GOWLING WLG

GROUND-BREAKING DECLARATORY RELIEF FROM ENGLISH HIGH COURT CLEARS THE ROUTE TO MARKET FOR HUMIRA BIOSIMILAR

06 March 2017

In a landmark judgment, the High Court has granted a novel type of declaratory relief to clear the route to market for a product facing a raft of pending patent applications incapable of challenge in the UK court: If the declaration serves a useful purpose, and upon considering the justice to the parties and any special reasons, the court can grant declarations that effectively offer an invisibility cloak against infringement actions based on patent applications which are later granted.

The High Court's 3 March 2017 decision in Fujifilm Kyowa Kirin Biologics v AbbVie Biotechnology [2017] EWHC 395 (Pat) marks the first declaration of its kind to be granted in the UK, and a turning point in patent litigation - allowing companies at risk of patent infringement to potentially "clear the way" even before patents are granted.

The judgment also resolves the uncertainty that remained after Arrow's battle with Merck in 2007, when the court refused to strike-out Arrow's claim for declaratory relief, but no final ruling emerged.

The highest turnover drug in the world

The case concerned AbbVie's network of patents and patent applications protecting dosing regimens for the use of its blockbuster anti-TNFα monoclonal antibody drug, Humira. Humira is used to inhibit the inflammatory effects of cell signalling protein "TNFα" in inflammatory diseases, including rheumatoid arthritis ("RA"), psoriatic arthritis ("PsA") and psoriasis.

With a **global** turnover of **over $16 billion** and **daily UK** sales of around **£1.2 million**, Humira is the world's highest selling drug.

Confronted with the imminent expiry of its basic product patent in October 2018 (EP 0,929,578 and SPC GB/04/002), AbbVie applied for "secondary" patents claiming the use of Humira in certain dosing regimens to treat various inflammatory diseases.

Clearing the way

In preparation for the launch of its monoclonal antibody biosimilar to Humira, in October 2015 FKB commenced litigation ("FKB1" proceedings) to **clear the way** of certain of AbbVie's secondary patents, seeking revocation of two of AbbVie's dosing regimen patents relating to RA and Psoriasis/PsA. As the Patents Act 1977 provides no mechanism to challenge the validity of **pending patent applications** in the UK courts, FKB also sought a new type of remedy - a declaration that using its own product in the relevant dosing regimens would have been obvious or lacking in novelty at the relevant date.

Such a declaration would give FKB **an invisibility cloak** from future patents for those dosing regimens - if using FKB's biosimilar in those dosing regimens was obvious or lacking in novelty, it could not infringe any future patent granted in respect of those regimens.

AbbVie applied to the High Court to strike out FKB's claim, but its application was refused in March 2016, [2016] EWHC 425 (Pat). On 12 January, the court of Appeal [2017] EWCA Civ 1 agreed with the High Court - the court had jurisdiction to grant declaratory relief, at its discretion.

In an unexpected twist, two months before the trial, AbbVie abandoned or de-designated the UK from its relevant dosing regimen patent and offered the court undertakings not to obtain future patent protection in the UK for those dosing regimens. With no relevant patents subsisting, AbbVie again attempted to strike-out FKB's claim. However, Henry Carr J. [2016] EWHC 3383 (Ch) found FKB had a real prospect of success in showing that the declaration would serve a **useful purpose**, and the case proceeded to trial.

Samsung Bioepis and **Biogen Idec** commenced proceedings (Claim HP-2016-000016, the "SB" proceedings) in 2016 seeking an equivalent declaration. The trials of the FKB and SB cases were heard together in January 2017 - the parties cooperating to present a single case with joint experts.

Declaratory relief: The law

The judge applied the following principles:

While declarations are a matter of **discretion** for the court, and negative declarations are unusual, 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" (Messier-Doughty v Sabena [2001] 1 All E.R. 275, Lord Woolf [41]).

The judge considered whether, in all the circumstances, it was appropriate to make a declaration, taking 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" (Financial Services Authority v Rourke [2002] CP Rep. 14, Neuberger J).

Declaratory relief is not appropriate in all cases. "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… 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" [93], but "an important factor to be borne in mind… is the existence of the statutory proceedings for revocation, which should be regarded as the normal vehicle for obtaining any desired findings of invalidity" [99] (FKB1, [2017] EWCA Civ 1, Floyd LJ).

