Fujifilm v Abbvie

The first Arrow declaration?

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AIPPI Rapid Response event

A&O 6 April 2017

What is an Arrow declaration?

- Has its origins in the well-known *Gillette defence* (1913) 30 RPC 465: see CA strike out decision of 17 January [2017] EWCA Civ 1 at [53]

- Lord Moulton at 40 RPC 480:

  > "It is impossible for an ordinary member of the public to keep watch on all the numerous patents which are taken out and to ascertain the validity and scope of their claims. But 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".

- In substance it is a declaration that a product proposed to be sold by the claimant is old or obvious – and cannot therefore be the subject of valid patent protection (CA decision [53])

- It is not a declaration that a particular claim of a patent or application is invalid

Why do we need Arrow declarations?

- The EPC permits the filing of divisional applications so long as an application is pending
- A divisional may be filed from a prior pending divisional leading to cascading divisionals
- Because cascading divisionals may be filed many years after the original application but keeping the original priority date, the determination of the final form of patent protection may be indefinitely delayed
- Subsidiary patents (e.g. formulation or dosage regime in pharmaceuticals) may be filed many years after the master patent
- Divisionals may be filed from these
- This creates long term commercial uncertainty as to the scope of patent protection which inhibits generic or secondary manufacturers from entering the market because the commercial risk of doing so far exceeds any potential profits
- Such anti-competitive effects are not in the public interest
- There is no statutory regime for establishing that a product is "patent-free"

The courts' "solution": declaratory relief

- A declaration is discretionary equitable relief
- Jurisdiction now codified in CPR Part 40.20:

  "The court may make binding declarations whether or not any other relief is claimed."

- Jurisdiction is therefore unlimited
- Discretion is unfettered but principles have been developed
- In practice the courts will only make a declaration where it would serve a useful purpose and advance the attainment of justice:

  Messier Dowty v Sabena [2001] 1 All E R, per Lord Woolf at [41]-[42]

  Financial Services Authority v Rourke [2002] CP Rep, per Neuberger J

Summary of principles for grant of declaratory relief

- Per Pumfrey J in *Nokia v Interdigital* [2006] EWHC 802 (Pat) at [20]
  - (1) The correct approach to the question of whether to grant negative declarations was one of discretion rather than jurisdiction
  - (2) The use of negative declarations should be scrutinised and their use rejected where it would serve no useful purpose, but where such a declaration would help ensure that the aims of justice were achieved, the court should not be reluctant to grant a negative declaration
  - (3) Before a court can properly make a negative declaration, the underlying issue must be sufficiently clearly defined to render it properly justiciable.

Arrow Generics v Merck & Co.

- First occasion on which the grant of such declarations was considered – in 2007 ([2007] EWHC (Pat), [2007] FSR 39, Kitchin J)
- Arrow sought a declaration that the product they proposed to launch was obvious in the light of the prior art
- Declaration sought because Merck, despite having had its patent held invalid in the EPO and revoked by the UK High Court (and Court of Appeal), had filed four divisional applications which it continued to pursue
- Merck had persuaded the EPO to grant one of the divisionals on the basis of new evidence
- Arrow therefore remained at risk of infringement proceedings and sought a declaration that its product was obvious
- Merck applied to strike out the claim
- Held arguable

Why was the Arrow declaration useful?

- There is no statutory regime for seeking a declaration of non-infringement of a patent application
- There is no statutory regime for obtaining declaration that a prospective claim is or would be invalid
- The courts have required generic competitors to "clear the path" before launching or be at risk of injunctive relief
- So there needs to be a mechanism for a manufacturer to determine whether hidden in the patent thicket which may be created by numerous cascading divisionals there is no possibility that a claim which covers his product could be validly granted – but the declaration does not inhibit the grant of such a claim: it is a declaration relating to the product and not to any particular prospective patent

