



Neutral Citation Number: [2016] EWHC 374(IP)(Ch)

Case No: HP-2015-000053

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
INTELLECTUAL PROPERTY

Royal Courts of Justice
Rolls Building
Fetter Lane
London EC4A 1 NL

Date: 01/03/2016

Before :

THE HON MR JUSTICE HENRY CARR

Between :

FUJIFILM KYOWA BIOLOGICS CO., LTD.
(a company incorporated under the laws of Japan)

- and -

Claimant

ABBVIE BIOTECHNOLOGY LIMITED

Defendant

Andrew Waugh QC and Geoffrey Pritchard (instructed by **Gowling WLG (UK) LLP**) for
the **Claimant**
Daniel Alexander QC and Jeremy Heald (instructed by **Herbert Smith Freehills LLP**) for
the **Defendant**

Hearing dates: 19 November 2016

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....
MR JUSTICE HENRY CARR

Mr Justice Henry Carr :

Introduction

1. The Defendant (“AbbVie”) is the proprietor of a number of patents relating to the antibody adalimumab, sold under the trade mark Humira. Humira is the highest selling prescription drug in the world by global sales, achieving net sales in 2014 in excess of US \$12.5 billion. Adalimumab is a fully human antibody that binds and neutralises the activity of TNF α . The basic patent for adalimumab (EP 0,929,578) and its associated UK SPC (GB/04/002) will expire on 15 October 2018.
2. Humira has been approved for the treatment in adults of rheumatoid arthritis, psoriatic arthritis and psoriasis. The basic dosage regimes for those indications, as set out in the Summary of Product Characteristics, specify or include the administration of 40 mg adalimumab every other week as a single dose via subcutaneous injection (“40 mg sc eow”). AbbVie has obtained or applied for a number of patents and divisionals for adalimumab which claim the use of this dosage regime in the treatment of various indications.
3. The Claimant (“FKB”) is a joint venture between FUJIFILM Corporation and Kyowa Hakko Kirin Co., Ltd, established in March 2012 to conduct development and manufacture of biopharmaceuticals and to offer biosimilar pharmaceutical products. It intends to market a biosimilar adalimumab product (“FKB327”). This product is in Phase III clinical trials and FKB intends to market FKB327 in the UK after expiry of the basic adalimumab patent and its associated UK SPC if it can clear the way of secondary patents before then. That is the purpose of this Claim.
4. This judgment concerns an application by FKB to amend the Claim Form and Particulars of Claim and a cross-application by AbbVie to strike out certain parts of the pleading as originally served.

The facts

5. This claim was issued by FKB on 29 October 2015. The Particulars of Claim in its original form sought to revoke two granted patents, namely EP (UK) 1, 406,656 (“the 656 Patent”) and EP (UK) 1,944,322 (“the 322 Patent”). Both of these patents relate to the 40 mg sc eow dosage regime for the use of adalimumab in the treatment of various indications. However, FKB was also concerned about a number of divisional applications which have been applied for by AbbVie and which relate, in some way, to adalimumab. Relying on the judgment of Kitchin J. (as he then was) in *Arrow Generics Ltd v Merck & Co Inc* [2007] EWHC 1900 (Pat): [2007] F.S.R. 39, FKB applied for a declaration that “products containing a biosimilar monoclonal antibody to the antibody adalimumab for the treatment of rheumatoid arthritis, psoriatic arthritis and/or psoriasis by the administration of 40mg every other week by subcutaneous injection...” would have been obvious at the priority dates of the 656 and 322 Patents.
6. This declaration was intended to prevent AbbVie from commencing infringement proceedings in the United Kingdom against FKB327 under pending applications once they have been granted. If it was obvious at the relevant priority date to treat these various indications by the 40 mg sc eow dosage regime, then the declaration would

create a squeeze between infringement and validity, such that an action for infringement could not succeed in the United Kingdom. AbbVie seeks to strike out this declaration and the pleading in support of it.

7. The 656 patent claims the use of adalimumab in the treatment of rheumatoid arthritis by the 40 mg sc eow dosage regime. The application for the 656 patent was filed on 5 June 2002. It was not granted by the EPO until eleven years later, on 9 June 2013. During the nine month opposition period following grant, fifteen oppositions were submitted. AbbVie eventually filed its observations in response to the oppositions, together with no less than nineteen statements of fact and expert reports, on 22 December 2014. On 24 April 2015 AbbVie requested the grant of a divisional from the 656 patent (“the Fourth Divisional Application”), having previously requested the grant of three other divisionals. Between August and October 2015 various opponents submitted replies to the observations filed on behalf of AbbVie. However, on 4 November 2015, six days after the Claim Form was issued in these proceedings, AbbVie wrote to the EPO stating that it no longer approved the text of the granted 656 patent. Accordingly, the EPO revoked the 656 patent on 16 November 2015. The Fourth Divisional Application, which claimed essentially the same subject matter as the 656 patent, was published on 4 November 2015.
8. FKB applies to plead these facts by amendment to its Particulars of Claim. It alleges that AbbVie intends to delay the entry of competing Humira biosimilar products by prolonging commercial uncertainty. FKB claims that the purpose of abandoning the 656 patent was to avoid adjudication on its patentability by the UK court and the Opposition Division, whilst seeking to ensure that the subject matter of the alleged invention of the 656 patent was maintained by the Fourth Divisional Application. The object, according to FKB, is to prevent FKB from clearing the way in respect of its FKB327 biosimilar after expiration of the SPC for the basic adalimumab patent. FKB submits that it will be many years before the EPO will be in a position finally to adjudicate on the patentability of the subject matter of the Fourth Divisional Application. FKB relies upon these allegations to demonstrate why the granting of the declaration which it now seeks would serve a useful purpose, by achieving commercial certainty in respect of its FKB327 product by the date of its intended launch in the autumn of 2018.
9. AbbVie does not accept that there was any connection between its decision to abandon the 656 patent and the commencement of the UK proceedings by FKB. It explains that on 23 September 2015 one of the opponents raised a new insufficiency objection concerning an in vitro L929 assay (“the L929 Requirements”) which was a feature of the claims of the 656 patent. Several opponents had objected to the presence of the L929 Requirements on the ground of added matter. The new objection alleged that the L929 Requirements rendered the claims of the 656 patent insufficient as the skilled person would not be able to determine whether a particular antibody satisfied those Requirements. On 4 November 2015 Mewburn Ellis LLP wrote to the EPO to explain that AbbVie no longer approved the text in which the 656 patent was granted and had decided to address the objections to the validity of the patent through pursuit of its existing divisional applications, which did not contain the L929 Requirements. It was asserted that this would avoid any controversy arising under Article 123(3) EPC that might be caused if the L929 Requirements were removed from the claims of the 656 patent by amendment.

