

SLAUGHTER AND MAY /

THE IP BRIEF

a quarterly update of key IP cases and news,
with a primarily UK and EU focus.

JUNE 2025



/ INTRODUCTION

Welcome to our latest edition of The IP Brief - a quarterly update of key IP cases and news, with a primarily UK and EU focus.

In this edition, we take a look at:

- Advocate General Szpunar's opinion on copyright protection for works of applied art in *Mio* and *konektra*;
- the EU's long-arm jurisdiction in patent infringement disputes;
- three recent UK Court of Appeal decisions in the SEP/FRAND space - one considering global FRAND terms and the correct approach for assessing FRAND royalties; the other two looking at interim SEP licence declarations;
- a flurry of recent decisions relating to the grant of interim injunctions against generic entry, in the context of AstraZeneca's dapagliflozin dispute with Glenmark; and
- the UKIPO's confirmation that the UK will maintain its UK+ exhaustion of rights regime.

Separately, in the coming weeks, we will also be publishing new content on copyright and AI - including a podcast and a detailed client briefing - as there continue to be numerous developments in that space.

COPYRIGHT

AG SZPUNAR ASSEMBLES THE PIECES OF COPYRIGHT PROTECTION FOR WORKS OF APPLIED ART

The law relating to copyright protection for works of applied art continues to remain a hot topic in the UK and the EU, with a number of material decisions being handed down in recent months. This includes the UK Intellectual Property Enterprise Court's decision in *WaterRower v Liking* (which we covered in our [March 2025 edition](#)), the CJEU's decision in *Kwantum v Vitra* (which we covered in our [November 2024 edition](#)) and a recent decision of the German Federal Supreme Court which looked at copyright protection for Birkenstock sandals.

This time around, it was the turn of Advocate General Szpunar, who published his opinion on the joint cases of *Mio and konektra* in early May. Both of those cases concern copyright protection for pieces of furniture - tables in *Mio* and a modular furniture system in *konektra* - and led to a number of material questions being referred to the CJEU. That included questions on the relationship between copyright and design right protection, the criteria for assessing the originality of a work of applied art, and how the courts of member states should assess infringement of copyright in such works.

The first of those questions - on the relationship between copyright and design protection - stemmed from the CJEU's decision in *Cofemel*, where the CJEU stated that "*although the protection of designs and the protection associated with copyright may, under EU law, be granted cumulatively to the same subject matter, that concurrent protection can be envisaged only in certain situations*". What does that mean?

In AG Szpunar's opinion, this statement shouldn't be understood as establishing a relationship of rule and exception between copyright and design right protection. The CJEU was simply reminding national courts that the criteria for copyright and design right protection differ and there is therefore no automatic connection between the two. He also concluded that this statement shouldn't be read as imposing a higher threshold of originality for works of applied art than other categories of work. The same test should be applied.

Turning to the second question. How should the national courts assess the originality of works of applied art and what factors can be taken into account?

As noted above, in the Advocate General's opinion, national courts should assess the originality of works of applied art in the same way as they assess other types of work. The key question is therefore whether the work is the author's own intellectual creation and, in particular, whether it constitutes "*the expression of the free and creative choices reflecting the personality of its author*".

Whilst the test may be the same for all types of work, the national courts must take into account the specific nature of the work concerned when the test is applied. Some aspects of works of applied art will, for example, be dictated by technical considerations, rules or other constraints. Choices dictated by such constraints are not creative. Nor are choices which, although freely made, do not reflect the author's personality.

As a result, according to AG Szpunar, only those works of applied art whose shape is determined, at least in part, by its author's creative choices and which reflect the author's personality will benefit from copyright protection. And those choices and the author's personality must be visible in the work itself (the author's intentions are not decisive).

As for what factors national courts can take into account when assessing originality and what weight should be given to them, AG Szpunar confirmed that things like the use of known shapes, the author's sources of inspiration, the likelihood of similar independent creation by others and recognition of the work in professional circles or museums may all constitute relevant circumstances for assessing originality. However, he noted that none of these things will be decisive. Ultimately, the fundamental question for the court will be whether the work itself

expresses the author's free and creative choices reflecting their personality.

