



Another arrow in the quiver

GSK succeeds in obtaining an Arrow declaration in its UK patent case against Vectura

Introduction

In the recent case of *GSK v Vectura*¹, GSK successfully obtained an *Arrow* declaration in respect of its dry powder inhaler products which Vectura asserted infringed its patents. The decision is significant as it is only the second occasion on which the UK Courts have actually granted such a declaration. It therefore provides a valuable illustration of the sort of circumstances which may encourage UK judges to grant such relief, namely a declaration that a specific intended commercial product would have been obvious at a specific date (usually the priority date of the patent(s) which it would be at risk of infringing). Such declarations take their name from the first case in which an application of its kind was made, in *Arrow v Merck*², and have recently been the focus of attention in other UK cases.

The facts in *GSK v Vectura*

Vectura owns a suite of patents relating to the delivery of drugs by inhalation. Common to all these patents is the concept of using magnesium stearate to form “composite active particles”,

which are forms of the chosen active pharmaceutical ingredient structurally modified to improve drug delivery.

In 2010, GSK and Vectura entered into an agreement under which GSK took a licence to a set of patents known as “Staniforth” and had an option to take additional licences to a set of later patents called the “Non-Assert Patents”. Since the grant of the original licence, GSK has marketed its product Ellipta™ and paid significant royalties until the Staniforth patents expired on 31 January 2016.

On 8 February 2016 GSK informed Vectura that it did not consider that it needed to exercise its option under any of the Non-Assert Patents. Vectura maintained that GSK’s products infringed them. In response, GSK commenced proceedings seeking declarations that:

1. its products did not infringe the Non-Assert Patents;
2. the Non-Assert patents were, in any event, invalid for insufficiency and obviousness and should be revoked; and
3. GSK’s products were obvious at the priority date of the Non-Assert Patents, on the basis they were an obvious development over the Staniforth patents (*i.e.* an *Arrow* declaration).

¹ [\[2018\] EWHC 3414 \(Pat\)](#)

² [\[2007\] EWHC 1900 \(Pat\)](#)

(Although Kitchin J, as he then was, refused to strike out Arrow’s application for such a declaration, the matter did not proceed to final judgment.)



The decision

Arnold J held that the Non-Assert Patents were themselves invalid for lack of sufficiency but rejected GSK's claims that they were obvious. He further held that Vectura had been unable to establish that GSK's products infringed the Non-Assert Patents.

These findings – that the patents in suit are invalid and not infringed – are significant (indeed such findings would normally be determinative in such a case), but the Court went on to consider the *Arrow* declaration request. Here, Arnold J held as a finding of fact that GSK's processes (and the products obtained directly from them) were indeed an obvious development over the Staniforth patents. However, that alone is not enough to justify a court granting the requested declarations. Arnold J reiterated the requirement that a declaration had to serve a "useful purpose" beyond the actual finding of obviousness. The significance of this additional requirement is illustrated by his previous decision in *Generics (UK) v Yeda Research and Development*³ where Arnold J came to a similar finding (that the claimant's product in suit was obvious) but no *Arrow* declaration was granted.

Useful purpose

The considerations that the UK Court should take into account when considering whether or not to grant an *Arrow* declaration were summarised in *Fujifilm Kyowa Kirin Biologics ("FKB") v AbbVie*⁴ (the first occasion on which the UK Court granted an *Arrow* declaration), as follows:

1. justice to the claimant;
2. justice to the defendant;
3. whether the declaration will serve a useful purpose. The attainment of commercial certainty in patent cases can constitute a useful purpose. The spin-off value of a judgment in other countries may also be such a factor, but a declaration sought solely for the benefit of foreign courts will rarely be justified; and

4. whether or not there are any other special reasons why the court should or should not grant the declaration.

GSK contended that the *Arrow* declaration was essential in the circumstances in order to obtain commercial certainty. It alleged that Vectura had pursued a strategy of filing multiple applications to create a thicket of patents covering essentially a single technical concept – the use of magnesium stearate for formulations for dry powder inhalers – by casting successive applications in different terminology, and in one instance framing a divisional to deliberately catch GSK's products. GSK said it would not obtain commercial certainty even if it succeeded in having all of the Non-Assert Patents revoked, since Vectura had the potential to continue to reformulate the inventive concept using applications which were still on file, and it was not possible to say what forms the final claims would take until grant.

