Arrow declarations: exploiting court flexibility to clear a path to market

Given the difficulty of clearing a path to market for generics and biosimilars, Arrow declarations can serve as a valuable defensive litigation tool in the United Kingdom when patent invalidation or non-infringement judgments are difficult to obtain

By Peter Damerell and William Hillson

Getting a pharmaceutical product to market takes significant technical development and investment, so why would a manufacturer ask the courts to make a public declaration that its products are un inventive? This may seem like a counterintuitive course of action given the importance of protecting products with a solid portfolio of IP rights. However, when faced with a steady stream of pending divisional patents, it can mean the difference between successfully launching a product and being subjected to a costly injunction.

With the expiry of many basic patents that protect blockbuster drug substances, research into new formulations, dosing regimens and specialised manufacturing processes is becoming increasingly important for pharmaceutical originators wishing to further improve their products and to mitigate the effects of generic or biosimilar competition. Wherever possible, these technical developments are protected by patent applications. The sheer volume of applications, together with the time taken to prosecute them, often leads to numerous patents and patent applications that protect reference pharmaceutical products.

In the United Kingdom, generic and biosimilar manufacturers tend to clear the way before launching their products in order to avoid preliminary injunctions that might affect a product launch. For granted patents, it is possible to apply for revocations or declarations of non-infringement. However, broad parent patent applications with cascades of divisional applications can be a headache for generic and biosimilar manufacturers as:

• it will be unclear what, if anything, will be the subject of granted patents; and
• the validity of pending applications cannot be challenged.

The courts of England and Wales have recently confirmed that there is a potential solution to this problem, which both pharmaceutical originators and generic and biosimilar manufacturers should be aware of: the Arrow declaration.

Origin of the Arrow declaration: the Gillette defence
The Arrow declaration is, in effect, an elaboration of the Gillette defence, named after a 1913 case in which the defendant became the first party to argue successfully that its allegedly infringing product was identical to a piece of prior art. Once this fact had been established, it was unnecessary for the defendant to establish that its product was non-infringing or that the claimant’s patent was invalid, as the claimant would lose regardless. If the claimant continued to argue that the patent covered the defendant’s product, the patent would also cover the prior art and be invalidated for lack of novelty. However, if the claimant tried to preserve its patent, the defendant would escape infringement. As the House of Lords (then the United Kingdom’s highest court) pointed out in its judgment, since it had already been established that there was no outcome in which the patentee could win, the defendant had a good legal defence and so the court did not need to undertake the effort and expense of investigating the matter further.

Since 1913 the Gillette defence has remained an important part of UK patent law, often deployed as a squeeze argument to constrain patentees in relation to both validity and infringement issues. In the original Gillette case, the defendant was fortunate enough to have a clearly novelty-destroying piece of prior art, but the situation can be somewhat murkier when the prior art falls short of a clear-cut anticipation.

However, it is logical that if a defendant’s product differs from the prior art only in a manner that was an obvious or trivial step at the priority date, it cannot infringe the patent unless the patent itself is also invalid for obviousness. However, this opens the door to another related possibility – if the obviousness or lack of novelty of a defendant’s own product can be used as a shield, can it also be used as a sword?

Given the flexibility inherent in the UK system when it comes to the availability of declaratory relief, could a manufacturer facing a number of pending patent applications whose validity cannot be challenged apply directly to the courts for a positive declaration that its own product was obvious in light of the prior art at the priority date? Such a declaration could immunise it against any future infringement proceedings, regardless of the form in which these patent applications are eventually granted.

Flexibility of declaratory remedies
Although no such remedy is provided for specifically in the Patents Act 1977 (the primary UK legislation implementing the European Patent Convention), the courts of England and Wales have inherent jurisdiction to devise equitable remedies when no adequate remedy
is provided for by statute. While this does not mean that the courts have carte blanche to devise remedies as they see fit, it does grant them considerable flexibility when dealing with fact-specific situations that arise in particular cases.