The final question AG Szpunar had to address was how EU national courts should assess infringement of copyright in works of applied art.

He began by distinguishing the tests for infringement of copyright and design rights, noting that questions about whether two works create a different overall impression are questions of design right law, not copyright law.

In order to establish copyright infringement, AG Szpunar said that the test is "*whether creative elements of the protected work, [i.e.] those elements that are the expression of choices reflecting the author's personality, have been reproduced in a recognisable manner in the allegedly infringing subject matter*".

He also concluded that the scope of protection afforded to any given copyright work does not depend on the degree of creative freedom exercised by its author. If a work is found to be original, it will be protected against others copying its creative elements.

The majority of this opinion is as expected and provides welcome clarification on how copyright protection for works of applied art should be assessed within the EU. It is broadly consistent with previous case law, although AG Szpunar does perhaps place more emphasis than previous cases on the nature of works of applied art (being primarily utilitarian objects) and the need for the work to reflect the author's personality and their free and creative choices, which may ultimately limit the protection available for certain works.

AG Szpunar's views on copyright infringement have, however, drawn some criticism as he appears to be suggesting that the CJEU introduce a novel concept of recognisability (which has previously only been applied in the context of sound recordings) into the test for copyright infringement. It will be interesting to see whether the CJEU follows that suggested approach and, if it does, whether it provides any further clarification of what that will mean in practice.

PATENTS

THE EU'S LONG-ARM JURISDICTION IN PATENT INFRINGEMENT DISPUTES

The CJEU and various local divisions of the Unified Patent Court (UPC) have recently considered questions relating to jurisdiction to hear cross-border patent infringement disputes - that is disputes relating to infringement of patents registered outside the country of the court. In each of these cases, the relevant court decided that it (or the relevant courts) did have jurisdiction to hear the infringement action where the defendant was domiciled in the place of the court, even where validity was challenged. In effect, this means that EU national courts and the UPC can hear cases in which patent infringement is alleged in multiple territories based on the defendant's domicile.

We take a closer look at the key cases below.

CJEU case law - BSH v Electrolux

On 25 February, in **BSH v Electrolux**, the Grand Chamber of the CJEU ruled on EU national courts' jurisdiction to hear cross-border patent infringement disputes where the validity of patents granted outside the country of the court seised is challenged.

BSH owns a European patent for vacuum cleaners designating a number of EU member states including Sweden, as well as the United Kingdom and Türkiye.

BSH brought an action against Electrolux before the Swedish courts alleging infringement of all the national parts of that European patent and sought an order requiring Electrolux to cease using the patented invention in all such states.

Electrolux argued that the foreign patents were invalid and that the Swedish courts did not have jurisdiction to rule on whether they had been infringed.

The key regulation governing jurisdiction in this context is the Brussels I bis Regulation. Under Article 4(1) of that Regulation, as a general rule, defendants should be sued in the place of their domicile. But there are exceptions to that general rule, including Article 24(4), which provides that where proceedings are concerned with the validity of patents (either as an action or by way of defence) the courts of the member state in which the patent is granted will

have **exclusive** jurisdiction, regardless of the domicile of the parties.

Three questions relating to the effect of these provisions were referred to the CJEU.

Patents in suit granted in EU member state

The first two questions related to cases where the patents in issue have been granted in an EU member state.

The referring court asked, in essence, whether Article 24(4) of the Brussels I bis Regulation meant that the courts of the EU member state where the defendant is domiciled would lose jurisdiction to consider infringement if the defendant seeks to challenge the validity of the patent in suit.

The CJEU found that they would not. Whilst the court seised of the infringement action (i.e. the court of the member state in which the defendant is domiciled) must decline jurisdiction to determine validity as per Article 24(4), it will not lose its jurisdiction to hear the infringement action merely because the defendant has challenged validity. However, this does not mean that the court of the member state in which the defendant is domiciled should disregard the fact that an invalidity action has been brought. It may decide to stay the infringement proceedings pending the outcome of the invalidity action where it considers that justified - in particular, where it takes the view that there is a "reasonable, non-negligible possibility" of that patent being declared invalid.