Arrow declarations are outside the statutory regime

- CA in [2017] EWCA Civ 1 decided that Arrow declaration:
- Does not affect future acts of the EPO even though it may affect an issue which may arise in future proceedings in the EPO
- Does not challenge past acts of the EPO
- It is inherent in the parallel jurisdiction of the EPO and national courts that they may give conflicting decisions on validity
- Patents Act provides a complete statutory code for the grant and revocation of patents but Arrow declarations are not a breach of the *Barraclough* principle (that statutory rights and remedies cannot be separated) because they do not challenge the validity of any granted patent.
- The eventual existence of the remedy of revocation is relevant to the court's discretion whether or not to grant a declaration

Fujifilm v Abbvie: the facts

- Abbvie's most successful product worldwide is monoclonal antibody adalimubab – sold as Humira – with worldwide revenues of US$12.4 billion
- Abbvie has SPC protection to 2018
- Abbvie has filed numerous subsidiary patents to various dosing regimens
- Has filed repeated divisionals covering administration of 40mg sc eow
- Lengthy EPO and UK proceedings in which Abbvie repeatedly withdrew patents when they were about to be adjudicated upon but carried on with divisionals (the existence of which they concealed)
- Abbvie ultimately tried to avoid the granting of a declaration by abandoning UK designations of patents and undertaking that it would not seek to obtain relief in the UK
- Court had to decide whether declaration nevertheless served a useful purpose

Fujifilm v Abbvie: the decision

- Henry Carr J decided:
- Abbvie's conduct in creating a patent thicket which threatened the possibility of future action whilst repeatedly shielding its patents from judicial scrutiny was sufficiently extreme to justify the grant of relief in principle to provide commercial clarity and certainty that a particular dosing regimen cannot infringe a valid claim
- Despite Abbvie's undertakings not to sue in UK, declaration would affect UK market because supplies would necessarily be made or packaged in other European jurisdictions
- Spin-off effect in other jurisdictions also of value
- Despite Abbvie's protects (unsupported by evidence) that settlement was out of the question, the declaration would promote the possibility of settlement
- The declaration provided justice to the claimant: it had won the technical argument
- There was no injustice to the defendant: it simply crystallises the technical and legal position

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Divisional Applications at the EPO

April 2017

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Patent Thickets – Generally Not Abusive

- Patent thickets are not unique to the pharma sector – see e.g. The (then) Rt. Hon. Sir Robin Jacob in his submission to the European Commission at the time of the Pharma-sector enquiry:
  - *"the phenomenon of evergreening is not confined to the pharma field. Nor is it new. Far from it. Every patentee of a major invention is likely to come up with improvements and alleged improvements to his invention. By the time his main patent has expired there will be a thicket of patents intended to extend his monopoly. Some will be good, others bad. It is in the nature of the patent system itself that this should happen and it has always happened. …* ***It has never been the law that patents are refused for incremental non-obvious improvements. Nor should it be****."*

- An Arrow declaration unlikely to be available for patent thickets based on subsequent improvements

Procedural Rules for Filing Divisionals

- UK-IPO : problem does not arise – Section 20(1) & Rule 30
  - Cascading divisional applications permitted in principle
  - Compliance period set by Section 20(1) & Rule 30
  - Possible injustice occasioned by compliance term assuaged by attitude of IPO and discretion of court

- Other approaches: *suo moto* divisional applications not allowed / restrictions on dividing divisional applications
  - Eg India

- EPO rules from 2010 to 2014 restricted right to file divisional application
  - Deadline 2 years from first Official Action in the patent family, unless disunity objection raised

Divisional Practice at the EPO: Currently Very Liberal

- Previous Rule 36 EPC was unworkable due inter alia to EPO backlogs
- New Rule 36 EPC is very liberal: intention was that control would be effected via official fees
  - Rule 36(1) EPC: The applicant may file a divisional application relating to **any pending earlier European patent application**
- Extra cost is trivial

Generation of divisional:	2	3	4	5+
Extra fee (EUR):	210	425	635	850

- Easy to keep families pending for 20 years
  - Enormous backlog before the Boards of Appeal can be exploited for procedural advantage