10. FKB strongly disputes this explanation. It points out that it is difficult to succeed on an insufficiency objection in the EPO because such an objection has to be proved on the basis of serious doubts, substantiated by verifiable facts. It alleges that this insufficiency objection appears weak and certainly no better than the other insufficiency objections to which AbbVie had already responded in the opposition proceedings. It also claims that the timing of the abandonment, so soon after commencement of the UK proceedings, cannot have been a coincidence.
11. I am unable to resolve this dispute on these applications, although, on the material which I have seen, there is a good arguable case that the allegations which are sought to be added by amendment are correct, for the reasons advanced by FKB. Mr Alexander QC, who appeared for AbbVie, was quite right to accept that, when considering whether to refuse permission to amend and whether to strike out, I should assume that the pleaded allegations of fact are true. His case is that this makes no difference, as there is no jurisdiction to grant the relief sought, or alternatively, it would be a wrong exercise of discretion to do so, even if the pleaded facts are established.
12. Mr Waugh QC, who appeared on behalf of FKB, invited me to find that AbbVie has generated a dense thicket of patents around uses and doses of adalimumab. He referred me to a “patent map” which was a graphical illustration of seventeen patent families, each family deriving from the same application, where AbbVie has often filed at least one divisional application and sometimes more, within each such family. However, many of the patent families do not concern the 40 mg sc eow dosage regime and appear to be irrelevant to these proceedings. Mr Alexander pointed out that in a ground-breaking invention such as Humira, it is unsurprising to find a portfolio of patents and patent applications directed to many different aspects of the invention. It is neither necessary nor appropriate for me to find, on these applications, that AbbVie has created “a dense thicket of patents” around Humira.
13. The 322 patent covers use of adalimumab in accordance with the 40 mg sc eow dosage regime for the treatment of psoriasis. The patent is in force and the validity of its UK designation will be determined by this Claim. In addition, there are a variety of pending divisionals in different patent families which concern the treatment of different indications by adalimumab in accordance with the 40 mg sc eow dosage regime. These indications include rheumatoid arthritis, which, commercially, is the most important. The table below summarises the relevant granted patents and divisionals of which FKB is currently aware, and which include this dosage regime as an integer of the claims. The details of the patent families in which the applications are to be found are not relevant to the issues which I have to consider:

Indication	Pat./App	Current state	c. Date of Grant	Expiry
Rheum. Arthritis	'656 div. 4	In exam	earliest - 8/16. prob. c. 2018	6/2022
Psoriasis	'322 pat.	In force	N/A	7/2023
Psoriasis	'322 div.	In exam	?	7/2023

Juv. Rheum. Arthritis	'322 div.	In exam	?	7/2023
Psoriatic Arthritis	'322 div.	In exam	?	7/2023
Erosive Polyarthritis in a human subject having psoriatic arthritis	'397 div.	In exam	several years	5/2026
Psoriasis	'824 div	In exam	ditto	2027
Rheum. Arthritis	'214 div	In exam	ditto	2027

14. It can be seen from this table that the likely date of grant of a number of these divisionals is uncertain and may well be several years away. Once granted, any opposition in the EPO, including any appeal to the Technical Board of Appeal, is likely to take several years before final resolution. Furthermore, FKB points out, correctly, that there is nothing to prevent AbbVie from requesting the grant of further divisionals which include the 40 mg sc eow dosage regime as a claimed feature.

The declaration sought by amendment

15. During the course of the hearing, the declaration sought by FKB was narrowed in scope. Its current form is as follows:

“A declaration pursuant to CPR 40.20 and/or the inherent jurisdiction of the Court that importing into the United Kingdom and offering to sell and dispose of, and to sell and dispose of, and to keep for such sale or disposal in the United Kingdom, the Claimant’s products containing their biosimilar monoclonal antibody to the antibody adalimumab (Humira) for the treatment of rheumatoid arthritis, psoriatic arthritis and/or psoriasis by the administration of 40mg every week by subcutaneous injection for:

(a) rheumatoid arthritis would have been obvious and/or anticipated at the date from which EP (UK) 1,406,656 was entitled to claim priority whether or not co-administered with methotrexate (as would administration every week in the case of monotherapy in rheumatoid arthritis); and

(b) psoriasis and/or psoriatic arthritis would have been obvious at the date from which EP (UK) 1,944,322 was entitled to claim priority (whether as an initial or continuing dosing regimen)”

16. The declaration seeks to establish that FKB’s products, which are biosimilar to adalimumab, were anticipated or obvious at the priority dates from which the 656 and

322 patents were entitled to claim priority. FKB challenges entitlement to the priority date that was claimed by the 656 patent prior to its abandonment, as it alleges that intervening prior art expressly discloses the 40 mg sc eow dosage regime. Mr Waugh points out, correctly, that for the purposes of the declaration it is necessary to decide on the date at which the prior art is to be considered. Therefore the declaration will bring in to the trial consideration of this issue, in the context of whether FKB's products were anticipated or obvious at the relevant date.