Patent in suit granted outside the EU

The third question asked whether Article 24(4) applies to the courts of non-EU member states.

The CJEU confirmed that Article 24(4) does not apply to the courts of such third states and consequently does not confer any jurisdiction, whether exclusive or otherwise, on such courts to hear validity actions relating to patents granted in their jurisdiction.

As a result, under Article 4(1), where a defendant who is alleged to have infringed a patent granted in a third state is domiciled in an EU member state, the courts of that member state have, in principle, jurisdiction to hear that infringement action. That jurisdiction extends, again in principle, to questions of validity that may be raised by way of defence.

However, the CJEU went on to say that jurisdiction over questions of validity may be limited by "special

rules” under Article 73 of the Brussels I bis Regulation. For example, the courts of countries that are party to the Lugano Convention (not the UK) will have exclusive jurisdiction to hear validity actions relating to patents granted in their country as the Lugano Convention contains provisions similar to Article 24(4) of the Brussels I bis Regulation. A similar position may arise where a bilateral convention has been concluded between an EU member state and a third state.

Jurisdiction over questions of validity is also restricted under general international law and the principle of non-interference, which, the CJEU concluded, provide that only the courts of the third state where the patent is granted have jurisdiction to declare that patent invalid.

Where, however, the issue of validity is raised as a defence to an infringement action, an EU national court seised of the infringement action based on the defendant’s domicile can rule on that defence as between the parties (but without impacting validity more broadly).

UPC case law

The local divisions of the UPC have been taking a similar approach to that adopted by the CJEU.

The first UPC decision considering this (*Fujifilm v Kodak*) was handed down before the CJEU’s decision in *BSH v Electrolux*. In that case, the Düsseldorf local division was asked to rule on infringement of a European patent that was in force in Germany and the UK. Validity was challenged in Germany, but not the UK.

Based on Article 4(1) of the Brussels I bis Regulation (which also determines the international jurisdiction of the UPC), the UPC decided that, where the defendant is domiciled in a UPC contracting member state (here Germany), the UPC has jurisdiction to hear an infringement action in respect of the UK part of the patent in suit.

Infringement was not, however, established on the facts of the case as the UPC found the German part of the patent to be invalid. Whilst the UPC found it had no jurisdiction to rule on the validity of the UK part of the patent in suit, the claimants did not claim that validity would have been assessed any differently in the UK (if, indeed, it had been challenged). In those circumstances, the court concluded that the infringement action couldn’t succeed.

Since the CJEU’s decision in *BSH v Electrolux*, a number of UPC local divisions have applied it, including:

- The Paris local division, which applied it to find that it has jurisdiction to rule on an alleged infringement by a French company of the Spanish, Swiss and UK parts of a European patent (*IMC Créations v Mul-T-Lock*). It also found it could assess the validity of the UK part of the patent, *inter partes*, in the context of the defendants’ defence to the infringement claim.
- The Milan local division, in *Dainese v Alpinestars*, which applied *BSH* to find it has jurisdiction to hear a patent infringement dispute relating to a European patent designating Spain (which is not a UPC contracting member state) where the defendant is domiciled in a UPC contracting member state (here Italy).
- The Munich local division, in *Syngenta v Sumi Agro*, which applied *BSH* when granting Syngenta leave to amend its claim to include infringement of the Polish, Czech and UK (all non-UPC territories) parts of the patent in suit.

Comment

These decisions will no doubt have a material impact on the patent litigation landscape and will be welcomed by patentees, who may now have additional options to bring cross-border infringement actions depending on the place of domicile of the alleged infringer.

The CJEU’s ruling is particularly material as it may (where the facts allow) enable the holder of a European patent, who believes that their patent has been infringed in multiple EU member states, to bring all of its infringement claims in a single forum and may therefore enable EU national courts to compete with the UPC in cross-border patent disputes where the defendant is domiciled in their country and is infringing in multiple member states.