Liberal Approach to Double-Patenting

- Historically, the EPO has sometimes taken a strict approach on double patenting
  - Art 125 EPC used as statutory basis
  - Marley's Patent [1994] RPC 231: no overlap permitted

- Enlarged Board G1/05:
  - "*the principle of prohibition of double patenting exists on the basis that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the* ***same subject-matter***"

- Current EPO Guidelines:
  - Reference to "*same subject-matter*" interpreted as "***identical*** *subject-matter*"
  - "*If the claims of those applications are merely partially overlapping, no objection should be raised*"

Cascading Divisionals: Current Practice at the EPO

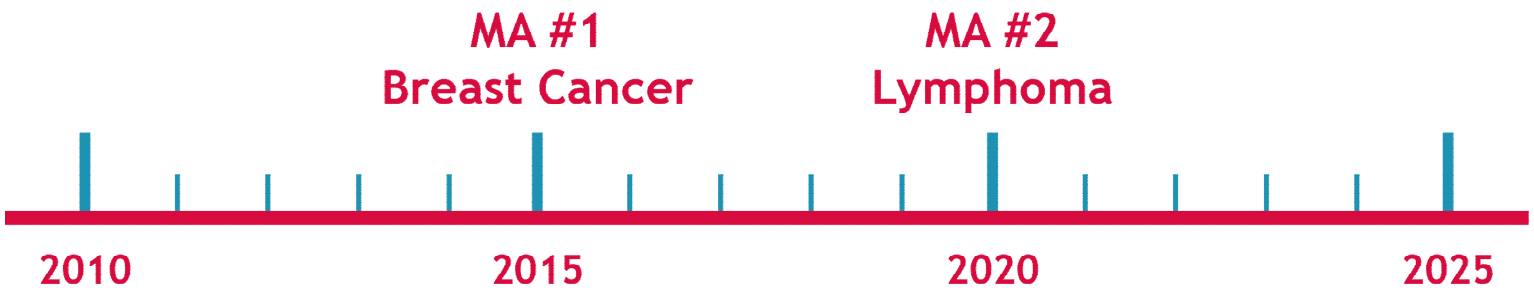
- Currently very easy to file divisional applications at the EPO to maintain pendency throughout full patent term, keeping open the option of filing new claims aimed at fixing problems that may be encountered with earlier cases

Legitimate Use for Cascading Divisionals

- Formal problems: Art 123(2)/(3)
  - Limiting amendment necessary to provide appropriate claims scope
- Worked Example: EP1411918
  - Invention involved using an agent to mobilize progenitor and/or stem cells, harvesting the cells, then later transplanting them back into the patient
  - EPO Examiner insisted the extraction part of the process is not a method of therapy so a second medical use claim was not available – so the granted claims included a claim directed specifically to the extraction part of the method
  - Extraction method claims then revoked in opposition for covering surgical methods, but problem could not be fixed without impermissibly broadening the claim scope in certain respects
  - ➢ Second medical use claims pursued in a divisional application

Further Example of Legitimate Use

Clinical Development Timeline



In this scenario, an application filed in 2010 would receive no SPC term based on MA #1, but could usefully be divided into:

- A parent application with a broad claim to treating cancer – normal patent term to 2030
- A divisional application specifically restricted to treating lymphoma – patent term to 2030, but SPC term to 2035 based on MA #2

Possibility of Abuse

- Procedural rules for EPO Appeals mean a sole Appellant can terminate the proceedings immediately simply by withdrawing their appeal
  - Board of Appeal cannot issue any Decision in this instance
  - Procedure can even be terminated mid-way through Oral Proceedings
- This procedural option can be exercised to avoid an adverse Decision being issued
- Current backlogs at the EPO Boards of Appeal mean significant delays can be achieved
  - For some Boards, Oral Proceedings are currently being appointed as much as six years after issuance of the first instance Decision

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Thank you. Any questions?

