within their territory".[106] Teva's appeal was dismissed.

4 *Shenzhen Carku Technology Co. Ltd v. The Noco Company*

Next, we had dispute concerning Noco's patent relating to battery-powered car jump starters and Carku's allegedly infringing products.[107] The patent was ultimately held to be invalid for obviousness but this case interestingly deals with whether Noco's use of Amazon's UK IPR complaints procedure amounted to an unjustified actionable threat against Amazon.

The issue arose in the context of statements made by Noco to Amazon when using its UK IPR complaints procedure and whether these amounted to a threat of patent infringement proceedings.[108] Meade J helpfully set out the law on unjustified threats in some detail,[109] noting that there have not yet been any cases in England and Wales relating to Amazon's IPR procedure, but that similar issues arose at the interim stage with respect to eBay's Verified Rights Owner programme.[110]

The judge found that the relevant communications to Amazon asserted the existence of patent rights and infringement of those rights, and called for action to be taken to end the alleged infringement.[111] Meade J stated that "[i]n most contexts they would be classic threats" but he needed to consider the present context.[112] Although Noco had submitted evidence that it would never sue Amazon, regardless of whether it delisted Carku's products, the judge concluded that Amazon did not know this and such an assurance was never given to Amazon.[113] As such, Noco's communications to Amazon via its complaints procedure were held to be threats of patent infringement against Amazon in the case that it did not delist Carku's products.[114] However, he was clear to emphasise that the finding was based on the present facts and "[i]t is not a general finding about online markets".[115] Although the judge noted the limitations of the judgment, it stands as precedent considering

[105] *Supra* note 81, [64].

[106] *Supra* note 81, [65].

[107] [2022] EWHC 2034 (Pat); [2022] 8 WLUK 10.

[108] *Ibid*, [207] *et seq*., especially [208].

[109] *Supra* note 107, [209] *et seq*.

[110] *Supra* note 107, [223].

[111] *Supra* note 107, [250].

[112] *Ibid*.

[113] *Supra* note 107, [254].

[114] *Supra* note 107, [255].

[115] *Supra* note 107, [258].

the use of Amazon's UK IPR complaints procedure and therefore has applicability to other types of IP infringement.

5 *Lisa Dräxlmaier GmbH v. Bos GmbH & Co. Kg*

This judgment[116] concerning an expedition application deserves mention after the spate of expedition applications we saw in the Patents Court last year.[117] Here, the claimant submitted an application for an expedited trial of a UK action concerning infringement only (after the defendant had submitted two applications for an extension of time to serve a defence and for strike out). The claimant then submitted a fourth application to combine the hearing of those three applications and to have an expedited hearing. The claimant's aim was to obtain an expedited trial and a decision from the UK courts before a German infringement trial. But this could only happen if the application to expedite the trial was heard before the end of July 2022.

In considering the fourth application for an expedited combined hearing, Mellor J applied the principles he set out last year in *Abbott v. Dexcom*.[118, 119] Of particular relevance to this case was the issue of the German injunction gap. The judge concluded that the following relevant points from the case law emerged:

a. A judgment on validity may be of assistance to a court of another EPC state. The Mellor J stated that this "makes sense" when considering the injunction gap, which often arises in states with a bifurcated system such as Germany where an infringement decision may be issued some time before a validity decision.[120]
b. Where there is the possibility of an injunction gap, and if there are other reasons to expedite, then a factor in favour of expedition can be that a UK decision on validity may be of assistance in persuading the German infringement court to stay the grant of an injunction. However, that factor alone is not enough to justify expedition.[121]

Here, the issue of validity was not in dispute, only infringement. Although the judge stated that he did not rule out the possibility that, in certain circumstances, the court may be persuaded that there is a good reason to expedite an infringement only trial "where the judgment may be deployed before the Court of another Contracting State to achieve greater commercial certainty for a party".[122]

However, the Mellor J concluded that the claimant had not given a reason, let alone a good one, that would justify expedition and therefore the application was rejected. The judge gave a number of reasons. Firstly, he stated that the injunction

[116] [2022] EWHC 1642 (Pat); [2022] 6 WLUK 629.

[117] *See* last year's case review, IIC 53:377–395 (2022), https://doi.org/10.1007/s40319-022-01161-2.

[118] [2021] EWHC 2246 (Pat); [2021] 8 WLUK 32. *See* last year's case review, IIC 53:377–395 (2022), https://doi.org/10.1007/s40319-022-01161-2.

[119] *Supra* note 116, [27].

[120] *Supra* note 116, [34(i)].

[121] *Supra* note 116, [34(ii)].

[122] *Supra* note 116, [41].

gap would not arise in this case.[123] Secondly, the infringement court in Düsseldorf did not need assistance from the UK court in the form of an infringement judgment relating to the UK designation.[124] Thirdly, the only reason for the UK action was to attempt to influence the German court. As such, if the "'spin-off' value" of a UK judgment is alone not enough to justify expedition in a validity case then the factor is "even less powerful" in an infringement only case where there is no injunction gap in Germany.[125] And, lastly, there was no reason why this case should "jump the queue and displace other litigants".[126]

Although we saw a flurry of expedition applications last year, which raised the question of whether it is getting easier to obtain expedition, this decision makes it clear there are limits to when expedition will be granted. A clear emphasis on validity decisions potentially being of use to a German court where the injunction gap issue may arise emerges from this case. Where a case involves only infringement then it seems like a high hurdle will have to be mounted to convince the court to expedite (although it wasn't ruled out entirely).