However, a number of material questions remain. For example, how likely is it in practice that the EU national courts will stay infringement proceedings where the validity of a patent granted in another EU member state is called into question? In what circumstances (if any) will infringement proceedings be stayed where the validity of a patent granted

outside the EU is challenged? And how will the courts of non-EU or non-UPC countries respond to this new found long-arm jurisdiction (particularly where the approach of such courts to infringement might be different)? Only time will tell...

UK COURT OF APPEAL CONSIDERS GLOBAL FRAND TERMS AND INTERIM SEP LICENCES

The UK Court of Appeal has had a busy few months considering questions relating to standard essential patents (SEPs), FRAND (fair, reasonable and non-discriminatory) terms and its ability to grant declarations that a willing licensor in the SEP owner's position would grant a given implementer an interim licence of its SEPs pending determination of the terms of a (F)RAND licence between the parties.

Global FRAND terms

In *Optis v Apple*, the Court of Appeal confirmed that a conventional comparables-based approach should be adopted by the English courts when assessing FRAND royalties, overturning the first instance decision and rejecting the High Court's novel, top-down approach. In doing so, the Court of Appeal reaffirmed the importance of expert evidence, comparable licences, unpacking and a broad brush approach, ultimately increasing the FRAND royalty Apple has to pay by a factor of ten.

At first instance, in determining the level of the FRAND royalty due, the High Court entirely rejected the evidence of the two accountancy experts before it and instead adopted its own approach. That approach was a form of "top down" approach, based on lump sums and averaging, which involved the court seeking to price the value of the entire stack (i.e. all patents declared to the standard) to Apple, and then apportioning that price pro rata to Optis in line with Optis' stake in the stack (see our [blog](#)). That ultimately led to the court landing on a total lump sum royalty of \$56.43m (excluding interest) over the 11 year term of the licence.

Optis considered the court's valuation too low and appealed its assessment on 11 grounds (with 14 additional grounds of appeal raised on other licence terms determined by the High Court).

The Court of Appeal agreed with Optis that the judge had made fundamental mistakes by rejecting the expert evidence before him and then adopting his own approach to calculating the FRAND rate. Instead, he should have applied a conventional comparables approach - using the unpacked data from the expert evidence, selecting the best comparable licence or licences, and then deriving a rate (per unit or percentage of average selling price) from there.

In spite of this finding, the Court of Appeal concluded that it wasn't necessary to order a retrial. Instead, it went on to choose five licences as the best comparables (one from Optis, four to Apple) and used those to calculate an estimated dollar per unit rate of \$0.15 - a figure which was between the unit rates derived from the Optis and Apple licences, once placed on a common scale. That rate was then converted into a lump sum payment of \$502m (excluding interest), resulting in a roughly tenfold increase in the amount Apple has to pay compared to the lump sum determined by the High Court.

This is another important decision in the SEP space, clarifying the approach the English courts should take when assessing FRAND royalties. It re-establishes the role and importance of expert evidence and unpacking, and provides further support for a broad brush approach - in line with the Court of Appeal's earlier decision in *InterDigital v Lenovo* (see our [blog](#)).

This decision will no doubt be looked on favourably by SEP holders and indicates that the English courts may not be as implementer-friendly as recent decisions may have suggested - although the final sum still remains a long way off from the amount Optis had contended for at trial (which was as large as \$7.4bn).

See our recent [blog](#) for more details.

Interim SEP licence declarations

There have been three recent UK Court of Appeal decisions in which the court has considered declarations about whether a willing licensor in the position of the SEP owner would enter into an interim licence of its SEPs pending determination of the terms of a FRAND licence between the parties - *Panasonic v Xiaomi* (which we covered in our [November 2024 edition](#)), *Alcatel v Amazon* and *Lenovo v Ericsson* (both considered below).