17. I should also mention that FKB sought to add a further declaration that Abbott Laboratories (Bermuda) Limited, the applicant for the PCT filing from which the 656 patent derives, was not the successor in title to the rights to the invention held by the inventors named on US Patent Application No. 60/296.961, and therefore that Abbott Laboratories (Bermuda) Limited was not entitled to claim priority from that US patent application. That declaration, and the pleading in support of it, was abandoned by FKB during the course of the hearing on the basis that it was unnecessary, as the issue was raised in any event by the declaration which I have set out above.

The Arrow judgment

18. The *Arrow* judgment is central to the present applications and requires detailed analysis. The facts, as recorded by Kitchin J, were unusual and may be summarised as follows:
 - i) The Defendant ("Merck") was granted a European patent (UK) ("the 292 patent") for the treatment of osteoporosis where the novelty lay in the dosage regime (70mg of alendronate per week rather than 10mg once per day).
 - ii) The 292 patent was held invalid by Jacob J. (as he then was) in January 2003 and his judgment was upheld by the Court of Appeal. Accordingly the UK designation of the 292 patent was revoked in November 2003.
 - iii) The 292 patent was also the subject of opposition by seven opponents in the EPO. The Opposition Division revoked the 292 patent on the same grounds as Jacob J. in July 2004. In March 2006 the Technical Board of Appeal dismissed the appeal.
 - iv) Since the revocation of the 292 Patent, Arrow had come on the market in Europe with 70mg once-weekly alendronate for the treatment of osteoporosis.
 - v) However, during prosecution, Merck had filed four divisional applications.
 - vi) At the time that Arrow came before the UK court seeking declaratory relief, the Examination Division had allowed one of the divisionals to proceed to grant ("the 904 patent"). The 904 patent covered the same key idea as the 292 patent, namely an osteoporosis treatment of 70mg of alendronate per week rather than 10mg once per day.
 - vii) Because of the period of time before any opposition to the 904 patent could be finally determined, Arrow was faced with a prolonged period of uncertainty. In addition, Merck had other divisional applications which were pending in the

EPO, the claims of which already included, or could be amended to include, the dosage regime of 70mg alendronate once-weekly.

viii) Therefore, despite having succeeded in revoking the 292 patent in both the UK and the EPO, Arrow was faced with a real threat to its European alendronate business from a granted patent and pending patent applications directed to the same subject matter.

19. As originally formulated, Arrow's claim sought declarations of invalidity in respect of non-UK patents. In particular, it sought a declaration that the 904 patent was and had at all times been invalid and a declaration that any other European patent for an alleged invention relating to osteoporosis medicaments for administration of about 70mg alendronate once-weekly would be invalid. Kitchin J stated at [17]:

“17 It is clear that this court could never have granted such declarations. They concern issues of validity which fall exclusively within the jurisdiction of other European courts in accordance with Article 22 (4) of Council Regulation (EC) No 44/2001, as Arrow has now accepted.”

20. The declaration ultimately sought by Arrow was directed at the obviousness of its own alendronate product for the treatment of osteoporosis, when administered once-weekly as a 70mg tablet. Kitchin J explained the relief sought at [37]-[38]:

“37 ...Arrow seeks to contend that as of July 1997 it was obvious to the skilled person to use sodium alendronate trihydrate in the manufacture of a medicament in the form of a tablet containing about 70mg sodium alendronate trihydrate for oral administration for the treatment of osteoporosis in a human (in need of such treatment) according to a continuous schedule having a once-weekly dosing interval. Particulars are then provided of those matters which formed part of the art and which rendered such use obvious. It further seeks to contend that its product is a product having such characteristics.

38 In short, therefore, Arrow seeks a declaration that its own product was obvious at the priority date of the divisional applications. Such a declaration would give Arrow the security that dealing with its own alendronate product in this country will not give rise to any liability to Merck for infringement of any patent granted pursuant to the divisional applications or any further divisionals arising under them. It says this court has jurisdiction to grant such a declaration and that it is appropriate so to do because Merck has shown every intention of (a) pursuing and (b) relying upon the divisional applications against Arrow inter alia in the UK. There is therefore an issue between the parties and a real commercial need for the clarification sought.”

21. Before dealing with the general principles concerning jurisdiction to grant the relief sought, Kitchin J identified the particular circumstances upon which Arrow relied in

support of its claim. He considered that, collectively, these circumstances made the case before him very unusual. In particular:

- i) Arrow was seeking a declaration of obviousness in respect of particular characteristics of its own product which were clearly defined. The patent rights to which the declaration extended were limited to the United Kingdom.
- ii) Arrow was not seeking a declaration that no valid patent could be granted to Merck based on the divisional applications.
- iii) Arrow had devoted significant resources to clearing the way for the launch of its product by bringing proceedings to revoke the 292 patent both in this jurisdiction and before the EPO. Having succeeded in those proceedings it launched its 70mg once-weekly alendronate tablet, but now faced the prospect of European patents (UK) being granted on divisional applications that would cover that very same product.
- iv) It was not possible on an application of this nature to accept Arrow's submission that it had a very strong case and that Merck was essentially seeking to recast the case that it had already lost. Nonetheless, the court was satisfied that Arrow had a real prospect of success in establishing that its product was obvious at the priority date.
- v) Arrow's sales of alendronate were very substantial and a large claim was hanging over it in respect of its current and future activities (including a claim to infringement from the date of publication of the application pursuant to s.69 of the Patents Act 1977).
- vi) Merck had made it quite clear that it would seek to enforce its patent rights in respect of generic 70mg once-weekly alendronate, including European (UK) patents that might be granted in the future.
- vii) Arrow could not commence revocation proceedings in the United Kingdom until the divisional applications had proceeded to grant, during which period the scope of the claims of the divisional applications could change. Therefore Arrow faced a considerable period of commercial uncertainty.

