This second edition of our regular patent and pharma update provides a round-up of significant cases and developments from United Kingdom and European patent law since our last update of 11 November 2014.

1. **Reference numerals in patent specification should not influence claim construction – Court of Appeal finds Jarden’s fryer does not infringe**


The proceedings were concerned with European Patent EP (UK) 2 085 003 owned by SEB which relates to food frying machines that use only a small quantity of oil, including that sold by the SEB Group as the Tefal Actifry fryer. SEB claimed that Jarden’s Breville Halo Health Fryer infringed the patent, and Jarden sought revocation on the basis of obviousness over a German patent (‘Vogt’). At first instance, amongst other findings, Arnold J held that claims 10, 11 and 13 of the patent were valid (and not obvious over Vogt) and were infringed by Jarden’s fryer. Jarden appealed against Arnold J’s construction of the patent on the grounds that, properly construed, those claims held to be valid were not infringed. Further, Jarden appealed against Arnold J’s decision that those claims (and Claim 15) were not obvious.

The main issue was whether the construction of the words ‘mounted on the main body’ in the claims included the lid. At first instance, Arnold J decided that Jarden’s fryer infringed as the ‘main body’ of the claimed fryer included the lid so that the patent claims covered an embodiment in which the heater was mounted on the lid. Amongst other points, in reaching his conclusion that the ‘lid’ was an (optional) part of the ‘main body’, Arnold J considered the fact that the specification described a ‘main body 2’ having three parts – a ‘base 2A’, a side ‘skirt 2B’ and a ‘lid 2C’; and that this numbering scheme was used to describe a number of assemblies.

The Court of Appeal considered the use of reference numerals in the context of construing a claim. Vos LJ in the court’s leading judgment found that Arnold J had erred by using the identifiers ‘2’, ‘2A’, ‘2B’ and ‘2C’ to conclude that the lid would form part of the main body, rather than simply using these identifiers to identify the relevant parts in the relevant figure, contrary to the Court of Appeal’s decision in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2009] EWCA Civ 1062. This earlier decision of Jacob LJ held that the reader of a patent can only use reference numerals in a claim to orient himself to the general notion of what the patent is about (ie, identify the parts of the device), but cannot be used to construe a particular term in a claim. Or, as expressed in the words of Jacob LJ, the numerals should be used only to enable the reader to ‘get the map the right way up’ but not ‘to help [one] read it to find out exactly where [one was]’. The claim must be construed as if the reference numerals are not there.
Reading the claim afresh, without impermissible use of the reference numerals, and by using the process of construction described in Virgin Atlantic, the Court of Appeal held that Arnold J had incorrectly construed the claim. As a consequence of this change in construction, the Court of Appeal overturned Arnold J's decision on infringement.

Given the finding of non-infringement, the Court of Appeal was not required to decide the appeal on obviousness. However, the Court of Appeal still considered in that context whether Arnold J was justified in holding that the skilled team would have disregarded Vogt. Vos LJ concluded that this point was open to Arnold J and that he was entitled to reach this conclusion, such that there was no need to consider any of the further points raised by Jarden on obviousness over Vogt.

2. Advocate General recommends limits on SEP injunctions against infringers who are 'objectively ready, willing and able' to conclude a licence

Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH, Case C-170/13, AG's opinion, 20 November 2014.

The Advocate General's opinion in Huawei Technologies is that an owner of a standard essential patent (SEP) who has given a FRAND undertaking, may be abusing its dominant position by seeking an injunction against an infringer, where it is shown that the SEP-holder has not honoured its FRAND commitment even though the infringer has shown itself to be 'objectively ready, willing and able' to conclude a licence.