In all three cases, the Court of Appeal has shown its willingness to grant such a declaration, overturning the first instance decision in each case. And, in all three cases, the decision appears to have focussed the parties' minds as all three disputes settled shortly after the respective declaration was made (or, in Amazon's case, permission was granted to amend their case to include a claim for such a declaration).

Either way, the upshot of these decisions is that they highlight the UK's continued status as one of the key

jurisdictions for determining SEP and FRAND licensing disputes.

Alcatel v Amazon

In [Alcatel v Amazon](#), the Court of Appeal held that Amazon had a real prospect of success on their claim for a declaration that a willing licensor in Nokia's position would grant Amazon an interim licence. Amazon was therefore granted permission to amend its pleadings to advance that claim.

The case concerned RAND (reasonable and non-discriminatory) obligations affecting certain video technology patents declared essential to the International Telecommunication Union Telecommunication Standardization Sector (ITU-T), rather than FRAND obligations affecting SEPs declared essential to European Telecommunications Standards Institute (ETSI) standards. Despite this, and the fact that the RAND obligations under the ITU-T standard are subject to Swiss law (as against French law under the ETSI standard), it wasn't suggested that there was any material difference between the two.

Amazon's initial application to advance a claim for an interim licence was refused by the Patents Court - largely because the court found that whilst the RAND commitment may have given rise to an enforceable obligation to enter into good faith negotiations for a RAND licence, it did not see how that lead to the conclusion that Nokia must agree to enter into an interim licence. As a result, the court found that Amazon's application to amend its statement of case should be refused because the proposed amendment had no real prospect of success.

In any event, the Patents Court said it "would have been inclined to refuse" the application to amend on case management grounds, on the basis that any interim licence would have to be on RAND terms and that determining such terms would be complex and time-consuming and would effectively lead to the court needing to hear two RAND trials.

Amazon appealed on two grounds. Firstly, that the Patents Court was wrong to find that Amazon's claim to an interim licence had no real prospect of success (relying on the Court of Appeal's decision in *Panasonic v Xiaomi*). Secondly, that if and to the extent that permission was refused on case management grounds, the court was wrong to do so.

The Court of Appeal allowed the appeal on both grounds. Whilst there were factual differences between this case and *Panasonic v Xiaomi* (including that, unlike Panasonic, Nokia hadn't commenced any proceedings in the UK seeking the determination of (F)RAND terms and Nokia hadn't given an undertaking to the Patents Court to enter into a licence on court-determined (F)RAND terms), the Court of Appeal found that Amazon had a real prospect of successfully arguing that none of those differences is material and therefore that *Panasonic v Xiaomi* is legally indistinguishable.

As for the case management side of things, the Court of Appeal agreed with Amazon that the claim to an interim licence would not lead to two RAND trials of the same scope. The application for an interim licence would be much simpler and only require the court to determine whether Amazon is entitled to such a licence and, if so, on what terms (with the interim licence being designed to "hold the ring" pending determination of the terms of the final RAND licence).

Previous cases have shown that this can be done in relatively short order - with both the *Panasonic v Xiaomi* and *Lenovo v Ericsson* (see below) interim licence hearings only taking three days. The Court of Appeal felt that the *Amazon v Alcatel* hearing may have taken even less time given: (i) the court would have the benefit of the Court of Appeal's decisions in the Panasonic and Lenovo cases; (ii) two of the distinguishing features relied upon by Nokia also arose in the *Lenovo v Ericsson* case; and (iii) there should be little need for argument over the terms of the interim licence as Amazon suggested that the scope should match the scope of the final licence offered by Nokia, leaving only the price open for argument (which the court said shouldn't take much time as the amount would be adjustable in light of the final determination in any event).

The Court of Appeal therefore granted Amazon permission to amend its pleadings to advance a claim for a declaration that a willing licensor in Nokia's position would grant Amazon an interim licence. Two months later, in March 2025, Nokia and Amazon settled their dispute.