22. Kitchin J then considered general principles relating to declaratory relief. He cited the following authorities:

- i) *Messier-Doughty v Sabena* [2001] 1 All E.R. 275 where Lord Woolf M.R. explained at [41] that the approach to the grant of declarations is pragmatic, and a matter of discretion rather than jurisdiction. He stated that the use of negative declarations should be rejected where it would serve no useful purpose. On the other hand, where a negative declaration would help to ensure that the aims of justice are achieved "the courts should not be reluctant to grant such declarations. They can and do assist in achieving justice."
- ii) *Financial Services Authority v Rourke* [2002] C.P. Rep. 14 where Neuberger J (as he then was) stated that the power to make declarations was unfettered, and that the court had to consider whether, in all the circumstances, it was

appropriate to make such an order. He held that when considering whether to grant a declaration, the court should take into account “justice to the claimant, justice to the defendant, whether the declaration would serve a useful purpose and whether there are any other special reasons why or why not the court should grant the declaration.”

- iii) The judgments of Pumfrey J. and the Court of Appeal in *Nokia Corp v Interdigital Technology Corp* [2006] EWHC 802 (Pat); [2006] EWCH Civ 1618; [2007] F.S.R 23. Nokia sought declarations of non-essentiality in respect of certain Interdigital mobile phone patents. In upholding the decision of Pumfrey J that there was jurisdiction to grant such declarations, Jacob LJ said at [20] that:

“I do not say that anyone could apply for declarations of the kind sought by Nokia. There would have to be real commercial reasons for the person seeking the declaration to have standing to do so. An interest in making 3G telephones which must therefore comply with the standard is clearly sufficient.”

23. In the *Arrow* case, Merck contended that section 74 of the Patents Act 1977 was a complete bar to the relief claimed by Arrow. Furthermore, it submitted that the framework of the 1977 Act and the EPC contemplated that patentability of European patent applications would be determined by the EPO and it would be wrong for the UK court to interfere with that process. Therefore, either there was no jurisdiction to grant the declaration sought, or there were special circumstances which meant that the court should not grant the declaration as a matter of discretion.

24. The relevant parts of section 74 provide that:

“(1) Subject to the following provisions of this section, the validity of a patent may be put in issue—

(a) by way of defence, in proceedings for infringement of the patent under section 61 above or proceedings under section 69 above for infringement of rights conferred by the publication of an application;

(b) in proceedings under section 70 above;

(c) in proceedings in which a declaration in relation to the patent is sought under section 71 above;

(d) in proceedings before the court or the comptroller under section 72 above for the revocation of the patent;

(e) in proceedings under section 58 above.

(2) The validity of a patent may not be put in issue in any other proceedings and, in particular, no proceedings may be instituted (whether under this Act or otherwise) seeking only a declaration as to the validity or invalidity of a patent.”

25. Merck contended that section 74(1) set out the various proceedings in which the validity of a patent may be put in issue and section 74(2) expressly provided that validity may not be put in issue in any other proceedings. The proceedings in the Arrow case did not fall within the list in section 74(1) and were therefore prohibited by section 74(2). Arrow responded that a “patent” is defined under s.130 of the Act as “a patent under this Act”. This does not cover declarations relating to an application under the Act, let alone an application for a European patent (UK). Furthermore, although s.69 provides that “patent” shall include an application in relation to certain sections of the Act, those sections do not include section 74. So section 74 does not prohibit a declaration relating to a published application. Merck's response was that the declarations did relate to patents under the Act because they referred to such patents, as and when granted.

26. Kitchin J. rejected Merck’s argument in relation to section 74 at [55]:

“55 Arrow seeks a declaration as to its right to make and sell its own product. In my judgment clear words are required to exclude that right and section 74 should be interpreted no more widely than necessary to give effect to its purpose. What then is that purpose? I consider it must be to ensure that patents which are invalid are not merely declared to be invalid but are in fact revoked. But revocation proceedings cannot be commenced until a patent has been granted. Had it been intended that section 74 should exclude the right of a person to seek a declaration in relation to his own product, particularly in circumstances where the need to do so arises from the existence of a published application, then it could have said so in express terms. But it does not and in my judgment it should not be so construed. Section 69 supports this conclusion. It expressly deals with the provisions of the Act that are to take effect in relation to a published application but contains no reference to section 74(2) or any equivalent prohibition.”

27. At [60] Kitchin J considered and rejected Merck’s argument that the declarations sought would usurp the function of the EPO in respect of the examination of EP applications. He said:

“It [Merck] says this court should not be making declarations in respect of the validity of patent applications because they are subject to examination by the EPO and their claims can change. For the court to start anticipating the examination process would be to usurp the function of the EPO and this is inconsistent with the framework of the EPC and the Act. I agree with all of these submissions. I find it hard to conceive of any circumstances in which it would be appropriate for this court to grant a declaration that no valid patent could be granted on a divisional application which is being prosecuted before the EPO. But that is not what is sought. Arrow only seeks declarations that its own product was obvious at the priority date. The existence of the divisional applications gives rise to the need and justification for seeking declaratory relief.

Merck could withdraw the “GB” designations of the divisional applications or acknowledge that it can have no claim under them in this country in respect of a product having the specified characteristics of Arrow's product. 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.”