With regard to declaratory relief specifically, the Civil Procedure Rules (which govern the conduct of civil litigation in England and Wales) explicitly state that “the Court may make binding declarations whether or not any other remedy is claimed”. Such declarations can relate to matters of either fact or law and may be positive or negative in nature. The courts have been willing to grant such declarations where they will serve a useful and valuable commercial purpose, even if no legal dispute between the relevant parties exists when the declaration is sought. Before the rise of the Arrow declaration, the Patents Court granted a declaration of non-essentiality in respect of an allegedly infringing SEP relating to the telecoms industry in *Nokia v InterDigital*. Other cases have also seen declarations granted in relation to:

- consent;
- the exhaustion of rights; and
- whether licensing offers made by SEP owners were done on FRAND terms (ie, *Unwired Planet v Huawei*).

However, the fact that the courts of England and Wales have the power to make a binding declaration when there is a bona fide commercial reason for doing so does not mean that they will actually exercise it. Being an equitable remedy deriving (via a long lineage) from medieval theological concepts of justice, declaratory relief fundamentally rests on the moral question of whether it is fair to the parties in the circumstances to grant the remedy. As Mr Justice Neuberger put it in *FSA v Rourke*: “As between the parties… it seems to me that the court can grant a declaration as to their rights, or as to the existence of facts, or as to a principle of law, where those rights, facts, or principles have been established to the court’s satisfaction. The court should not, however, grant any declarations merely because the rights, facts or principles have been established and one party asks for a declaration. The court has to consider whether in all the circumstances, it is appropriate to make such an order.” ([2002] CP Rep 14.)

In deciding whether to exercise their jurisdiction to grant declaratory relief, the courts of England and Wales have developed a body of case law on how decisions to grant declarations should be made on a case-by-case basis. They must consider not only doing justice to each of the parties, but also whether the declaration serves a genuinely useful commercial purpose and (notwithstanding this) whether there are any special reasons or circumstances which mitigate either for or against granting the declaration. In *Nokia v InterDigital* the court held that:

- these criteria had been met because the essentiality (or lack thereof) of the patents at issue would have been an important (although not necessarily decisive) piece of information to parties seeking to negotiate a licence; and
- there was therefore a genuine commercial interest in providing certainty on this point.

**Arrow v Merck – first attempt**

*Arrow* declarations take their name from the 2007 case *Arrow v Merck* ([2007] EWHC 1900 (Pat)). This was the first decision in which the Patents Court recognised, in principle, a party’s right to seek a pre-emptive declaration of obviousness or lack of novelty in relation to a product. In this case, the patentee (Merck) had obtained a patent through the EPO protecting a specific weekly dosage regimen for the treatment of osteoporosis patients with the drug alendronate. Arrow had successfully revoked the UK designation through the

