

English Patents Court Setting Out its Stall?

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In a much-awaited decision handed down on 22 May 2017, the US Supreme Court in *TC Heartland v Kraft Foods*¹ held that the "patent venue statute" (28 USC §1400(b)) should be construed narrowly. This was the provision which the US courts had previously construed so as to define a defendant's "residence" as a state in which the defendant merely had business activities. This construction had allowed the blossoming over the last 30 years of an entire patent litigation industry in the Eastern District of Texas based upon forum shopping where patent trolls (non-practising entities) could sue in order to secure royalty settlements. The Eastern district of Texas had a record of finding for patentees around 80% of the time. In a unanimous ruling, the Supreme Court held that companies can only be sued for patent infringement where they reside or where they have regular and established place of business. If, as seems likely, patentees will now forum shop elsewhere, they will be faced with district courts with fewer resources to handle high volumes of patent infringement cases – Marshall Texas was home to around 30% of all patent actions filed in the US.

In the circumstances, patentees seeking a venue which affords more opportunities could well be looking overseas to Europe, and more specifically to the UK. The English courts' recent approach to make itself more outward looking in the field of patent law could well be a master stroke. This paper reviews some of the recent decisions of the UK Patents Court which have the feel of a determined pitch to a wider audience than usual.

Construction of Foreign Patents – *Actavis v Eli Lilly*

A more detailed expansion of the key issue contained in the Supreme Court decision in the *Actavis v Lilly* litigation is discussed in an earlier paper² by this writer. A secondary issue in the same case bears closer examination and related to the UK courts' willingness to construe and judge infringement of foreign patents. Actavis commenced an action in the English Patents Court seeking a declaration of non-infringement, not only in respect of the EP (UK) designation but also for the French, Spanish and Italian designations. Actavis gave an undertaking not to challenge the validity of the patent, so as to avoid the effects of the Brussels regulation when it came to exclusive patent jurisdiction.

Although Actavis had undertaken not to challenge the patent's validity, it nonetheless advanced an argument, in aid of its claim construction, that the patent would have been rejected by the EPO on the basis of added matter, if Lilly's claim construction were correct. Lilly contended that the Actavis argument placed the patent's validity in issue and so was barred by the Brussels regulation. However, Arnold J accepted Actavis' argument citing the Protocol on Article 69 EPC and holding that the Protocol's requirement for "*fair protection for the patentee*" meant that an analysis of scope of protection of a claim had to allow for a consideration of rival claim constructions which might invalidate the claim. This was because a construction which led to invalidity could not be said to be fair to a patentee. The Judge's decision was upheld by the Court of Appeal on this point.

¹ *TC Heartland LLC –v- Kraft Food Group Brands LLC -* SCOTUS Docket 16-341 (30 May 2017)

² <https://www.twobirds.com/news/articles/2017/uk/actavis-v-eli-lilly-are-we-clear-now>

The court at first instance considered the propriety of an English court ruling on the infringement of foreign IP rights. Actavis relied heavily upon the 2011 judgment of the UK Supreme Court in *Lucasfilm v Ainsworth*³ a case brought by George Lucas to seek to restrain infringement in the UK of USA-subsisting copyright by a purveyor of replica Star Wars Imperial Stormtrooper helmets. The Supreme Court held that the English courts did have jurisdiction to hear the action. Lords Walker and Collins stated:

*"We have come to the firm conclusion that in the case of a claim for infringement of the present kind, the claim is one over which the English court has jurisdiction, provided that there is a basis for in personam jurisdiction over the defendant."*⁴

In the Actavis case, Mr Justice Arnold declined to grant Lilly a stay on grounds of *forum non conveniens*, observing that:

"I find it difficult to believe that, if Mr Ainsworth had been domiciled in a country outside Europe, but had been resident and validly served in England, the Supreme Court would have held that considerations such as the need to apply foreign law, the extra-territorial effect of any injunction and the economic effect of enforcing foreign intellectual property rights meant that it was appropriate to stay the proceedings on the ground of forum non conveniens."

He continued:

"As to the different national approaches, I accept that there are differences. In my view, however, the differences are rather less now than they have been in the past. Certainly, in recent years the European patent judiciary have been striving for consistency. I am sceptical that the remaining differences of approach, as opposed to other factors, are responsible for different outcomes in parallel cases. In any event, it seems to me to be manifest that it will reduce the likelihood of inconsistent decisions if one court at first instance and one court on appeal determines all five of Actavis' claims."