Declaratory relief: The submissions

"Useful purpose"

The main debate related to whether there was a **useful purpose** in granting the declaration. AbbVie argued that, by the time of the trial, there remained no useful purpose as the way had been "cleared" in the UK. By then, AbbVie had abandoned/ de-designated the relevant patents and had given undertakings.

FKB contended that a useful purpose must remain, or AbbVie would have submitted to judgment. In refusing to do so, there remained commercial uncertainty created by AbbVie's behaviour:

a. From the outset of the litigation, AbbVie had created a moving target by delaying applications from being granted, abandoning applications (even once approved for grant) and filing duplicative "divisional" applications.
b. AbbVie's CEO repeatedly expressed AbbVie's intention to seek injunctive relief to

prevent "at-risk" launches of Humira biosimilars and FKB considered these threats to apply to Europe.

AbbVie produced no evidence at trial as to whether there was a **useful purpose** and, during the second week of the trial, chose not to cross-examine FKB's and SB's witnesses.

Finding on "useful purpose"

The judge indicated that he must concern himself with whether the declaration sought would serve a useful purpose **in the UK.** While he considered there to be a **useful purpose** regardless of AbbVie's intentions, he found that:

"subsequent events have confirmed, in my judgment, that 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" [349].

AbbVie's "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 may be launched" [388].

The declaration was found to serve a **useful purpose** in light of ([394-410]):

a. AbbVie's strategy of filing of divisional patent applications, perpetuating commercial uncertainty;
b. AbbVie's public statements of confidence in its patent portfolio while shielding its patents from scrutiny by the court;
c. commercial uncertainty arising from AbbVie's threats to enforce its patents anywhere in the world;
d. the "chilling effect" those statements would have (including on third party suppliers) and the need to protect FKB's supply chain for the UK by addressing that "chilling effect" and providing a persuasive UK judgment reducing the risk of injunctive relief in other jurisdictions which could disrupted the UK supply chain; and
e. the potential to promote settlement (which would have a direct benefit in the UK were AbbVie to seek to enforce other patents relating to Humira).

In considering FKB's submissions that the declaration would serve a useful "spin-off" purpose as a persuasive authority in other jurisdictions, the court accepted that while spin-off "can be very valuable", "it is important not to extend this principle too far"; "a

declaration which is sought solely for the benefit of foreign courts will rarely be justified". It also rejected AbbVie's suggestion that FKB's solicitors were not qualified to make assessments of the value of a UK judgment in the EU.

In the present case, "AbbVie has abandoned its UK patent protection shortly before trial, and has a long record of similar conduct. This is quite different from a case which has never had any connection with the United Kingdom, and is brought purely to influence foreign courts" [392]. It was found that there was more than spin-off value here. Central to this finding were the risks to the **UK** supply chain of injunctive relief in other jurisdictions and, given the pan-European nature of the pharmaceutical industry, in the absence of a declaration, the "chilling effect" on the market would make it more difficult for manufacturers to find European marketing partners.

In relation to AbbVie's **undertakings** and failure to submit to judgment, the judge commented:

"If, as AbbVie submits, the declarations have no useful purpose, and the steps that they have taken have the same effect in achieving commercial certainty, there is no coherent explanation as to why it refuses to submit to judgment, or alternatively to give an acknowledgement in the same form as the declarations" [386].

Although the undertakings would have prevented AbbVie from obtaining future UK patents claiming the relevant dosage regimens, they were "complicated" and "difficult to follow". The judge accepted FKB's submission that the declaration would provide clarity to third parties in the UK and "such clarity is necessary, given AbbVie's conduct to date, and is not provided by AbbVie's undertakings" [389-399].

Justice to the Claimants and the Defendants

FKB submitted that it was just to grant the declarations, that such determination should be made within a reasonable timeframe and that AbbVie's acts had prevented such a determination. The judge accepted that the declarations would serve a useful purpose and having heard the technical case, it was just to grant them and there would be no injustice to AbbVie in doing so.