Lenovo v Ericsson

In **Lenovo v Ericsson**, the Court of Appeal agreed to grant a declaration that a willing licensor of a portfolio of SEPs declared essential to the ETSI standard in Ericsson's position would grant an interim licence to Lenovo, as an implementer of

those standards who had undertaken to take a licence of those SEPs on UK court-determined FRAND terms.

The essential question before the Court of Appeal in this case was whether *Panasonic v Xiaomi* was a decision confined to the specific facts of that case or whether it is of more general application. The court's findings confirmed it to be the latter.

The facts of the case are that both Lenovo and Ericsson have a portfolio of SEPs declared essential to the ETSI 4G and 5G standards. Both parties are therefore SEP owners and implementers, but Lenovo were the net implementer (i.e. they would be the ones paying under a FRAND cross-licence).

Lenovo (as net implementer) instigated the English proceedings, seeking, amongst other things, the determination of FRAND terms for a global cross-licence. They also gave an undertaking to the English courts to enter into a licence on terms determined by the Patents Court to be FRAND. Ericsson gave no undertakings to the English courts and continued to pursue claims for injunctions against Lenovo in a number of jurisdictions (including the US, Brazil and Colombia).

Lenovo's position was that given they had undertaken to enter into a global cross-licence on UK court-determined FRAND terms, there could be no justification for Ericsson pursuing claims for injunctions against Lenovo in other jurisdictions. The only purpose of Ericsson doing so, Lenovo submitted, would be to place pressure on Lenovo to agree to terms which are more favourable to Ericsson than any UK court-determined terms would be.

Ericsson's position was that they were entitled to enforce their SEPs in any court or tribunal of competent jurisdiction unless and until Lenovo actually enter into a cross-licence. They also sought to distinguish their case from *Panasonic v Xiaomi* on three grounds - unlike Panasonic: (i) Ericsson had not invoked the jurisdiction of the English courts to determine global FRAND terms; (ii) Ericsson had not undertaken to enter into a cross-licence on UK court-determined FRAND terms; and (iii) if any court is to determine what terms are FRAND, it should be the EDNC (the Federal Court for the Eastern District of North Carolina), which was first seised of the dispute, not the English courts.

At first instance, the Patents Court refused to grant the requested declaration to Lenovo. Lenovo appealed on four grounds, namely that the judge was

wrong to conclude that: Ericsson's obligation of good faith did not require it to enter into an interim licence; the interim licence proposed by Lenovo was not FRAND; the declaration sought by Lenovo would serve no useful purpose; and making the declaration would be contrary to comity.

The Court of Appeal agreed and allowed the appeal on all grounds. In particular, it found that:

- Whilst Ericsson's conduct was not as egregious as Panasonic's, it was in breach of its obligation to negotiate a FRAND licence with Lenovo in good faith by pursuing claims for injunctions in foreign courts and tribunals, despite Lenovo having undertaken to enter into a licence on terms determined by the Patents Court to be FRAND and offered to submit to determination of FRAND terms by the EDNC. In the Court of Appeal's eyes, Ericsson was seeking to coerce Lenovo into accepting terms more favourable to Ericsson than the English courts would determine to be FRAND.
- Ericsson's argument that it was simply seeking to exercise its legal rights was not made out. The Court of Appeal noted that the whole point of an SEP owner's ETSI obligation is that it is a derogation from the patentee's normal right to enforce its patents by means of an injunction and the purpose and effect of an obligation of good faith is to act as a constraint upon a party's ability to enforce its strict legal rights solely with regard to its own interests.
- A willing licensor in the position of Ericsson would enter into an interim licence with Lenovo pending determination of FRAND terms.
- As per *Alcatel V Amazon* (see above), an application for an interim licence declaration does not require the court to determine most of the issues which will arise in the FRAND trial. It is simply intended to "hold the ring" pending determination of the final terms.
- The declaration sought by Lenovo would serve a useful purpose in forcing Ericsson to reconsider its position.
- With respect to comity, if the declaration does induce Ericsson to reconsider its position and to grant Lenovo an interim licence, that would

promote comity because it would relieve the courts and tribunals in other jurisdictions of burdensome and wasteful litigation. If, on the other hand, Ericsson decide to ignore the declaration and to pursue proceedings elsewhere, it will be for those courts/tribunals to make their own assessment of the parties' conduct and to decide what, if any, relief to grant Ericsson for any infringements that are established.