On two fronts therefore, Arnold J in the *Actavis* case advertised that the English court was open to adjudicate on foreign patents; first via pan-

European declarations of non-infringement and second, via determinations of scope of claim of foreign patents, in both cases entertaining considerations of invalidity issues.

Construction of Foreign Patents – Chugai v UCB

More recently, the May 2017 decision by Henry Carr J in *Chugai v UCB Biopharma*⁵ was another interesting situation where the English court accepted jurisdiction over a foreign patent by finding that validity was not in issue but only proper claim construction.

The patent in suit was a US patent belonging to UCB, which was the last surviving patent in a portfolio which had been licensed to Chugai. The dispute concerned Chugai's humanised anti-IL-6 receptor antibody (tocilizumab) an immunosuppressive treatment for rheumatoid arthritis and whether this product fell outside the scope of the claims of the patent in suit, properly construed. Chugai argued that it did so fall, and as a result, it was entitled to a declaration from the court that it owed no royalties to UCB under the licence for manufacture and sale of tocilizumab after a certain date. The licence was governed by English law and English exclusive jurisdiction. Although the contractual issues fell to be considered under English law, the scope of protection of the US patent in suit had to be considered under the relevant US principles of claim construction.

A key argument by Chugai in aid of its claim construction related to a file wrapper estoppel argument, which was similar to the point argued by Actavis above. Chugai alleged that UCB during prosecution in the USPTO had made representations to the examiner regarding a key piece of novelty prior art (known as "Queen"). According to Chugai, *"the USPTO would not have granted the patent based on a construction that would be invalidated by Queen"*.

As a result, Chugai alleged that the proper claim construction must be the one that upheld the validity of the patent over Queen and, as such, that its tocilizumab product was outside the scope.

This argument had very much the same "quasi-squeeze" flavour as was seen in *Actavis*. For its part, UCB alleged (as Lilly had done in the *Actavis*

³ *Lucasfilm Ltd –v- Ainsworth & Anr* [2011] UKSC 39 (27 July 2011)

⁴ *Lucasfilm @ ¶106*

⁵ *Chugai Pharmaceutical Co. Ltd. –v- UCB Pharma SA & Anr* [2017] EWHC 1216 (Pat)

case) that Chugai was in fact advancing a classic squeeze between infringement and validity albeit dressed up as a claim for a declaration about royalties. The Judge accepted Chugai's submission finding that it was not asking the court to determine that the UCB patent was invalid but merely requiring the court to ask itself, as a guide to construction, what would be the hypothetical consequences for validity of the rival claim constructions. The court dismissed UCB's application for strike-out finding that the English court did have jurisdiction to decide the matter.

Promise of Clarity on Supplementary Protection Certificates

In the crossover between pharmaceuticals and patent law, supplementary protection certificates (SPCs) play a central role. Pharmaceutical companies had long maintained that a 20 year patent monopoly was insufficient recompense for the long years of research and development, the vast expense involved in securing a regulatory marketing authorisation (MA) and bringing a new drug to market. The 20 year monopoly runs from the when the patent application for a new drug is filed, which can be at a very early stage of the R&D process - as early as the stage of identification of lead compounds, well before the identification of clinical candidates. With the 20 year clock ticking from such an early stage, pharmaceutical companies complained that increasing regulation, clinical trials etc. had the result of reducing the effective patent term during which their R&D costs could be recouped.

In Europe, since enactment of the European SPC regulation in 1993, patent term for pharmaceuticals can effectively be extended through the use of SPCs. An SPC is not a patent itself but comes into effect upon the expiry of the "basic patent" protecting a product. The SPC confers a limited extension of time during which the patentee can continue to enforce the basic patent, save that it only protects the particular pharmaceutical product which a European marketing authorisation has been granted. The SPC has a maximum duration of 5 years, depending on the actual regulatory delay incurred by the pharmaceutical company. Obviously, in the era of blockbuster drugs with billions of dollars of annual revenue, even an SPC with a duration of a few months can be of enormous significance and litigation relating to the validity of SPCs is extremely hard fought.