**TABLE 1. Summary of key cases relating to Arrow declarations in the United Kingdom**

<table>
<thead>
<tr>
<th>Parties</th>
<th>Court</th>
<th>Date</th>
<th>Strike-out application or full trial?</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrow v Merck [2007] EWHC 1900 (Pat)</td>
<td>High Court</td>
<td>July 2007</td>
<td>Strike-out application</td>
<td>Application rejected – claim for <em>Arrow</em> declaration allowed to proceed</td>
</tr>
<tr>
<td>FKB v AbbVie [2016] EWHC 425 (Pat)</td>
<td>High Court</td>
<td>March 2016</td>
<td>Strike-out application</td>
<td>Application rejected – claim for <em>Arrow</em> declaration allowed to proceed</td>
</tr>
<tr>
<td>FKB v AbbVie [2016] EWHC 2204 (Pat)</td>
<td>High Court</td>
<td>September 2016</td>
<td>Strike-out application</td>
<td>Application rejected – claim for <em>Arrow</em> declaration allowed to proceed</td>
</tr>
<tr>
<td>FKB v AbbVie [2016] EWHC 3383 (Pat)</td>
<td>High Court</td>
<td>December 2016</td>
<td>Strike-out application</td>
<td>Application rejected – claim for <em>Arrow</em> declaration allowed to proceed</td>
</tr>
<tr>
<td>FKB v AbbVie [2017] EWCA Civ 1</td>
<td>Court of Appeal</td>
<td>January 2017</td>
<td>Appeal of strike-out application</td>
<td>Application rejected – claim for <em>Arrow</em> declaration allowed to proceed</td>
</tr>
<tr>
<td>FKB v AbbVie [2017] EWHC 395 (Pat)</td>
<td>High Court</td>
<td>March 2017</td>
<td>Trial</td>
<td><em>Arrow</em> declaration granted</td>
</tr>
<tr>
<td>Generics UK (t/a Mylan) v Yeda [2017] EWHC 2629 (Pat)</td>
<td>High Court</td>
<td>October 2017</td>
<td>Trial</td>
<td><em>Arrow</em> declaration refused</td>
</tr>
<tr>
<td>Glaxo v Vectura [2018] EWHC 375 (Pat)</td>
<td>High Court</td>
<td>February 2018</td>
<td>Strike-out application</td>
<td>Application rejected – claim for <em>Arrow</em> declaration struck out</td>
</tr>
<tr>
<td>Glaxo v Vectura [2018] EWCA Civ 1496</td>
<td>Court of Appeal</td>
<td>June 2018</td>
<td>Appeal of strike-out application</td>
<td>Appeal granted – claim for <em>Arrow</em> declaration allowed to proceed</td>
</tr>
<tr>
<td>Glaxo v Vectura [2018] EWHC 3414 (Pat)</td>
<td>High Court</td>
<td>December 2018</td>
<td>Trial</td>
<td><em>Arrow</em> declaration granted</td>
</tr>
</tbody>
</table>
Patents Court and opposed the grant at the EPO, with those decisions being upheld by both the Court of Appeal of England and Wales and the EPO’s Technical Board of Appeal. Having cleared the way, Arrow then launched its generic product in the United Kingdom and gained a large market share. However, during prosecution at the EPO, Merck had filed four divisional applications from the original parent application, one of which was subsequently granted by the EPO, despite covering essentially the same subject matter as the parent application that had already been declared invalid. Arrow was therefore faced with Merck asserting the newly granted divisional against it and the other divisional patent applications proceeding to grant. Merck had “vowed to enforce its intellectual property rights on the drug” and had brought proceedings against the Arrow group and other generic companies elsewhere in Europe based on the granted patent.

Arrow therefore commenced proceedings against Merck in court in which it sought to revoke the newly granted divisional. It turned out that before the mention of grant in the European Patent Bulletin, Merck had written to the EPO withdrawing the UK designation, which meant that the European (UK) patent was never granted and could thus not be revoked. However, Arrow also sought the court’s permission to amend its pleadings to seek declarations that:

- any other UK patent covering the same subject matter would be invalid; and
- Merck was not entitled to rely on the granted patent (or any related divisional application) to prevent Arrow from selling its alendronate product with the specified dosage regimen.

Arrow subsequently refined its application to a declaration that its own product was obvious at the priority date of the divisional applications. Essentially, Arrow sought to contend that at the priority date, it was obvious to the skilled person that the drug was a medicament with a specified dosage regimen. The purpose of this declaration was to provide Arrow with a *Gillette* defence if any of the other divisionals were granted covering the same subject matter.

As Merck did not consent to these amendments, the issue came before the courts. The court had to decide whether it had jurisdiction to grant the declaration and, if so, whether it was satisfied at the early stage of the proceedings that the claim had no reasonable prospect of success such that the amendments should not be allowed and the claim should be struck out. Arrow argued that the UK court had jurisdiction to grant such a declaration and that it was appropriate to do so because Merck had shown every intention of pursuing and relying on the divisional applications against Arrow in the United Kingdom and elsewhere. Therefore, there was both an issue between the parties and a real commercial need for the clarification sought. Merck argued that Arrow was attempting to undermine the validity of its pending divisionals (which is impermissible under the Patents Act, which does not include declaratory relief among its exhaustive list of scenarios in which a patent’s validity may be challenged).