6 *Optis Cellular Technology LLC & Ors v. Apple Retail UK Ltd & Ors*

In late October, the Court of Appeal gave us an important decision[127] in relation to standard essential patents (SEPs) and the licensing of them on fair, reasonable and non-discriminatory (FRAND) terms. This appeal (the appeal of what was known as Trial F[128]) provided clarity that once a UK court finds that a SEP is valid and infringed, an implementer must undertake to take a court-determined FRAND licence or be subject to a FRAND injunction (a FRAND injunction being the correct form of injunction).[129]

Apple had appealed on four grounds[130] – all of which were swiftly rejected. One was a pleading point, but this found no favour.[131] The others related to whether Meade J had interpreted the ETSI Undertaking correctly.[132] The main submission being that ETSI could not have required implementers to agree to take a licence without knowing the terms. This was referred to as the "blank cheque" argument.[133] Arnold LJ (giving the leading judgment) stated that Meade J's interpretation of the ETSI Undertaking only required an implementer to commit to taking a licence on

[123] *Supra* note 116, [43(i)].

[124] *Supra* note 116, [43(ii)].

[125] *Supra* note 116, [43(iii)].

[126] *Supra* note 116, [43(iv)].

[127] [2022] EWCA Civ 1411; [2022] 10 WLUK 342.

[128] [2021] EWHC 2564 (Pat); [2021] 9 WLUK 276.

[129] *Supra* note 127, ([64] *et seq*., in particular [80]–[81]).

[130] *Supra* note 127, [50]–[53].

[131] *Supra* note 127, [53].

[132] *Supra* note 127, [50]–[52].

[133] *Supra* note 127, [71].

terms "the court objectively determines to be FRAND" and that this is not a "blank cheque".[134]

Optis had also cross-appealed on three grounds[135] – again, these were rejected fairly quickly by Arnold LJ.[136] The cross-appeal was directed at whether Optis was entitled to a permanent unqualified injunction, not a FRAND injunction. Importantly, here Arnold LJ said: "There is no reason why an implementer should not be able to change its mind [after the court has decided whether or not to grant an injunction] for commercial reasons and every reason why it should be able to do so given that a key purpose of the ETSI IPR Policy is to ensure access to technology covered by SEPs."[137]

In discussing that a FRAND injunction is the right form of injunction, the judge said:

> As matter of principle, the court should make provision for the possibility of Apple changing their mind now, rather than leave the parties to the uncertainty of a contested application to discharge or vary [if a normal unqualified injunction was granted]. It might be different if the court was being asked to make provision for a future event the possible occurrence of which was merely speculative, but in the present case there is a very real likelihood of Apple accepting the Court-Determined Licence (at least once the parties' rights of appeal have been exhausted) and hence being entitled to enforce the ETSI Undertaking.[138]

As such, the Court of Appeal upheld the first instance finding that Optis was entitled to a FRAND injunction after one of its SEPs had been found valid and infringed and before the terms of the FRAND licence were determined.

In a postscript to the judgment, Arnold LJ went on to say this appeal illustrated the "dysfunctional state of the current system for determining SEP/FRAND disputes" and that each side had tried to "game the system in its favour".[139] He finally noted that "[t]he only way to put a stop to such behaviour is for SDOs like ETSI to make legally-enforceable arbitration of such disputes part of their IPR policies".[140] ETSI, however, rejected an arbitration clause in the 1990s.

7 Conclusion

This review article has sought to provide an overview of some of the most notable patent decisions of 2022, although there were many more cases that couldn't be covered. The upcoming year looks set to be another interesting one in the patent

[134] *Supra* note 127, [71].

[135] *Supra* note 127, [55]–[57].

[136] *Supra* note 127, [84]–[91].

[137] *Supra* note 127, [86].

[138] *Supra* note 127, [91].

[139] *Supra* note 127, [115].

[140] *Supra* note 127, [115].

world. After years of planning, the much anticipated Unitary Patent and the Unified Patent Court (UPC) are due to launch in Europe in mid-2023. This presents one of the biggest shake-ups to the patent world, affecting the granting and litigating of patents in Europe. Although the UK will no longer be participating in the UPC system, it will remain a key jurisdiction for parallel litigation and we await to see how the two systems interact.

Artificial intelligence will be back on the agenda in the anticipated Supreme Court appeal concerning the AI machine, DABUS. The case raises a practical point – can a patent be granted for an invention created by an AI machine? In the Court of Appeal, Birss and Arnold LJJ disagreed on approach, with Birss LJ giving a dissenting judgment.[141] An interesting point of law likely to be explored is whether the owner of an AI machine is entitled to own the inventions the machine creates. In the Court of Appeal, Arnold LJ had drawn a distinction between the ownership rights of owners of tangible and intangible property objects.[142] More next year …

[141] *Thaler v. Comptroller General of Patents, Trade Marks and Designs* [2021] EWCA Civ 1374; [2022] Bus LR 375.

[142] *Ibid*, [131] *et seq*.