As for the terms of the interim licence itself, the Court of Appeal applied the approach taken in *Panasonic v Xiaomi* and set the sum payable by Lenovo as the mid-point figure between Lenovo and Ericsson's pleaded offers (adjustable in accordance with the Patents Court's determination of FRAND terms for the final cross-licence).

Following the Court of Appeal's judgment, Ericsson refused to accept the interim terms and the Court of Appeal declared it to be an unwilling licensor and in breach of its FRAND obligations. Shortly afterwards, Ericsson and Lenovo agreed to enter into binding arbitration to determine final terms for a global patent cross-licence and to settle all pending litigation worldwide.

UK COURTS CONSIDER THE GRANT OF INTERIM INJUNCTIONS AGAINST GENERIC ENTRY

A recent dispute between AstraZeneca (AZ) and Glenmark has led to a flurry of decisions relating to the grant of interim injunctions against generic entry. These decisions provide helpful guidance on the application of the test laid down in *American Cyanamid* in the context of generic entry and emphasise the importance of preserving the status quo where it is not possible to form a reliable view as to which side is more at risk of receiving an inadequate remedy in damages and where the duration of the injunction is expected to be short.

The dispute itself centres around the planned launch of Glenmark's generic version of a prescription-only medicine called dapagliflozin, which is used in the treatment of Type-2 diabetes.

AZ owns two UK Supplementary Protection Certificates (SPCs) relating to dapagliflozin, both of which are due to expire in May 2028. Those SPCs are based on a European patent (UK) (the "Patent") which expired in May 2023.

In an effort to clear the way for generic entry, Glenmark, along with two other generic companies, brought proceedings to revoke the SPCs, arguing that the Patent on which the SPCs are based is invalid.

Shortly before the revocation trial commenced, Glenmark informed AZ that it had obtained a marketing authorisation for its dapagliflozin product and that it planned to launch that product "at risk" (i.e. prior to the court's determination of the revocation action and in the knowledge that AZ might bring proceedings against it for infringement of the SPCs). In response, AZ applied for an interim injunction against Glenmark to prevent it from selling its dapagliflozin product in the UK until the form of order hearing (FOO hearing) following the trial, which the parties estimated would take place between one and three months later.

The High Court heard the application shortly after the conclusion of the revocation hearing and ultimately decided against granting an injunction, applying the classic *American Cyanamid* guidelines - the decisive factor being that the judge considered damages to be an adequate remedy for AZ as they could be 'calculated to a reasonably high degree of accuracy'.

In reaching that conclusion, the judge found that if Glenmark were the sole generic entrant prior to the FOO hearing, the quantity of products Glenmark sold over that period would be known, every such sale would be a lost sale to AZ and AZ had an established profit margin per pack, so the damages to AZ could be calculated. The court also found it "highly unlikely" that AZ would reduce its list price in the period before the FOO hearing and, even if it did, there was no evidence that it wouldn't be able to reverse that without obstacle. The judge went on to reach the same conclusion even if other generics were to enter the market before the FOO hearing.

In contrast, the judge found that it would be significantly more difficult to quantify the damages due to Glenmark if an interim injunction were granted and the SPCs were later revoked. Damages would not therefore be an adequate remedy for Glenmark.

AZ appealed and put forward new evidence which indicated that, if no injunction was granted, at least two other generic companies would enter the market prior to the FOO hearing; that would likely happen more quickly than the judge had anticipated; and that would quickly lead to price competition between the generic entrants and consequently a downward price spiral. In that context, AZ would likely have to reduce its price for dapagliflozin and it would be difficult for AZ to restore its price even if the generic entrants were later excluded from the market.