Vectura argued that GSK could obtain commercial certainty from an undertaking given by Vectura early in proceedings, which provided that, if none of the claims of the Non-Assert Patents were found valid and infringed at trial, Vectura would not sue GSK under any future divisionals arising out of the Non-Assert Family. GSK said this did not provide certainty since Vectura continued to formulate the inventive concept in patent families that are distinct from the Non-Assert Patent families. Considering these arguments, Arnold J identified an "unusual combination of circumstances":

- Vectura had failed to establish infringement of the Non-Assert Patents because it had not been able to identify a suitable analytical technique to demonstrate that certain requirements of the claims were satisfied. Vectura would not necessarily face the same difficulty based on future divisionals with differently formulated claims.

³ [2017] EWHC 2629 (Pat)

⁴ [2017] EWHC 395 (Pat)



- The Non-Assert Patents had not themselves been found obvious (they had been found to lack sufficiency), and it would be an open question as to whether patents with differently formulated claims were obvious or not.
- Most significantly (according to Arnold J), Vectura had given an undertaking designed to give GSK comfort that, if it was successful in defeating Vectura's claims for infringement of the Non-Assert Patents, then it would not be vexed by further claims for infringement of other patents by the same process and products – yet Vectura's undertaking did not extend to patents deriving from other (relevant) patent families.

Accordingly, Arnold J accepted that an *Arrow* declaration would give GSK commercial certainty and therefore serve a “useful purpose”. GSK had sought two forms of declaration: Declaration B, which stated that GSK's specific processes were obvious as of the priority date; and Declaration A, which stated that a more general process (which GSK necessarily followed) was obvious as of the priority date. Arnold J made a declaration in the terms of Declaration B, but not A.

Interim appeal

An interesting footnote to GSK's success in obtaining its *Arrow* declaration is that, at an earlier interim stage in the proceedings, HHJ Hacon (sitting as a High Court Judge) struck out GSK's claim for an *Arrow* declaration, agreeing with Vectura that Court of Appeal case law required “something more” than the presence of pending divisionals before the Court should exercise its discretion. On interim appeal, however, the Court of Appeal reversed this decision, holding that the discretion to grant an *Arrow* declaration lies with the trial judge since the facts and circumstances at the date of the trial will ultimately be determinative of whether the discretion should be exercised or not.

Declarations vs undertakings

In two of the three recent cases where *Arrow* declarations have been sought, undertakings have been offered by the patentee in an attempt to provide equivalent commercial certainty without the need for a declaration. In the third case, *Generics (UK) v Yeda Research and Development*, no such undertakings were offered and it was in that case that no *Arrow* declaration was granted.

In the present case, it was the terms of the undertaking offered that turned out to be the “most significant” factor in favour of granting an *Arrow* declaration. In particular, it was Vectura's reluctance to extend its proposed form of undertaking not to sue to other relevant patents in its portfolio. At paragraph [256] the decision itself records the fact that the judge asked counsel for Vectura at trial why Vectura had not given a broader undertaking to, at least, a specific further but closely related patent family and considered that he had received no satisfactory answer.

Similarly, in *FKB v AbbVie*⁵, AbbVie provided undertakings not to apply for patent protection in the UK for certain dosage regimes of its Humira™ product, but only in certain limited circumstances. Those circumstances were set out in a form of undertaking which ran to some ten clauses or sub-clauses, culminating in a final clause beginning “for the avoidance of doubt”. The undertakings were described by the judge as “complicated and very long” and “certainly not a masterpiece of drafting” and were held not to provide the commercial certainty that the *Arrow* declarations sought by FKB would provide.

Whilst such an approach may appear to put pressure on patentees to offer undertakings that may not strictly reflect the confines of the pleadings in the case (*i.e.* a patent family not covered within the definition of “Non-Assert Patents”), these declarations, when granted, do seem to be closely tied to the specific commercial product for which commercial certainty is sought.

⁵ As above (4)



The UK Patents Court is keen to avoid declarations that are overly-broad since this risks further uncertainty and undesirable litigation. Parties seeking such declarations should therefore be aware of the importance of formulating them in suitably specific terms. GSK, for example, succeeded only in achieving its narrower declaration for the specific processes and products in issue, as set out in Arnold J's Order sealed on 26 February 2019:

The Claimants' Processes described in Annex A hereto and the Claimants' Products which are direct products of those Processes (and save for the active ingredients therein) were obvious as of 30 November 2000 and at any date thereafter.

Final observations

The three cases discussed above all relate to situations where multiple divisionals were being applied for and granted. To an extent, that practice appears to give rise to the request for the grant of an *Arrow* declaration. However, it is clear that the existence of multiple divisionals is not enough in itself for the Court to exercise its discretion and grant declaratory relief: rather, the Court carefully scrutinises the surrounding circumstances of the case before deciding whether to grant this discretionary remedy. Since the UK Patents Court has already granted Vectura leave to appeal, it will be interesting to see whether the Court of Appeal is given the opportunity to provide further guidance on this developing area of law.

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