28. Kitchin J concluded at [62] that:

“...in the unusual circumstances of this case I am not satisfied this court has no jurisdiction to grant the declarations sought in respect of Arrow's product. Nor am I satisfied this court would necessarily refuse such declarations in the exercise of its discretion. In my judgment these claims have a reasonable prospect of success and must be allowed to proceed”

The Dutch decision in Arrow v Merck

29. During the course of the hearing Mr Alexander mentioned his recollection that that a Dutch court had reached the same decision as the UK court in the *Arrow* judgment concerning the jurisdiction to make a declaration that a generic 70 mg once-weekly alendronate tablet was obvious at the priority date of the 904 patent. He was quite right to refer to this and it was consistent with the very high quality of his submissions. Subsequent to the hearing, the parties’ solicitors sent me translations of the judgment of the Court of the Hague in *Merck Sharpe & Dohme Manufacturing v Ratiopharm Nederland BV and others* (February 13 2008 case number/docket number 288241/ HA ZA 07-1689). In particular at paragraph 6.10 the Dutch Court, having found that the Dutch designation of the 904 Patent was invalid, issued the following declaratory judgment:

“... that the tablets referred to in these proceedings of [various generic drugs companies] consisting of tablets that contain 70mg alendronate as active ingredient, which tablets are intended to be taken once a week for the treatment of osteoporosis, on July 22, 1997 followed from the state of the art in a way that was obvious to persons skilled in the art.”

30. This declaration was made because Merck had requested further divisionals with the same subject matter as the 904 patent which were still at the application stage in the EPO. The court’s reasoning at [5.14]-[5.15] is consistent with that of Kitchin J in the *Arrow* Judgment. The difference is that whereas Kitchin J held that the case for a declaration was arguable, the Dutch court granted the relief sought:

“5.14 The Court furthermore holds that the statement requested... that the generic 70mg once-weekly dose of alendronate products is obvious, is capable of being allowed on the above grounds. There are more voluntary divisionals of Merck looming. Merck was unwilling to give its undertaking that it would not use those against the 70 mg once-weekly alendronate preparations of the Generics following the possible grant by the EPO. Be that as it may, based on the above the

Court can accept the Gillette-type substantiation of the statement demanded by the Generics of obviousness of their 70 mg once-weekly alendronate medication for the treatment of osteoporosis. After all, for the same reasons that EP 904 lacks inventive step, said generic preparations follow in an obvious manner from the state-of-the-art on the oldest priority date...

“5.15 That the Generics have an interest in the requested declaratory judgment, after having had to cancel 70mg alendronate once-weekly patents twice, the last time in the form of an unsuccessful Swiss-type use claim, requires little further explanation...”

Departing from a decision of a court of co-ordinate jurisdiction

31. AbbVie invites me to find that the *Arrow* judgment was wrongly decided. It is correct that a judge at first instance can decline to follow a judgment of a court of co-ordinate jurisdiction, but only where he or she is convinced that the judgment is wrong. This is explained in *Halsbury's Laws of England Civil Procedure* (Volume 11, 2015) page 67 at [32]:

“There is no statute or common law rule by which one court is bound to abide by the decision of another court of co-ordinate jurisdiction. Where, however, a judge of first instance after consideration has come to a definite decision on a matter arising out of a complicated and difficult enactment, the opinion has been expressed that a second judge of first instance of co-ordinate jurisdiction should follow that decision; and the modern practice is that a judge of first instance will as a matter of judicial comity usually follow the decision of another judge of first instance unless he is convinced that that judgment was wrong. Where there are conflicting decisions of courts of co-ordinate jurisdiction, the later decision is to be preferred if reached after full consideration of earlier decisions.”

AbbVie's contentions that the *Arrow* judgment was wrongly decided

Section 74 of the Patents Act 1977

32. AbbVie submits that Kitchin J was wrong in the *Arrow* judgment to hold that the declaration was not barred by section 74. In summary, it argues that section 74(1) contains a complete list of proceedings in which the validity or invalidity of a patent may be put in issue. This conclusion is made express by section 74(2). It would subvert its purpose if it were used to permit the doing indirectly of that which it specifically forbade directly and there is no basis for construing the statute to have that effect. Kitchin J was therefore wrong to interpret the section in a way which meant that it could be circumvented.
33. Furthermore, AbbVie alleges that he was wrong to conclude that the purpose of section 74 was to prevent patents from merely being declared invalid without also being revoked. Four out of the five types of proceedings listed in section 74(1) do not

lead to revocation in the event of a finding of invalidity. Thus, ensuring revocation cannot be its only purpose.