Mr Justice Kitchin refused to strike out the claim, noting that the facts made it a “very unusual case”. He found that, by its refined declaration, Arrow was seeking not to challenge the validity of any of Merck’s divisional applications, but rather only a declaration of obviousness in respect of particular characteristics of its own product. He found that, if granted, the declarations would undoubtedly serve a useful purpose, stating as follows:

“There is a public interest in commercial certainty in patent matters as in any others. Business needs to know where it stands. I believe this court should assist in providing the certainty where it properly can. The declarations sought would provide Arrow with the assurance that its alendronate product cannot offend against Merck’s patent rights arising in this country from the remaining divisional applications. Accordingly, the declarations have a valuable commercial purpose.

The judge also considered that the declarations sought were sufficiently defined to make them properly justiciable. Arrow had identified the essential characteristics of its product and the prior art which it claimed rendered that product obvious, so the declaration was in respect of a clearly defined issue, which was readily susceptible to determination. The judge also concluded that there were no other special circumstances or reasons why the court should not grant the declarations sought. He noted that Merck could have:

- withdrawn the UK designations of its remaining divisional applications; or
- acknowledged that it could not claim under them in the United Kingdom in respect of Arrow’s product.

Either of these actions would likely have removed any commercial purpose of the declarations sought. However, Merck chose not to pursue them.

Arrow and Merck settled their dispute before the matter proceeded to trial. It therefore remained uncertain whether the courts of England and Wales would grant *Arrow* declarations and, if so, what conditions a successful applicant would need to meet.

**FKB v AbbVie – from theory to reality**

Fast forward 10 years to 2017, when the issue of *Arrow* declarations was raised again in *FKB v AbbVie*, which was part of a larger dispute between AbbVie and several manufacturers of biosimilars of its blockbuster anti-inflammatory antibody adalimumab (Humira).

The facts of *FKB* were not dissimilar to *Arrow*. FKB sought to launch its adalimumab biosimilar in the United Kingdom as soon as AbbVie’s supplementary protection certificate (SPC) protecting adalimumab

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**FIGURE 1. Example of sequence of divisional applications**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 0</td>
<td>Parent application</td>
</tr>
<tr>
<td>Year 8</td>
<td>First divisional application</td>
</tr>
<tr>
<td>Year 15</td>
<td>Second divisional application</td>
</tr>
<tr>
<td>Year 18</td>
<td>Third divisional application</td>
</tr>
</tbody>
</table>

Refused | Withdrawn | Granted
Divisional patent applications may be filed only for subject matter which does not extend beyond the content of the parent application. An application is deemed to have the same filing and priority date as the parent application.

A parent application can itself be a divisional application, allowing for chains of divisional applications.

Key considerations regarding divisional patent applications at the EPO

- Divisional patent applications may be filed only for subject matter which does not extend beyond the content of the parent application as filed.
- Divisional patent applications are deemed to have the same filing and priority date as the parent application.
- Divisional patent applications may be filed in respect of any pending earlier European patent application. An application is pending until:
  - the European Patent Bulletin mentions its grant; or
  - it is finally refused, withdrawn or deemed to be withdrawn.
- A parent application can itself be a divisional application, allowing for chains of divisional applications.

AbbVie had filed a large number of formulation, treatment regimen and manufacturing process patents relating to various medical uses of adalimumab with a number of divisionals, many of which were still pending at the EPO. During the period leading up to the SPC’s expiry, AbbVie senior management made repeated statements to the markets that the company intended to fully enforce all of its applicable IP rights. For regulatory reasons, FKB needed to use the dosing regimens authorised for Humira. FKB therefore launched revocation actions to clear the way of dosing regimen patents for a number of indications that had already been granted. Further, as divisional applications were still pending, it applied for Arrow declarations in respect of its own adalimumab biosimilar.