The Court of Appeal accepted this and, when considered in conjunction with the potential damage to AZ arising after the FOO hearing due to Glenmark and other generic entrants having come onto the market, the Court of Appeal found that there was 'real doubt as to the adequacy of damages for both parties'.

Given that it was impossible to conclude which side was more at risk of receiving an inadequate remedy in damages, and that the injunction would cover only a short period of time, the Court of Appeal concluded that it would be 'prudent to preserve the status quo until the conclusion of the FOO Hearing'. This conclusion was reinforced, in the Court of Appeal's opinion, by (i) Glenmark's failure to 'clear the path' before its intended launch and (ii) its 'jumping [of] the gun' by seeking to launch its dapagliflozin product in the middle of the validity trial, without waiting for judgment.

The result of this was that the Court of Appeal overturned the High Court's decision and granted the injunction sought by AZ.

But that's not the end of the story! Twelve days later, the High Court handed down its decision in the validity trial, finding that the Patent and the SPCs were invalid. AZ appealed and sought an interim injunction to restrain Glenmark and a number of other generic manufacturers from marketing their dapagliflozin products pending the resolution of that appeal (a period expected to be within the region of 4-8 weeks). For similar reasons to those given by the Court of Appeal in its earlier decision, the High Court found that each side would likely suffer irreparable harm if the decision to grant an injunction or not went against them. In those circumstances, and given the limited duration of the injunction sought, the court again concluded that it was appropriate to maintain the status quo and grant the injunction.

GENERAL IP

UKIPO CONFIRMS UK+ EXHAUSTION REGIME

The UKIPO has recently **confirmed** that the UK government has chosen to maintain the UK+ exhaustion of rights regime.

At its simplest, registered and unregistered IP rights (such as trade marks, patents, design rights and copyright) enable IP rights holders to control the first sale of their goods on the market. However, the principle of exhaustion sets a limit on the ability of IP rights holders to control the further distribution of genuine goods that have been placed on the market by them or with their consent.

Whilst the UK was part of the EU, it was subject to a system of EEA exhaustion. This meant that IP rights in goods first placed on the market in the EEA by the rights holder or with their consent were considered exhausted in all other EEA countries. The practical effect of this was that goods placed on the market in one EEA state could be parallel imported into another EEA state (including the UK) without needing the rights holder's permission.

Following Brexit, on 1 January 2021, the UK moved to a non-reciprocal system - commonly referred to as the UK+ system - in which the UK unilaterally participates in the EEA regional exhaustion regime. This means that IP rights in goods first placed on the market in the EEA are considered exhausted in the UK (i.e. they can be imported from the EEA into the UK without needing the UK rights holder's consent). But IP rights in goods first placed on the market in the UK are not considered exhausted in the EEA. So, anyone wanting to parallel export legitimate goods from the UK to any EEA state has to obtain permission from the rights holder before exporting the goods.

In June 2021, the UKIPO launched a consultation to gather views on whether this was the correct approach or whether an alternative exhaustion regime should be put in place. Four different options were put forward for consideration.

- (1) Keep the current status quo and stick with the UK+ system.
- (2) Adopt a system of "national" exhaustion, such that IP rights would be considered exhausted in the UK only if the relevant goods

have been put on the market in the UK. Under this regime, there would be no ability for businesses to parallel import goods from outside the UK into the UK without obtaining permission from the relevant UK rights holder(s).

- (3) Adopt a system of “international” exhaustion. This is the polar opposite of a national system and would mean that IP rights in goods would be considered exhausted in the UK once they have been legitimately put on the market in any country in the world. As a result, goods could be parallel imported into the UK from any such country without needing to get the UK rights holder’s permission.
- (4) Adopt a “mixed” regime. This is a regime where a specific good, sector or IP right is subject to one regime and all other goods, sectors and IP rights are subject to a different regime.

The UK government has now finally confirmed that it will be maintaining the UK+ regime, bringing much needed certainty to UK businesses.

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CONTACTS

If you would like to discuss any of the above in more detail, please contact your relationship partner or email one of our IP team.

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