While SPCs are national rights which are enforced through infringement litigation in the national patent courts, questions on the interpretation or effect of the SPC regulation can be referred by the national courts to the Court of Justice of the EU. Unfortunately, the CJEU, not being a court particularly familiar with patent law issues, has a less than stellar record of providing the clarity sought by the referring national courts. The SPC regulation necessarily spans the two distinct fields of patent law and medicine regulation, fields which have different rationales, different aims and different approaches, albeit with common end-users. As a result the CJEU has encountered problems of definition, in particular defining what is the "product" which is actually the subject of the SPC – i.e. what is meant by "*product protected by a basic patent in force*" within the meaning of Article 3a of the SPC regulation. This has resulted in some incomplete, unclear, confusing and inconsistent decisions which have then been interpreted by the UK courts as best they can.

In subsequent cases, the ongoing lack of clarity has resulted in questions of interpretation supposedly already answered by the CJEU effectively being resubmitted by the UK courts. Mr Justice Arnold in the English Patents Court has been particularly in the vanguard of this approach and 2017 has seen a number of cases all concerning SPCs which he has heard. These were *Teva v Gilead*⁶, *Abraxis' SPC*⁷, *Teva v Merck*⁸ and *Sandoz v Searle*⁹. Arnold J's frustration with the CJEU is evident from the decisions in which he refers questions to the CJEU and includes in the referral his own suggestion as to how the question may be properly answered "*in case it assists the CJEU*". In the *Teva v Gilead* decision, Arnold J conducted a detailed and clear analysis of previous CJEU case law including *Farmitalia*, *Medeva*, *Yeda*, *Queensland*, *Daiichi Sankyo*, *Actavis* and *Eli Lilly*. The decision illustrates the inconsistencies in the CJEU case law and the efforts made by the UK judges over the years to make sense of those decisions. The final part of the decision sees Arnold J referring a question to the CJEU. The question is stark in its simplicity – "*What are the criteria for deciding whether 'the product is protected by the basic patent in force' in Article 3(a) of the SPC Regulation?*" A newcomer to this field would be forgiven for wondering why such a fundamental

⁶ *Teva UK Limited & Ors -v- Gilead Sciences Inc* [2017] EWHC 13 (Pat)

⁷ *Abraxis Bioscience LLC -v- Comptroller of Patents* [2017] EWHC 14 (Pat)

⁸ *Teva UK Limited & Ors -v- Merck Sharpe & Dohme Corp* [2017] EWHC 539 (Pat)

⁹ *Sandoz Limited & Anr -v- GD Searle & Anr* [2017] EWHC 987 (Pat)

question had never been adequately answered by the CJEU before. Indeed, the starkness of the question posed illustrates very well Arnold J's clear impatience with the CJEU.

The judge ends the judgment by setting out his suggested answer to the fundamental question. According to Arnold J, a product (or combination product) will only be protected by a basic patent, if it contains an active ingredient or combination of active ingredients which embodies the inventive advance (or technical contribution) of the basic patent. This was not, the Judge said, a question of the wording of the claims of the basic patent, which can be manipulated by the patent attorney who drafts it, but of its substance¹⁰.

In the context of Brexit, this clarifying approach by Arnold J takes on special significance. A key feature of the UK government's approach for Brexit is the European Union (Withdrawal) Bill. This Bill which at the time of writing is awaiting its detailed committee stage reading, has the function, not merely of formally taking the UK out of the EU but at the same time dealing with the status of EU law on the day of Brexit. Under the Bill, the entire accumulated legislation, legal acts, and court decisions which constitute the body of European Union law (the so-called *Acquis Communautaire*) would be lifted and enacted en bloc into UK law so that it would be in place upon Brexit. This is intended to ensure a seamless transition on Brexit Day.

Obviously, as part of the *Acquis*, the SPC Regulation would be enacted into domestic UK law. At that point, it will then be the UK courts which will have the final say on interpretation of the relevant provisions of the SPC regulation. By indicating how the UK court would propose to answer various questions of interpretation, Arnold J has sought to dispel the inconsistencies and lack of clarity which arose from the previous CJEU decisions, clearly seeking to show international litigants that the UK jurisdiction will be the key venue for SPC litigation.