34. In addition, AbbVie argues that section 69 does not support the contrary conclusion as, regardless of the fact that at present, the divisionals are pending patent applications, the declarations are directed, prospectively, at the validity of any patent that may be granted from those applications.
35. Finally AbbVie submits that although in this case, as in the *Arrow* judgment, a declaration is sought that the Claimant's own product would have been obvious (or anticipated) at the priority date, the product is defined by reference to the integers of the prospective patents which have been applied for. That is another way of pleading a case that the claims are or would be obvious or anticipated. Accordingly Kitchin J was wrong to hold that the court had jurisdiction to consider the declaration sought in *Arrow*.
36. In order to evaluate these submissions it is necessary to consider the purpose and effect of section 74. In the *CIPA Guide to the Patents Act* seventh ed. (2011) [74.03] notes that section 74(1) lists the proceedings in which the validity of a patent may be challenged. It includes, for example, declarations of non-infringement under section 71, which was a jurisdiction created by the 1977 Act. The authors of the *CIPA Guide* state that "the subsection also prohibits proceedings for a mere declaration of validity or invalidity, thereby making statutory previous decisions of the court to this effect." Accordingly, its purpose is to list proceedings under the 1977 Act in which validity of granted patents can be challenged, and to give statutory effect to previous case-law.
37. The operation of section 74 was considered by Jacob J. in *Organon Teknika Limited v F. Hoffmann-La Roche AG* [1996] F.S.R. 383. The Claimant issued proceedings in the United Kingdom pursuant to the inherent jurisdiction of the court seeking a declaration that it had not infringed any valid claim of the Defendant's patent. The Statement of Claim also put in issue the validity of the patent and particulars of objections were served. The Defendant applied to strike out those aspects of the Statement of Claim relating to validity on the basis that section 74(1) set out a list of proceedings in which validity of a patent may be put in issue and section 74(2) specified that validity may not be put in issue in any other proceedings. Since proceedings for a declaration of non-infringement of a patent pursuant to the inherent jurisdiction was not on the list, the Defendant submitted that all references to the validity of the patent should be struck out.
38. The Claimant contended that this led to an absurd anomaly. The validity or scope of the patent was central to the dispute concerned in all of the other proceedings listed in the section, and it would be absurd if a claim under the inherent jurisdiction was the one dispute which was left out. Jacob J. had considerable sympathy for the Claimant's argument. Since, under English law, validity and infringement are part of the same question, he observed that "you cannot infringe an invalid claim, even if you fall within its language." However, he could not bring himself to read the language used by section 74(2) as allowing questions of validity to arise in a claim for a declaration of non-infringement of a patent pursuant to the inherent jurisdiction. Jacob J. stated that "I come to my conclusion with some regret but I think the language forced me to do so." Even though the application to strike out a validity challenge from the

Statement of Claim as originally served was successful, Jacob J. permitted an amendment to apply for revocation of the patent in the same proceedings.

39. It is, of course, the duty of the court to apply section 74, as Jacob J. did in the *Organon* case. However, I do not consider that the court is obliged to give the section a broad construction beyond that which its plain language allows. It contains a list of proceedings concerning granted patents in which validity may be put in issue. In the circumstances, resolution of the question before me is simple. A “patent” is defined in section 130 of the Act as “a patent under this Act” and does not include applications for a patent. Although section 69 provides that “patent” shall include an application in relation to certain sections of the Act, those sections do not include section 74. So section 74 does not prohibit a declaration relating to a published application. I entirely agree with Kitchin J that, had it been intended that section 74 should exclude the right of a person to seek a declaration in relation to his or her own product, particularly in circumstances where the need to do so arises from the existence of a published application, then it could have said so in express terms. But it does not, and it should not be so construed.

No pre-grant opposition

40. AbbVie pointed out that the procedure for opposing a patent during the pre-grant process provided for in section 14 of the Patents Act 1949, was abolished when the Patents Act 1977 was enacted and there is no corresponding provision in the 1977 Act. It submits that the position is *a fortiori* with respect to European patents: Parliament can hardly have contemplated that despite the abolition of the pre-grant opposition with respect to 1949 Act patents regulated by UK law, the court would nonetheless take it upon itself to act as a forum for pre-grant examination of European applications under the 1977 Act. The European Patent Convention does not provide for pre-grant oppositions but instead states that opposition may be filed within nine months “from the publication of the mention of the grant of the European patent” (Article 99).
41. A clear summary of the history and structure of the European patent system, including the deliberate exclusion of pre-grant oppositions; the provision for post-grant opposition proceedings; and the ability to apply for revocation of national designations of European patents whilst an opposition is continuing; was provided by Jacob LJ in *Unilin Beheer BV v Berry Floor NV* [2007] EWCA Civ 364; [2007] F.S.R 25 at [5]-[18]. This supports the conclusion that, both as a matter of UK law and under the EPC, pre-grant opposition is excluded. AbbVie submits that, in effect, the *Arrow* judgment impermissibly introduces such pre-grant opposition by way of declaratory relief.
42. I agree that there is no provision for pre-grant oppositions, either in respect of UK or European patents. That is why, in common with Kitchin J., I agree that the UK Court cannot conduct a pre-grant opposition to European Patent applications, as this would usurp the function of the EPO, which would be inconsistent with the framework of the EPC and the Act. This is why Kitchin J. stated at [60] that “I find it hard to conceive of any circumstances in which it would be appropriate for this court to grant a declaration that no valid patent could be granted on a divisional application which is being prosecuted before the EPO.”

43. There is considerable force in Mr Alexander's submission that FKB was seeking such relief in its declaration as to lack of entitlement to priority, which did not relate to any of its products. That has now been abandoned by FKB. The current position is that FKB only seeks a declaration that its own product was obvious or anticipated at the priority date. The existence of the divisional applications gives rise to the need and justification for seeking declaratory relief. AbbVie could withdraw the "GB" designations of the divisional applications or acknowledge that it can have no claim under them in this country in respect of a product having the specified characteristics of FKB's product. If it did so then the commercial purpose of the declaration sought would fall away. But, in common with Merck in the *Arrow* case, AbbVie has chosen not to take that course.
44. In this context I have also considered Mr Alexander's submission that FKB will contend, if it is successful in obtaining the declaratory relief sought, that *res judicata* or an issue estoppel would arise, thereby precluding AbbVie from contending in subsequent proceedings that any EP (UK) granted pursuant to a pending application was valid. This, he submits, demonstrates that these proceedings have as both their object and effect the final determination of the issue of validity of any patent that may be granted pursuant to the pending divisional applications.
45. The effect of the declaration would be to prevent AbbVie from bringing proceedings in respect of FKB327. This is the object of FKB's attempt to clear the way for this product launch. This would also apply to other biosimilar products of FKB which are not materially different from FKB327. I do not agree that the declaration would mean that AbbVie would be prevented by *res judicata* or issue estoppel from asserting any such granted patent against other companies, who are neither party nor privy to these proceedings.
46. In summary, I do not consider that the *Arrow* judgment was wrongly decided for this reason. On the contrary, I agree with Kitchin J.'s reasoning at [60] of the *Arrow* Judgment, which explains why the relief sought in this case does not introduce pre-grant opposition proceedings.