Special reasons

The short summary of the "special reasons" for the grant of the declarations was as follows:

"On the most unusual facts of this case, there are special reasons which support the grant of the declarations. These include AbbVie's conduct of threatening infringement whilst abandoning proceedings at the last moment (in order to shield its patent portfolio from scrutiny); the amount of money at stake for the Claimants in terms of investment in clinical trials and potential damages if they launch at risk; and the need for commercial certainty, having regard to AbbVie's threats to sue for infringement throughout the world" [416].

Award of the declaration

The reasons for judge's award of the declaration centred on the unusual facts of the case - including AbbVie's patent filing strategy and its attempts to avoid adjudication on the validity of its patents. This serves as a warning to patentees: although an act may be within the rules laid down by the EPO, the UK courts can grant declaratory relief when the circumstances justify it, and a patentee's behaviour is likely to be a key factor.

The technical case

We also write briefly here on some points of interest from the technical case.

Shortly before the trial of the action, AbbVie accepted the obviousness/anticipation of a number of the dosing regimens at certain dates (in one case, that date was later than the relevant date in the declaration, and Henry Carr J. proceeded to find it obvious/anticipated at the earlier date based on a prior use).

This left only one regimen to be considered at trial (every other week dosing with 40mg in RA). FKB sought to establish the obviousness of using FKB's biosimilar in that regimen on the basis of two prior art papers by Dr Kempeni and three conference abstracts referenced in the papers.

AbbVie's prior art

AbbVie supplemented FKB's pleaded prior art with "Additional Prior Art" - every paper and conference abstract referencing Humira before the relevant date. FKB argued this was impermissible and had FKB sought to "mosaic" these publications it would not have been allowed (unless the mosaic was obvious).

Henry Carr J agreed with AbbVie. The Additional Art was "material which is not common general knowledge, which nonetheless, as a matter of routine, the skilled person would

look for and find when approaching a particular problem".

However, the judge rejected AbbVie's attempts to draw conclusions from individual abstracts in the Additional Prior Art, when the pleaded Kempeni papers were an overview of (almost all) of the Additional Prior Art studies, and did not draw the conclusions AbbVie sought to draw.

Dosing regimen design

While AbbVie's experts pursued dosing regimens that would be maximally effective in every patient, the judge preferred the evidence of Prof Edwards (for FKB) that "the skilled clinician would be looking for a dosage regimen which would **help the condition of the majority of patients**" and that the dosing regimen would be designed **"having regard also to cost considerations, patient convenience and, accordingly, patient compliance**" [114].

The dosing regimens were ultimately found to be obvious in light of both of the Kempeni papers.

A warning to experts

Henry Carr J. gave a number of warnings regarding expert evidence. In discussing AbbVie's experts, he commented that while there is no issue with experts being used in multiple jurisdictions, it is not satisfactory for them to claim in the UK court that they are unable to comment upon an issue which they have commented on in other proceedings [208].

He also cautioned experts to reference their experience where it contradicts their written evidence. In relation to AbbVie's rheumatologist, he wrote:

"I am also concerned about the failure to mention in her reports that she had worked on a biological for the treatment of RA known as anakinra, the history of which contradicts material parts of her evidence. I am prepared to accept that this was a mistake, rather than a deliberate omission, but it should not have happened" [118];

"…she should have referred to anakinra and explained why she was able, nonetheless to give this evidence" [201].

To ensure experts comply with their duty to the court, the judge commented:

"it is not merely a question of an expert stating that he/she has read and understood the relevant duties. Rather, the expert needs to adhere to them strictly. This is likely to involve careful additions and alterations by the expert to draft reports, which are often worked on by many hands. Furthermore, if, during cross-examination, it becomes clear that some part of the expert report is mistaken, it is necessary to say so, rather than doggedly to adhere to the party line."

Representation

The Gowling WLG team of partners **Paul Inman** and **Luke Kempton**, Principal Associate **Jenny Davies** and Senior Associates **Chris Freeth** and **Tom Foster** advised FKB, with **Andrew Waugh QC**, **Justin Turner QC**, **Geoffrey Pritchard** and **Katherine Moggridge** as counsel.

Related Life Sciences, Intellectual Property

Author(s)

Jenny Davies
Legal Director - London

Email
jenny.davies@gowlingwlg.com

Phone
+44 (0)203 636 7996

vCard
Jenny Davies

Paul Inman
Partner - London

Email

paul.inman@gowlingwlg.com

Phone

+44 (0)20 3636 7950

vCard

Paul Inman