Although the Advocate General's opinion is not binding, it is likely that the Court of Justice of the European Union (CJEU) will adopt most of the Advocate General's guidance in its judgment that is expected early this year. Importantly, the Advocate General's opinion sets out a framework for determining whether the infringer is in fact 'objectively ready, willing and able' to conclude a licence. The framework can be summarised as follows:

- Before commencing proceedings seeking injunctive relief, the SEP-holder must alert the alleged infringer to its infringement, specifying the SEPs concerned, the manner in which they have been infringed, and including a written licensing offer on FRAND terms including setting out the precise royalty due and the way that amount has been calculated. This precludes suing an infringer first for injunctive relief, and then negotiating afterwards. However, it is not an abuse of a dominant position for an SEP-holder to bring a claim for damages for past acts for the sole purpose of obtaining compensation for previous infringements, or to take legal action to secure a rendering of account, provided that such measures are reasonable and proportionate.

- The infringer must then respond to the SEP-holder's offer in a diligent and serious manner. In particular, if it does not accept the offer, it must respond in writing with a reasonable counter-offer in respect of the clauses with which it disagrees. It is implicit in this that the infringer should set out its counter-offer in relation to the proposed royalties due.

- The timeframe for the exchange of offers and counter-offers, and the duration of negotiations must be assessed in the light of the 'commercial window of opportunity', something that will depend upon the particular industry sector in question. However, an infringer will lose its protection from injunctive relief if its conduct is 'purely tactical and/or dilatory and/or not serious'.

- If negotiations are unsuccessful, it seems that an infringer can avoid the immediate threat of injunctive relief if it requests that FRAND terms be fixed either by a court or by an arbitration tribunal. However, if the infringer does so, the SEP-holder can then ask for the infringer to provide a bank guarantee or to deposit funds at court, in respect of its past and future use of the SEPs.

- During the negotiations for a FRAND licence, the infringer is entitled to reserve the right, 'after concluding an agreement for such a licence', to challenge the validity or essentiality of the SEPs. One reading of this is that the infringer could be at risk of an injunction if it seeks to use essentiality/validity proceedings as a means of delaying entering into a licence. However, the practical reality is that, to obtain injunctive relief, the SEP-holder would have to establish essentiality anyway and, depending upon whether the proceedings are bifurcated in the jurisdiction concerned, perhaps also validity.

It is important to note that all of the above is predicated on the SEP-holder actually being in a dominant position. If it is not, then its behaviour in relation to its SEPs (whether it seeks injunctive relief or not) cannot be contrary to Article 102 of the Treaty on the Functioning of the European Union. None of the questions referred related to that issue. However, the Advocate General emphasised that the fact an undertaking owns an SEP does not necessarily mean that it holds a dominant position. That is for the national court to determine, although the circumstances in which an SEP-holder is in a dominant position at all remain unclear. This is likely to be of particular interest to non-practising entities and those approached by them. It is highly likely that any SEP-holder will argue that it is, in fact, not in a dominant position. It also remains to be seen how the framework in the Advocate General's opinion will be applied in practice.

Read more
3. Clarification of European Law relating to stem cell patents

International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, Case C-364/13, 18 December 2014. The press release announcing the decision of the CJEU decision can be found here.

- The Court of Justice of the European Union has confirmed that, in the context of the exclusions from patentability in the Biotech Directive, an organism must have the 'inherent capacity of developing into a human being' in order to be considered a 'human embryo'.
- This decision may allay some of the concerns regarding the patentability of inventions in the field of stem cells following the CJEU decision in Oliver Brüstle v Greenpeace e.V. of 2011, which held that the term 'human embryo' should be defined broadly including, inter alia, 'any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis'.

In 2012, the UK-IPO Hearing Officer rejected applications for two UK patents by International Stem Cell Corporation on the grounds that in Europe uses of human embryos for industrial or commercial purposes are excluded from patentability under the Biotech Directive. These applications related to the process of 'parthenogenetic activation' which involves the use of chemical or electrical techniques to activate unfertilised human eggs ('ova'). The activated ova (known as 'parthenotes') start to divide and develop in a way which is similar, at least initially, to the process by which an embryo forms from a fertilized egg. This process of division and development includes the formation of pluripotent stem cells, which are of interest for medical research.

International Stem Cell Corporation appealed this decision to the Patents Court, which in turn referred the following question to the CJEU:

'Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term 'human embryos' in Article 6(2)(c) of [the Biotech Directive]?'