EU and English law and policy suggest that the Court should not usurp the EPO's examination of validity directly or indirectly

47. AbbVie points out that under Article 27 of Regulation (EU) No 1215/2012 ("the Recast Brussels Regulation") where a court of a Member State with exclusive jurisdiction is seized of a matter, another national court must decline jurisdiction over a claim which is "principally concerned with" such matter and must stay its proceedings. It was made clear by the Court of Justice in Case C-403 *GAT (Judgments Convention/Enforcement of Judgments)* [2006] F.S.R. 45 at [25]-[27] that the obligation to decline jurisdiction arises regardless of the form of the proceedings in which the issue of validity of a patent is raised. What matters is the substance and the Court of Justice has prohibited circumvention of the mandatory rule in that context. AbbVie draws an analogy with the position of the EPO, although Article 27 is not directly applicable as the EPO, is not a "court" of a "Member State".
48. AbbVie also draws attention to *Lenzing AG's European Patent* [1997] R.P.C. 245, where Jacob J. cited *Arab Monetary Fund v. Hashim (No. 3)* [1990] 3 W.L.R. 139, [1990] 2 All E.R. 769 (C.A.), where the court disapproved of action which would

“hijack an organisation to which [one sovereign state] and other states had given birth and subject it (contrary to the treaty terms) to its own domestic jurisdiction.” Jacob J. rejected a collateral attack on the EPO in the English court, by way of judicial review, which would create a forum for challenge by the English court to the EPO which was not provided for under the EPC. AbbVie argues that the policy reasons for not permitting the English Court to usurp the functions that Member States have exclusively allocated to the EPO are particularly strong. The application of the principle that the English Court should not usurp the EPO cannot depend on the form that the challenge to validity takes. It submits that Kitchin J. was wrong in the *Arrow* judgment in that he permitted an amendment which was an implied or indirect challenge to validity which conflicts with the exclusive jurisdiction of the EPO to conduct pre-grant examination.

49. I reject this criticism of the *Arrow* judgment for the reasons that I have already indicated. Kitchin J. expressly dealt with the importance of not usurping the function of the EPO in its examination of European patent applications. That is why the UK court will not make a declaration that no valid patent could be granted on a divisional application which is being prosecuted before the EPO. The declaration sought in the present case is directed at clearing the way for the launch of the FKB327 product, by creating a squeeze between infringement and validity. This cannot be done before the EPO, which has no jurisdiction over issues of infringement. This is a matter of substance, not merely form.

Whether exceptional circumstances are required to justify the relief sought

50. AbbVie submits that exceptional circumstances are required for the court to exercise its jurisdiction to grant this form of declaratory relief if, contrary to its primary case, there is jurisdiction to do so. This is disputed by FKB, which contends that a declaration should be granted in circumstances where it serves a useful purpose to do so. It is clear from the *Arrow* judgment that Kitchin J. considered that there was a reasonable prospect that the declaratory relief would be granted because of the unusual circumstances of that case. He expressly referred to this in his conclusion at [62]. Accordingly, whilst I would not use the expression “exceptional circumstances” I do accept that caution should be exercised when considering whether to grant this form of declaratory relief.
51. This provides a further answer to AbbVie’s primary submissions concerning the absence of pre-grant oppositions and the exclusive jurisdiction of the EPO to examine European patent applications. It is important to appreciate that *Arrow* declarations will not be granted as a matter of course, simply because there are pending applications in the EPO. A full analysis of the facts will be required, to ensure that any such declaration is justified.
52. AbbVie points out that *Arrow* was decided some nine years ago and only at first instance. It submits that since then, the appellate courts have been more willing to permit the EPO procedures to take their course without interference by the English courts. In particular it points to the decision of the Supreme Court in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2013] UK SC 46; [2014] A.C. 160, as summarised by Floyd LJ in *IPcom GmbH & Co KG v HTC Europe Co Ltd & Ors* [2013] EWCA Civ 1496; [2014] R.P.C. 12. At [62] Floyd LJ said that a stay of UK revocation proceedings whilst opposition proceedings were pending in the EPO was

“the default position”. In the light of this case-law, AbbVie submits that, even assuming the jurisdiction exists, it is hard to envisage circumstances sufficiently exceptional to justify the relief sought by FKB.

53. I do not accept that the cases cited by AbbVie support this proposition. In *IPcom*, Floyd LJ referred to the fact that opposition proceedings before the EPO may take many years to resolve, and stated at [21] that “the EPO has been a victim of its own success”. At [23] he said:

“23 A procedure which allows disputes over patent rights to take in excess of a decade cannot meet the needs of industry, particularly in rapidly moving areas of technology. Although such a procedure may technically comply with Article 6 of the European Convention on Human Rights, which guarantees a trial before an independent tribunal within a reasonable time, the opportunity for successive appeals and remittals means that there is in practice no final determination of the parties' rights for many years. Given their procedures, the Boards have a difficult task in seeking to achieve justice and finality”

54. This is why, when recasting the *Glaxo* guidelines following the observations of Lord Sumption in *Virgin*, Floyd LJ said at [68];

“8. The Patents Court judge is entitled to refuse a stay of the national proceedings where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO. It is true that it will not be possible to attain certainty everywhere until the EPO proceedings are finally resolved, but some certainty, sooner rather than later, and somewhere, such as in the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.”

55. The *IPcom* decision, in my view, does not suggest that *Arrow* has been superseded by subsequent case-law. On the contrary, it confirms that the underlying problem which *Arrow* confronts is still a very real issue.