FRAND Injunctions - Unwired Planet v Huawei

The mobile telecoms and standards-essential patents (SEP) field has been a rich source of litigation in the English (as in other countries') patent courts since the early 2000s. The field has in the past demonstrated the flexibility of the English Patents Court to deal with disputes. The old cases had considered the effect of standards body membership, under which a telecoms company would give notice of patents in its portfolio which had been assessed to be essential to compliance with the relevant mobile telecoms standard – e.g., GSM, UMTS, LTE etc. A patent is essential if it is not possible on technical grounds to make, sell or use telecoms equipment which complies with a standard, without infringing that patent. As part of the notification, the member is required to provide an undertaking to grant patent licences for SEPs to other members on fair, reasonable and non-discriminatory (FRAND) terms. The first such case *Nokia v Interdigital* included a conventional validity attack, but also an application by Nokia for an entirely novel form of relief, a declaration of non-essentiality of certain Interdigital patents. The declaration sought had the aim of demonstrating that Interdigital's portfolio was not as strong as it asserted. The declaration was ruled allowable in principle (and subsequently granted) by Pumfrey J at first instance¹¹ and upheld by the Court of Appeal¹². A key feature of the discussion related to the question of whether such a novel form of declaratory relief was one that the English courts could and should grant. It was held in both courts that the grant or refusal of the declaration would resolve a real live commercial dispute between the parties and therefore was a legitimate form of relief. Declarations of essentiality and non-essentiality thus became a settled feature of SEP litigation in the UK.

Recently, the flexibility of the English Patents Court has been clearly demonstrated once again in the mobile telecoms field in a dispute between patent holder Unwired Planet and equipment manufacturer Huawei about SEPs¹³. In a series of technical judgments during the course of 2015 and 2016, Birss J assessed whether various Unwired

¹⁰ Interestingly, by focusing on the substance (inventive core/concept) of the claim rather than its language, Arnold J was here foreshadowing Lord Neuberger's approach to scope of claim and infringement by equivalents in *Actavis v Lilly*.

¹¹ *Nokia Corp -v- Interdigital Technology Corp* [2006] EWHC 802 (Pat)

¹² *Ibid* [2006] EWCA Civ 1618

¹³ *Unwired Planet International Ltd -v- Huawei Technologies Co. Ltd.* [2017] EWHC 711 (Pat)

Planet patents were valid and essential in that they would be infringed by Huawei equipment that complied with the relevant telecoms standards. Having found that two UP patents were valid and essential, Birss J then considered in his judgment of 5 April 2017, what rate should apply to the FRAND licence which Unwired Planet was required to offer. This was the first occasion on which the English court assessed FRAND obligations and considered the royalty rates on a portfolio basis.

Birss J held that there were only one set of FRAND licence terms for any given set of circumstances and for these parties it was a global licence. The FRAND undertaking did not mean that Huawei was already licensed per se but meant that only an unqualified commitment to accept a FRAND licence could enable the implementer to avoid a final injunction to restrain infringement. Where the implementer refused a licence on terms later held to be FRAND, an injunction could be granted. Following the decision, the parties agreed a form of licence which reflected the Judge's rulings on FRAND. In a subsequent decision of 7 June 2017, Birss J considered the form of final injunction which was appropriate in situations involving SEPs and expanded the jurisprudence of the English patent courts by the granting of a novel form of injunction – a "FRAND injunction". Birss J held that a FRAND Injunction should be in the normal form to restrain infringement of the relevant patent(s) with a proviso that it will cease to have effect if the defendant enters into that FRAND licence. As in this case the FRAND licence was for a limited time (until 31 December 2020), shorter than the lifetime of the relevant patents then the injunction was also subject to an express liberty to either party to return to court in future to address the position at the end of the term of the FRAND licence.

Arrow Declarations – Fujifilm v AbbVie

Showing similar flexibility as the court in Unwired Planet, the Patents Court in *Fujifilm v AbbVie*¹⁴ likewise granted a novel form of relief – a so-called *Arrow* declaration. The decision to grant this form of declaration was based upon Henry Carr J's finding that AbbVie had behaved unconscionably in its patenting strategy and indeed its strategy in the court proceedings.

Fujifilm was one of the parties which sought to bring a biosimilar product to market in the UK. The reference product was AbbVie's blockbuster Humira (adalimumab) antibody, for treating rheumatoid arthritis. In order to clear the path prior to launch of the biosimilar, Fujifilm commenced UK proceedings to revoke three key granted patents belonging to AbbVie which related to new dosage regimens. One of the patents in suit ("656") which was under EPO opposition by 15 opponents, had four divisional applications spun off it. Six days after the commencement of the UK action, AbbVie notified the EPO that it was abandoning the granted 656 patent. On the very same day, the fourth of the AbbVie divisional applications (044) was published and this was subsequently added into the revocation proceedings by Fujifilm. As well as seeking revocation of the patents in suit, Fujifilm sought an unusual type of declaratory relief, an *Arrow* declaration.

