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“ARROW DECLARATIONS”

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WHAT IS AN ‘ARROW DECLARATION’

- Arises out of UK case-law
- New mechanism to deal with threat from pending applications
- Effectively a declaration from the court that the alleged infringement was ‘not new’, or was ‘obvious’ at a particular date
- **The declaration is NOT tied to any particular patent** – refers only to the alleged infringement
 - Theoretically can be decided without reference to any patent
 - But, to be useful, is linked to the priority date of the patent(s) of interest
- **To deal with “over-enthusiastic” patentees**
 - Patentees out to “get you” with their patent portfolio
 - “Patent thickets”; Serial licensors; NPEs; ... where ‘commercial uncertainty’ results

BACKGROUND: CASE LAW

- *Gillette Safety Razor v Anglo-American Trading* (1913) 30 RPC 465 - UK House of Lords (Lord Moulton) – “**Gillette defence**”
 - “The defence that ‘*the alleged infringement was not novel at the date of the plaintiff's Letters Patent*’ is a good defence in law”
 - “...the Defendants' right to succeed can be established without an examination of the terms of the Specification of the Plaintiffs' Letters Patent.”
 - “... he is entitled to feel secure if he knows that *that which he is doing differs from that which has been done of old only in non-patentable variations*, such as the substitution of mechanical equivalents or changes of material shape or size.”



UK COURT'S DISCRETION

- UK Courts have discretion to grant declaratory relief (CPR 40.20): "*The court may make binding declarations whether or not any other remedy is claimed.*" (orig. 1883)
- Declarations of non-liability ("negative declarations") were initially rare
- But – by 2000 – may be granted IF they serve a "useful purpose"
 - "*The approach is pragmatic. It is not a matter of jurisdiction, it is matter of discretion. The deployment of negative declarations should be scrutinised and their use rejected where it would serve no useful purpose.*" (Messier-Dowty v Sabena 2000 CoA)
 - "*justice to the claimant; justice to the defendant; whether the declaration would serve a useful purpose and; ... any other special reasons*" (Financial Services Authority v Rourke ChD 19 Oct 2001)



ARROW v MERCK [2007] EWHC 1900 (PAT)

- Arrow had “cleared the way” of Merck’s UK Alendronate “dosing regimen” patents.
 - But - Merck had 4 divisionals (same d.r.) - Publicly stated its intention to enforce
 - Arrow applied for declaration that: “*its own product was obvious ... at priority date*”
 - Merck sought Summary Judgment – No jurisdiction, and; Contrary to Patents Act.
- Court disagreed:
 - Arrow “has identified the *essential characteristics of its product and the prior art which it says renders that product obvious*. In my judgment this is a clearly defined issue which is readily susceptible to determination. *Indeed, it is the kind of determination which this court is well used to making.*”



ARROW v MERCK [2007] EWHC 1900 (PAT)

- Court agreed there was a commercially useful purpose in granting a declaration that: *'Arrow's product administered according to the patented dosing regimen – was obvious at the patent's priority date'*.
- Noted that:
 - *"Merck could **withdraw the "GB" designations** of the divisional applications or **[undertake not to sue under the divisionals]**. If it did so then the commercial purpose of the declarations sought would likely fall away. But it has chosen not to take that course"*
- Court refused to strike out the application for declaratory relief
- BUT - No final decision – parties settled (?)



SUBSEQUENT “ARROW” CASES

- *FujiFilm v AbbVie* (2017) – ‘Clear the way’ dosing regimen case –
Declaration granted
- *Generics v Yeda* (2018) – ‘Clear the way’ dosing regimen case –
Declaration refused
- *GSK v Vectura* (2018) – Licensing dispute (formulation patents) –
Declaration granted
- *Pfizer v Roche* (2019) – ‘Clear the way’ dosing regimen case –
Judgment pending



WHAT CONSTITUTES ‘USEFUL PURPOSE’

- Effect within the UK:
 - Multiple duplicative divisionals (*although only one needed*)
 - Shielding patents from scrutiny by Court (*AbbVie*)
 - Reframing inventive concept (*Vectura*)
 - Threats of enforcement (*not in itself enough*)
 - “Chilling effect” on supply chain through EU to the UK
- Wider (Extra-territorial?) effect
 - Persuasive effect on other EU courts
 - Promotion of settlement
- **But**, unlikely if patent defended but found obvious (*Yeda*)
- **And**, undertakings may remove useful purpose, if properly framed (*none yet!*)

PFIZER V ROCHE (TRIAL HEARD APRIL 2019)

- Roche had multiple dosing regimen patents – but UK de-designated before (or very shortly after) “Arrow” claim filed
- Parties agreed no UK patents existed (or could exist)
- Pfizer accepted main “useful purpose” was in other EU jurisdictions
 - Manufactures in Belgium – Filed expert evidence that reasoned UK judgment would be of persuasive effect to defend against PI there.
- During closing arguments – Judge suggested abandoning UK patents may be enough to warrant a declaration
 - de-designation is *"a factor if proved that weighs in favour of granting a declaration"*
- Judgment expected shortly ...



EUROPEAN APPROACHES

- Dutch cases
 - *Arrow v Merck (2008)* – Declaration allowed
 - Pending divisionals remained an issue
 - *Synthon v Yeda (2018)* – Declaration refused
 - Yeda de-designated NL from the parent and divisionals - (no scope for further patents)
 - Dutch court decided it did not have jurisdiction – it could only adjudicate on claims with respect to patent protection in NL
- No other EU jurisdictions have granted Arrow declarations – yet!

POINTS FOR PATENTEES

Beware:

- Duplicative divisionals
- Re-framing inventive concept
- Delaying prosecution
- Inconsequential claim amendments (to delay grant)
- Abandoning granted patents (or late-stage applications) in favour of pending divisionals

Result: Commercial uncertainty



POINTS FOR PATENTEES

- Apply for divisionals according to standard practice
 - Conduct technically within EPO rules may still create a “*useful purpose*”
 - If pending applications or granted patents are abandoned and new applications are filed, have good reasons
 - Even a good reason may not be enough if the objective effect is shielding and/or uncertainty
- Consider consequences of threatening enforcement if patents or applications are being abandoned
- Abandoning UK designation of EU patents could cause problems ...





QUESTIONS

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