Conclusion on jurisdiction

56. In spite of Mr Alexander's most attractive submissions, I am not convinced that the *Arrow* judgment was wrongly decided. On the contrary, I am convinced that it was correctly decided. If there was no jurisdiction to grant *Arrow* declarations, then it would be impossible for parties who wished to clear the way for the launch of a product to do so, without facing years of commercial uncertainty posed by cascading divisionals pending before the EPO. This would be so even where a patent had already been revoked or abandoned in the jurisdiction of intended launch, as the patentee could seek to re-monopolise essentially the same subject matter by filing further divisionals. Whilst the jurisdiction needs to be exercised with caution, both the UK and the Dutch courts have found that it exists. I agree with their conclusions and will proceed to consider whether there is a realistic prospect that the trial judge will exercise the discretion to grant the declaration in the present case.

Factors relevant to the exercise of discretion

Would the declaration sought by FKB serve a useful purpose?

57. I believe that there is, at least, a good arguable case that the declaration sought in the present case would serve a useful purpose. If FKB launches FKB327 in the autumn of 2018 it is likely to be faced, at some point in the future, with patent infringement actions arising from AbbVie's pending divisionals, if they are granted. FKB's evidence sets out a confidential estimate of potential loss of revenue if FKB327 is not launched. As one would expect, given the sales figures for Humira, the anticipated revenue, and therefore potential damages, is very substantial. The declaration, if granted, would dispel real commercial uncertainty and remove the risk of a large damages claim in the United Kingdom.
58. In addition, FKB has adduced evidence which shows, at least, that there is a real likelihood that it will be ready to launch FKB327 in the fourth quarter of 2018. By the time of its launch, FKB will have invested many millions of pounds in obtaining regulatory approval for its biosimilar product. This investment is put at risk by commercial uncertainty.
59. FKB has produced in evidence a transcript of statements by AbbVie's Chief Executive Officer, Mr Gonzalez, where he expressed AbbVie's intention to seek injunctive relief to prevent "at-risk" launches of products which are biosimilar to Humira. Mr Inman stated at 5.41 that "FKB therefore takes AbbVie's statements that it *"intends to enforce [its IP] vigorously"* and that it will *"seek injunctive relief"* to apply equally to its European Humira patent portfolio." This was not challenged in reply evidence served on behalf of AbbVie. Given the commercial importance of Humira, it would be surprising if AbbVie did not intend to enforce patent rights which it may be granted in the future by seeking injunctive relief.

Is the underlying issue sufficiently clearly defined to make it properly justiciable?

60. In respect of the declaration now sought, there is no doubt that the issue, namely whether FKB's own product was obvious or anticipated at the priority date, is sufficiently clearly defined. There is also no doubt that it is readily susceptible of determination by the UK Patents Court.

Are there special circumstances why the court should not grant the declaration sought?

61. I find that, cumulatively, the facts of this case are sufficiently unusual that there is a realistic prospect that the trial judge will exercise his or her discretion to grant the relief sought. In particular:
- i) The 656 patent was applied for in 2002. Having vigorously defended the opposition to that patent in the EPO, AbbVie abandoned it in November 2015, a few days after proceedings for its revocation were commenced in the UK.
 - ii) By the time it was abandoned, FKB had devoted significant resources in seeking to revoke the 656 patent in the EPO, and to establish that the 40 mg sc eow dosage regime was (amongst other things) anticipated or obvious in respect of adalimumab at the priority date to which it was entitled.

- iii) For the purposes of this hearing I must assume that the facts pleaded by FKB are correct, and that AbbVie abandoned the 656 patent in order to avoid a determination of its validity by the UK court and the Opposition Division, and to prolong commercial uncertainty by pursuing a divisional application in the EPO with the same subject matter. Even if this was not AbbVie's intention, it is the objective effect of its conduct.
- iv) The amount of money at stake for FKB, both in terms of investment in clinical trials and potential damages if it launches at risk, is unusually high. AbbVie has indicated, and it is clearly foreseeable, that it will seek to enforce its patent rights in respect of biosimilar products to Humira, including European Patents (UK) that may be granted in the future.
- v) FKB is only seeking a declaration of obviousness/anticipation in respect of particular characteristics of its own product which are clearly defined. The acts to which the declaration extends are limited to the United Kingdom. FKB is not seeking a declaration that no valid patent could be granted to AbbVie based on the divisional applications.
- vi) It is not possible on an application of this nature to accept FKB's submission that it has a very strong case. Nonetheless, I am satisfied that FKB has a real prospect of success in establishing that its own product was anticipated or obvious at the relevant priority date.

Justice to the parties

62. For the reasons given above, there is a real prospect that the judge at trial will consider that it is just to FKB to grant the declaration. I have considered AbbVie's claim that it should not have to face the costs and burden of a UK trial in respect of the issues raised by the declaration. I do not accept that this outweighs the potential injustice to FKB if it cannot clear the way prior to the launch of FKB327. In particular, AbbVie already faces a trial in the UK in respect of the 322 patent, which will proceed in any event and which concerns very similar subject matter. The commercial value of Humira is such that I do not accept that costs will operate as a deterrent to AbbVie in pursuing a vigorous defence of the claims made against it. Finally, if AbbVie is correct in its contentions, then it will recover a significant proportion of its costs.

Conclusion

63. I am satisfied that the court has jurisdiction to grant the declaration sought by FKB in respect of its own product. I consider that there is a reasonable prospect that the court at trial will decide to exercise its discretion to grant this declaration, in the unusual circumstances of this case. Therefore, I shall dismiss AbbVie's application to strike out this part of the claim, and allow the amendments in the form currently pursued by FKB.