The CJEU noted that in Brüstle, the written observations before the court indicated that parthenotes did have the capacity to develop into a human being and this explained why, in that case, they were found to fall within the definition of human embryos and so were excluded from patentability. Whereas, in the International Stem Cell Corporation case, it was common ground between the parties that parthenotes are not capable of commencing the process of development which leads to a human being, as described above.

In light of that finding and following the approach proposed by the opinion of Advocate General Cruz Villalón, the CJEU held that parthenotes would not, in and of themselves, constitute human embryos, provided that they are not inherently capable of developing into human beings. The CJEU said that the question of whether a parthenote is inherently capable of developing into a human being was one which the referring court should determine, 'in light of current scientific knowledge'. The case will now return to the Patents Court where we anticipate that, in light of the comments in the initial judgment of Mr Carr QC (sitting as a Deputy Judge) and the evidence before him, Mr Carr QC will find that parthenotes are not excluded from patentability.

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4. Court of Appeal agrees there is no patentable invention in Lantana's data transfer system


- The Court of Appeal unanimously upheld Birss J's dismissal of an appeal from the UK-IPO's rejection of Lantana's patent application, which related to a method of extracting and transferring files from a remote computer to a local computer using email, as falling within the exclusion from patentability under section 1(2)(c) of the Patents Act 1977 for computer programs as such.
- This case is a timely reminder of the scrutiny with which the UK-IPO and the courts will consider patent applications involving computer implemented methods for the purposes of patentability.

Section 1(2)(c) of the Patents Act 1977 excludes computer programs from patentability to the extent that the application relates to a computer program 'as such'. This is to be assessed by reference to the four-step test in Aerotel Ltd v Telco Holdings Ltd [2006] EWCA Civ 1371, which involves construing the claim, identifying the actual contribution of the invention, determining whether that contribution relates to a computer program 'as such' (ie, excluded matter) and determining whether the invention makes a technical contribution. If the technical contribution solely comprises excluded matter, then the invention is not patentable. To assist in determining the presence of a technical contribution in the context of computer implemented inventions, the courts have developed 'signposts', which were refined in HTC Europe Co Ltd v Apple Inc [2013] EWCA Civ 451.

In this case, the Court of Appeal emphasised the following in its decision:
• As the determination of the technical contribution involves the application of a multifactorial evaluation, the appeal court should be reluctant to interfere with the judge's assessment, unless an error of law is shown. As a consequence, if the judge has used the signposts to determine the presence of a technical contribution, then, unless an error in law is shown, the appellant has a high hurdle to overcome to change that assessment.

• There was no inconsistency in a novel and inventive method or contribution being excluded from patentability, as the exclusions under section 1 of the Patents Act 1977 reflect a deliberate policy decision to exclude such matter from patentability. As held by Birss J at first instance, 'Being novel and inventive is not what takes a contribution outside the excluded area nor is it what makes an effect or contribution technical'.

• As the EPO has adopted a different approach to Article 52 and the patentability of computer programs, decisions of the EPO are of limited assistance in the context of identifying appealable errors on the part of the judge at first instance in relation to section 1(2) of the Patents Act 1977.

5. Idenix' patent for compounds with anti-Flaviviridae activity revoked


Arnold J in the Patents Court has found that Idenix' patent (EP (UK) 1 523 489) relating to compounds for treating Flaviviridae infections is invalid for anticipation, obviousness, and insufficiency. One claim was also found invalid for added matter, and Idenix' application to amend the claims was not allowed.

Idenix' claim that Gilead's anti-Hepatitis C (HCV) drug sofosbuvir (sold as SOVALDI) infringed the patent therefore failed, though Arnold J held that had certain claims been valid, Gilead would have infringed them.

6. Court refuses Genentech's amended claims to lyophilised formulations of Herceptin (trastuzumab)


• This is the latest in a series of related proceedings in which Hospira has challenged the validity of Genentech's patents relating to the breast cancer treatment drug Herceptin, which has as its active ingredient the monoclonal antibody trastuzumab. During the proceedings Genentech sought permission to unconditionally amend the two patents-in-suit (EP (UK) 1 516 628 and EP (UK) 2 275 119) that were both divisional patents of a common parent and which were concerned with lyophilised formulations of trastuzumab.