AbbVie applied to strike out FKB’s claims for Arrow declarations, arguing that Arrow had been wrongly decided and that the Arrow declarations were an impermissible attempt to challenge the validity of its pending patent applications. In two sets of proceedings, both Mr Justice Henry Carr and Mr Justice Arnold refused to strike out the claims and AbbVie appealed to the Court of Appeal. In FKB v AbbVie ([2017] EWCA Civ 1) the Court of Appeal upheld the first-instance decisions against the strike-out, confirming once again that Arrow declarations can in principle be granted to the effect that a given product was either not novel or obvious at the relevant priority date, thus providing a Gillette defence to any manufacturers and distributors of that product. The Court of Appeal clarified that the Arrow declarations sought would not declare any patent invalid. As regards the relationship between Arrow declarations and the statutory remedy of revocation, the court stated as follows:

*The eventual existence of the statutory remedy of revocation is, in our judgment, of relevance to the question of whether a declaration should be granted in the exercise of the court’s discretion. A claimant cannot seek an Arrow declaration simply because it would like to know whether a patent application in the course of prosecution will result in a valid patent. The course envisaged by the statute is that he should wait and see what, if any, patent is granted. The statutory remedy does not constitute a bar in principle to the granting of declaratory relief in appropriate cases, however. Where, for example, it appears that the statutory remedy is being frustrated by shielding subject matter from scrutiny in the national court, it should be open to the court to intervene. Just as in Nokia, the statutory remedy does not provide, in practical terms, the relief which the claimant needs.*

Later in 2017, the Patents Court held the first full trial on the granting of an Arrow declaration (FKB v AbbVie [2017] EWHC 395 (Pat)), finding that, on the facts of that case, the claimants were entitled to the declaration that their adalimumab biosimilars were obvious at the priority date. The key issue at trial was whether the declarations would serve a useful purpose.

AbbVie claimed that the declarations would not serve a useful purpose. It argued that it had taken steps leading to the revocation or withdrawal of all patents that were or might have been at issue in the proceedings and that, as such, no granted patents were at issue at the trial date. In particular, in relation to the two parent patents concerning the dosage regimen for use in rheumatoid arthritis and psoriasis, respectively, AbbVie had disapproved of the text of the patents at the EPO, which had had the effect of revoking them centrally. A divisional relating to rheumatoid arthritis was subsequently granted and AbbVie de-designated that patent for the United Kingdom only. As such, no European (UK) patent was granted. AbbVie also argued that it had given the court clear and unambiguous undertakings, which were just as useful as the relief sought by the claimants, including the undertaking not to obtain in the United Kingdom patent protection that would be infringed by the claimants’ products. However, AbbVie had refused to submit to judgment, which would have ended the proceedings and resulted in the grant of the declarations.

The claimants argued that the declarations would serve a useful purpose (and that this was why AbbVie had refused to submit to judgment) – namely, by:

- removing confusion in the marketplace;
- promoting settlement;
- preventing interference with the claimants’ supply chains between Europe and the United Kingdom; and
- influencing other courts throughout Europe.

The claimants also argued that AbbVie’s proposed undertakings were part of an established course of conduct, whereby AbbVie had dragged out proceedings
for as long as possible while threatening to sue for infringement only to abandon its patent rights at the last moment and file further divisionals with similar claims. The claimants argued that this strategy was designed to encourage market uncertainty, while shielding AbbVie’s patents from the risk of a finding of invalidity by the courts of England and Wales.

Mr Justice Henry Carr decided that the declarations would serve a useful purpose for the following reasons:

- The declarations would provide commercial certainty. It was held that the intention and objective effect of AbbVie’s conduct was to shield its patent portfolio from examination of validity while continuing to file further divisionals and threaten infringement proceedings against biosimilars, wherever they may be launched. Given that AbbVie had threatened to enforce its patents against biosimilar competition worldwide, the declarations would serve a useful purpose of dispelling the commercial uncertainty which those threats had created in the UK (and European) market.