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AIPPI - FUJIFILM

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6 APRIL 2017

COMPETITION ISSUES

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BRICK COURT CHAMBERS
BARRISTERS

FINDINGS OF FACT

- Para 349: “Abbvie has abandoned all relevant UK patent protection in order to avoid scrutiny by the UK Court, and to prolong commercial uncertainty as to the validity of those patents.”
- Para 388: “I consider that the intention and the objective effect is to shield its patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten infringement proceedings against biosimilars, wherever they be launched..”

COMPEITTION ISSUES - 2

- Para 395: “Abbvie has consistently adopted a policy of publicly expressing its confidence in its Hunira patent portfolio, and its intention to enforce it against competition from biosimilars, whilst at the same time shielding patents within the portfolio from scrutiny by the court. When patent protection has been abandoned by Abbvie, another sub-divisional has been applied for, thereby perpetuating Commercial uncertainty”
- Question: is this an abusive distortion of competition?

ABUSE AND FREE MOVEMENT

- Case 16/74 Centrafarm – exhaustion of trade mark rights: cannot rely on trade mark to prevent importation of pharmaceutical bearing same trade mark affixed with consent.
- Case C-143/00 Boehringer – re-boxing of pharmaceutical products allowed if necessary to gain effective access to market.
- Case C-429/08 QC Leisure – distortion of competition exists where national copyright licence for Premier League matches prevents customers using decoding devices outside licensed territory.

ABUSE AND REFUSAL TO LICENCE

- Case C-418/01 IMS Health
- Case T-201/04 Microsoft
- Case T-167/08 Microsoft – abuse where (1) licence is necessary for appearance of a new product and (b) refusal to licence unjustifiably prevents competition on that secondary market
- Unwired Planet: Birss J] [2017] EWHC 711 (Pat) – refusal to licence on FRAND (fair, reasonable, non discriminatory) terms:

ABUSE AND EXCESSIVE PRICING

- Unwired Planet: (a) contractual FRAND enforceable as a matter of French law: (b) Article 102(a) prevents an “offer which is so far above FRAND as to act to disrupt or prejudice the negotiations (para 765) – To make an opening offer to Huawei which is 3 times the upper level of FRAND benchmark is not an abuse contrary to article 102(a)
- Pfizer v CMA – Pfizer through a third party genericised Epanutin and Phenytoin Sodium capsules and prices increased by 2000%: 80 year off patent epilepsy drug: fine of £84 million

ABUSE AND GAMING REGULATIONS

- Case T-321/05 AstraZeneca
- Case C-457/10P AstraZeneca: fine of 52 million euros for (a) misusing the patent system by misleading patent offices to obtain SPCs and (b) misusing the pharmaceutical regulatory system by selective withdrawal of marketing authorisations
- Reckitt (OFT decision 12 April 2011) – £10 million fine by OFT on Reckitt for withdrawing NHS Gaviscon packs to hinder entry of generics

ABUSE AND SETTLMENTS

- Pay for delay
- Case t-472/13 Lundbeck – anti-depressant drug off patent but subject to process patents: potential entry by generics subject to risk of process patent: settlement agreement whereby Lundbeck paid the generics not to enter: and payment roughly equal to profit generics would have made
- CMA Decision (12 February 2016) Paroxetine: substantial payments were in effect to pay generics to delay entry

ABUSE AND PREMATURE LITIGATION

- Case C-170/13 Huawei v ZTE
- Applied in Unwired Planet – if patentee (subject to FRAND undertaking) seeks injunction for patent infringement without first offering a FRAND licence, the claim for injunctions is abusive

ABUSIVE LITIGATION

- Case T-111/96 ITT Promedia: right of access to the court is a fundamental right: no abuse unless the claim by the dominant undertaking (a) cannot objectively be regarded as an attempt to establish its rights and (b) is part of a plan to harass competitors and weaken competition.
- Applied in case T-119/09 Protege International

CONCLUSION ON FUJIFILM

- If Dominant? Humira is highest selling prescription drug in the world and treats arthritis
- Abuse? Para 388: "... the intention and the objective effect is to shield its patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten infringement proceedings against biosimilars, wherever they be launched.."
- Probably conduct capable of being abusive
- Probably straight objective test and not ITT Promedia test

Thank you

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