• Birss J in the UK Patents Court held that the proposed amendments included impermissible product-by-process claims, that the amendments would add matter and that the amended claims in issue would lack inventive step. As a consequence, Birss J ordered the partial revocation of EP (UK) 1 516 628 (as the validity of claims 8 to 11 as granted was not challenged) and the entire revocation of EP (UK) 2 275 119.

For EP (UK) 1 516 628, Genentech proposed two amended claims to replace the original seven claims in issue. The amended claims claimed a formulation comprising a lyophilised mixture of trastuzumab along with three excipients: a lyoprotectant (trelahose), a buffer (histidine) and a surfactant (polysorbate 20). Proposed claim 1 was a product-by-process claim which expressed the formulation to be 'obtainable by' lyophilizing a solution containing specified amounts of trastuzumab and the three excipients. Whereas, proposed claim 2 required that the formulation of trastuzumab and the three excipients must satisfy a reconstitution test. The proposed amended claim set for EP (UK) 2 275 119 was four claims, comprising two claims directed to each of the formulations of Claims 1 and 2 of EP (UK) 1 516 628: one being directed to the use of the claimed lyophilised formulation in the preparation of a medicament for the treatment of breast cancer characterised by overexpression of the HER2 receptor and the other directed to the use in a method for that therapeutic indication.

Birss J considered that section 75(5) of the Patents Act 1977 meant that the court should follow the principles applied by the EPO when considering claim amendments in the course of UK proceedings. Birss J highlighted that product-by-process claims expressed in the form proposed by Genentech as products 'obtainable by' a process cover products that are not made by the process defined in the claims, with the intention of the process language being to define a particular characteristic (or characteristics) of a product. As a consequence of the EPO approach, such claims are only permissible if there is no other way of defining that particular characteristic (or characteristics). As the claims proposed by Genentech did not specify the characteristic defined by the process, the only realistic conclusion would be that every conceivable characteristic of the product is caught by the process definition. As the reader of the proposed claims would be unable to identify all these attributes of the product, the proposed claims were impermissible.

Birss J also held that the proposed amendments added matter and were impermissible as a consequence. The applications containing only two disclosures upon which the original claims were based (which could not be maintained) and a narrow disclosure contained in Example 1. Birss J held that the proposed amendments impermissibly generalised out from the narrow disclosure contained in Example 1 as the amended claims did not have a limitation of protein concentration that the skilled reader would understand to be part of the teaching of the patent.
In any event, even if the amended claims were allowed, these would be obvious in light of the prior art ‘Carter’. As this prior art taught that trastuzumab was in phase II clinical trials and in light of the common general knowledge, Birss J concluded that the difference between the amended claims and the disclosure in Carter was that Carter disclosed a liquid formulation while the patent claimed lyophilised formulations with relevant characteristics. Birss J held that the skilled team would be motivated to investigate lyophilisation and that all the differences between the claims and Carter were the result of an application of a conventional screening techniques to common general knowledge excipients.

7. BT granted stay of a final injunction


- The Court of Appeal permits a stay of a final injunction in circumstances where such an injunction would normally be granted.

These proceedings form part of a series in which Adaptive is asserting its patents EP (UK) 1 869 790 (the 790 Patent) and EP (UK) 2 259 495 (the 495 Patent) relating to ADSL broadband technology against the Next Generation Access (NGA) system, part of the Dynamic Line Management System responsible for controlling the operation of BT’s broadband services. Birss J in his judgment of 3 December 2013 ([2013] EWHC 3768) held the 790 Patent to be valid and infringed by that system (amongst others), and held that the 495 Patent was valid but not infringed. In light of Birss J's decision, BT modified its NGA system and sought a declaration of non-infringement for the modified NGA system in relation to the 790 Patent. Birss J granted a stay of the final injunction for the 790 Patent on that basis. By its judgment of 11 November 2014 ([2014] EWCA Civ 1462), the Court of Appeal upheld Birss J's finding that the 790 Patent was infringed by the unmodified NGA system, but allowed Adaptive's appeal against Birss J's finding in relation to the 495 Patent such that claim 6 of this patent was held to be valid and also infringed.