- AbbVie’s proposed undertakings did not remove the useful purpose afforded by the declarations. They did not acknowledge that the claimants’ products were anticipated or obvious at the priority date. The declarations, by contrast, provided clarity for third parties in the United Kingdom, which was necessary given AbbVie’s conduct and would not be provided by the undertakings.

- The declarations would serve an additional useful purpose in protecting the claimants’ supply chains for the UK market, which involved other European countries. Any injunction in those countries would have had an impact on the supply of products to the UK market, and the grant of the declarations would make such injunctive relief in other jurisdictions less likely.

- The declarations would also assist in promoting settlement.

**Post FKB – opening the floodgates?**

Following the judgment granting the Arrow declaration in FKB, there has been debate as to how frequently and in what circumstances the courts of England and Wales will grant Arrow declarations. One of AbbVie’s rejected arguments in favour of the strike-out had been that granting permission for Arrow declarations would open the floodgates to such claims, but the Court of Appeal was not persuaded and stated that “the circumstances in which such declarations will be justified, will, we would have thought, be uncommon”. The judge then stressed the “most unusual facts of this case” when granting FKB’s Arrow declaration.

There have been two key cases relating to Arrow declarations since FKB:

- **Generics UK (trading as Mylan) v Veda** ([2017] EWHC 2629 (Pat)); and
- **Glaxo Group v Vectura** ([2018] EWCA Civ 1496 and [2018] EWHC 3414 (Pat)).

In Generics the claim for an Arrow declaration made it to full trial, but was ultimately refused. As in previous cases, the claimants sought the revocation of a patent already granted in the United Kingdom and an Arrow declaration for their products to defend themselves against two further pending divisionals which they claimed covered the same subject matter. The applicants tried to rely on similar arguments to those that were successful in FKB, but Mr Justice Arnold held that the factual circumstances were different and that the applicants were not entitled to the same relief. The key difference was that the validity of a granted patent had been considered, with the patent revoked. In the circumstances, the judge considered that granting an Arrow declaration would provide no additional commercial certainty. If the pending divisionals were granted covering exactly the same ground, the claimants would be able to seek summary judgment for revocation of those patents. As the patentee would be stopped from re-litigating issues already decided at trial, the claimant would have adequate protection without an Arrow declaration. For similar reasons, a declaration was also found to have no additional collateral value in other jurisdictions over and above the invalidity judgment.

The more recent case of Glaxo provided the first opportunity for the Court of Appeal to revisit its judgment in FKB and offer further guidance on Arrow declarations to the lower courts. In this case, the first-instance judge had distinguished the factual circumstances from FKB and granted Vectura’s (the patentee’s) request to strike out Glaxo’s application for an Arrow declaration. On appeal, Glaxo argued successfully that Vectura had an established history of amending the language of multiple independent patents during prosecution so that they converged on covering essentially an identical inventive concept, and the Court of Appeal agreed that this could, in principle, justify an Arrow declaration. The Court of Appeal also clarified that a valid Arrow declaration need not specify every detail of the obvious product or process; rather, it need only contain enough detail to identify every feature of the product that the applicant claims was obvious.

“Although the largely uncodified practices of UK common law and equity may produce uncertainty, they also offer a considerable advantage over more rigid civil law jurisdictions when the courts encounter unprecedented situations”

When the Glaxo case returned to trial in the Patents Court, the Arrow declaration was granted. As in FKB, Vectura had offered an undertaking and argued that the Arrow declaration would therefore serve no useful purpose. However, Glaxo argued that the undertaking did not provide the required certainty. Mr Justice Arnold stressed the following unusual combination of circumstances in the case when finding that the Arrow declaration would serve a useful purpose:

- Although the granted patents were found to be invalid (as in Generics), this was on the basis of insufficiency rather than obviousness, so the invalidity judgment on its own did not provide Glaxo with certainty that other patents covering the same invention would be held to be invalid. In addition, Vectura’s allegation of infringement had failed because the analytical technique that it had used was incapable of proving...
Although Arrow declarations are likely to remain fairly uncommon, they raise key considerations for generics and originators. Generic and biosimilar manufacturers should bear in mind the following considerations:

- When assessing the prior art for patent validity challenges in the United Kingdom, manufacturers should consider its novelty-destroying or obviousness effects not only in relation to the patent that they seek to revoke, but also in relation to their own products.
- It should be considered whether an Arrow declaration would help to resolve commercial uncertainty in the United Kingdom and beyond and whether the factual circumstances are such that it could be granted.
- Other alternatives must be exhausted before an Arrow declaration may be granted, such as seeking to clear the way of granted patents with revocation actions.
- The product or process for which an Arrow declaration is sought must be defined in sufficient detail for the declaration to be granted.
- Records of statements by originators about the enforcement of future pending patent rights should be kept.

Originators should:

- acknowledge the risk of Arrow declaration applications in the United Kingdom and consider ways to mitigate this;
- bear in mind the significance of the patentee’s conduct in the court deciding whether to exercise discretion and avoid the perception of attempting to shield patents from the scrutiny of the English courts;
- consider the potential adverse consequences of making expansive statements to the market about enforcing IP rights for pending patents; and
- consider which undertaking or assurances about the scope or use of pending patent applications they might be willing to concede to avoid the risk of an Arrow declaration.

In 2017 Synthon and Yeda also undertook proceedings in the Netherlands. In that case, the court, like the courts of England and Wales, rejected the request for Arrow-type declaratory relief, albeit for somewhat different reasons. After considering the English judgment in FKB, the Dutch judge decided that the facts were different. In FKB the judge had concluded that it was still possible for other patents relating to the same subject matter as the revoked patent to be granted in the United Kingdom, whereas in Yeda the patentee had withdrawn all of the Dutch designations of the patents at issue and removed any possibility of further divisionals. A declaration would therefore be of collateral value in other jurisdictions only, which the judge held was not sufficient reason to grant a declaration that would have effect only in the Netherlands.

### Strategic implications

The Arrow declaration provides a potentially important strategic tool for patent litigation in the United Kingdom, as it enables parties to obtain some certainty in respect of pending patent applications whose validity cannot be challenged in the courts. However, as the grant of declarations is a discretionary remedy, it will not always be appropriate for Arrow declarations to be granted, as shown by the cases discussed here.

In practice, Arrow declarations are unlikely to be granted routinely just because there are pending divisionals in a patent family. Special circumstances will be required to warrant the grant of the declaration. In both Arrow and FKB, important factors included:

- the patentee’s public threats to assert the patents against companies launching competing products; and
- the fact that there were no remaining granted patents for the court to consider.

Both cases also involved the patentees taking steps to prevent the court from scrutinising the validity of their patents, although this was identified as a relevant factor in the grant of the declaration in FKB only. Such behaviour was absent in Generics, which appears to have been part of the reason why the Arrow declaration was refused, while in Glaxo there was found to be sufficient evidence of a history of behaviour by the patentee to warrant the declaration. Although the patentee’s conduct appears to have been one of the key factors in the decisions to date, the wide discretionary nature of declaratory relief means that other factors may be decisive in future cases.

This open-ended flexibility is perhaps the most important attribute of Arrow declarations. Although the largely uncodified practices of UK common law and equity may produce uncertainty, they also offer a considerable advantage over more rigid civil law jurisdictions when the courts encounter unprecedented situations. This is the true domain of Arrow declarations – not as a routine aspect of defensive litigation, but as a way out of unusual situations where the traditional approaches of seeking to revoke a patent or declaration of non-infringement do not provide the certainty required to resolve a dispute.

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