This type of declaration was based on the 2007 judgment of Kitchin J. (as he then was) in *Arrow Generics Ltd v Merck & Co Inc.*¹⁵ in which the judge decided at an interim stage of those proceedings that such declarations had a reasonable prospect of success and should be allowed to proceed. The *Arrow* relief is sought pre-patent grant is for a declaration that the accused products would have lacked novelty/been obvious at the priority date. The relief is intended to prevent a patentee from commencing infringement proceedings under pending patent applications, once they have granted. It effectively declares that the defendant would have a successful *Gillette*¹⁶ defence to infringement if it were sued under any of the relevant patent applications when granted. The *Gillette* defence relies upon the principle that a defendant ought to be permitted to deal in products which are merely prior art or which are no more than obvious developments of the prior art.

The *Fujifilm* case proceeded with preparation of extensive expert reports dealing with the invalidity arguments for the two remaining patents in the original suit, and the 044 divisional. A few months before trial AbbVie, without explanation, de-designated the UK from the 044 patent, disapproved the text of one of the other patents, leading to its revocation and indicated that it would submit the final patent to revocation in the UK. At

¹⁴ *Fujifilm Kyowa Biologics Co. Ltd & Ors –v- AbbVie Biotechnology Ltd* [2017] EWHC 395 (Pat)

¹⁵ *Arrow Generics Ltd & Anr –v- Merck & Co., Inc* [2007] EWHC 1900 (Pat)

¹⁶ From *Gillette Safety Razor v Anglo-American Trading* (1913) 30 RPC 465

the same time, AbbVie offered undertakings in the UK not to secure future patent protection in the UK for claims that would be infringed by Fujifilm's dealings in its biosimilar product being for treatment of rheumatoid arthritis under certain dosage regimens. Essentially, AbbVie was submitting existing UK patents to revocation and offering undertakings not to create future blocking patents in the UK for the Fujifilm product. In this way, AbbVie was seeking to render the proceedings irrelevant. Despite the AbbVie undertakings appearing to give Fujifilm as much protection as it was seeking via the Arrow declarations, Fujifilm was not prepared to accept the undertakings. Instead it invited AbbVie to submit to the court's judgment. AbbVie refused and instead commenced a series of interim applications seeking to strike-out the *Arrow* declarations.

In his judgment of 3 March 2017, Mr Justice Henry Carr found that despite its undertakings and abandonments with regard to its UK granted patents, AbbVie had maintained a public position that it would make every effort to enforce its patent estate against biosimilar competition anywhere in the world. The reason for AbbVie's abandonments was to shield its patents from scrutiny in the EPO and in the UK court. But for the abandonments, Fujifilm would have had an opportunity to seek findings of invalidity of the patents and to secure firm commercial certainty, not only in the UK, but potentially elsewhere in Europe and beyond, by relying on the persuasive nature of UK judgments. Despite abandoning patents, AbbVie sought further divisionals and sub-divisionals thereby maintaining commercial uncertainty for its competitors. The Judge held that there would be a real commercial value in granting the *Arrow* declarations to Fujifilm and proceeded to do so.

Conclusion

The English Patents Court has historically been accepted to have a particular role in European patent enforcement or FTO strategies. The English court was the high cost/high quality forum where discovery was available almost as of right and where rigorous testing of evidence with full expert witness cross examination by technology-savvy barristers before technically qualified judges would guarantee to reach the right answer and where patentees with weak patents feared to tread. For this reason, it was historically the venue of choice for generics to revoke patents. On the other hand, the German district courts were beloved of patentees. A sliding scale of court fees, preliminary

injunctions available almost as of right, decisions on infringement within 6-9 months, a bar on revocation actions during pending EPO oppositions and a bifurcated system which meant that potentially weak patents would avoid detailed scrutiny for 18 months until the case came up before the Federal Patents Court. As a result, the standard pan-European patent litigation strategy would involve a patentee commencing infringement proceedings before the Dusseldorf or Mannheim district court and the alleged infringer "counterclaiming" via commencement of revocation and/or declaratory proceedings in the English Patents Court.

These recent decisions of the English patents court could be the signs of a pre-Brexit battle to make the UK a more attractive venue for patent litigation. When viewed against the background of particularly one recent patentee-unfriendly case emerging from the US courts, this could mark the start of a genuine push to make UK courts more attractive forum for patent disputes. With only 18 months until the UK exists from the EU, this could be shrewd move by the UK IP courts to set out their stall to the international patent community and to vie with their usual continental competitors, the German district courts.

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