The Court of Appeal refused BT permission to appeal to the Supreme Court in relation to its findings on either patent and, as a consequence, the usual order of the court would have been to grant a final injunction in relation to the 495 Patent. (This was not the case for the 790 Patent, as the final injunction remained stayed pending a hearing before Birss J on whether the modified NGA system infringed that patent.) BT therefore sought a two week stay of the final injunction in relation to the 495 Patent (with liberty to apply for an extension to this stay) to enable BT to further alter its systems to render them non-infringing. Adaptive was prepared to agree this stay on the condition that BT paid £250,000 for each week of the stay. This amount was proposed by Adaptive as it was, based on its calculations, 10% of BT's estimated weekly revenue from BT's products using the NGA system. The Court of Appeal was 'narrowly persuaded' to grant the stay on these terms given that Adaptive was primarily interested in a financial remedy and given that the public would suffer if an injunction was granted. The court recognised that the 10% royalty rate sought by Adaptive was very substantial, but agreed to it as the monies would be paid as an interim payment on account of damages in relation to the entire period for which BT infringed this patent, such that an overpayment was unlikely and BT would in any event be reimbursed should the total damages be less than this amount. The Court of Appeal also included a further condition that BT confirm the steps it had taken to render their products as non-infringing.

When considering the pending proceedings before the European Patent Office or the possibility of a material amendment being allowed to the patent at the European Patent Office, the Court of Appeal:

- Refused BT's request that Adaptive provide a cross-undertaking in damages (for harm caused to BT by the injunction), as neither of these eventualities would demonstrate that the court's judgment was wrong or that the final injunction was wrongly granted (if either arose, the final injunction would become ineffective from the date of revocation or amendment but Adaptive would not have to pay any damages for the effective period of the final injunction); but

- Required Adaptive to undertake to repay to BT any financial relief subsequently obtained (including any interim payments made on account as per the condition of the stay) following the enquiry as to damages in the event of either of these eventualities. The court required Adaptive to make these undertakings as, following the Court of Appeal Guidelines in IPCom, it was 'now more or less inevitable' that Adaptive would have been required to give such undertakings if BT had sought a stay of the UK proceedings pending the determination of any proceedings before the European Patent Office.

After the final order was lodged, in his judgment of 18 December 2014 Birss J also held that the modified NGA system infringed the 790 Patent ([2014] EWHC 4194).
8. **CJEU holds that SPC possible, in principle, for a covalently linked active ingredient**

*Arne Forsgren v Österreichisches Patentamt*, Case C-631/13, 15 January 2015.

The Austrian Patent Office refused to grant Mr Forsgren a Supplementary Protection Certificate (SPC) for Protein D based on his patent for 'Protein D – an IgD-binding protein of *Haemophilus influenzae*’ (EP 0,594,610) and GSK's marketing authorisation for Synflorix, a pneumococcal polysaccharide conjugate vaccine that uses Protein D as a carrier protein for some of its serotypes. In answering a reference to it following Mr Forsgren's appeals against the Patent Office's refusal, the CJEU held that for the purposes of the SPC Regulation (Regulation 469/2009), the grant of an SPC cannot be excluded purely on the basis that an active ingredient is covalently bound to other substances. However, such an SPC can only be granted where:

- the substance for which the SPC is sought (in this case Protein D, as a carrier protein covalently conjugated to polysaccharides in a vaccine) has a pharmacological, immunological or metabolic action of its own, which is independent of it being covalently bound to other substances. This is a question for the referring court to determine in light of the facts and evidence before it – unless this is established no SPC can be granted; and
- the therapeutic effects of that product fall within the therapeutic indications for which a marketing authorisation has been granted. The CJEU noted that there was no indication that trials or data concerning the therapeutic effects of Protein D against *Haemophilus influenzae* had been integrated into the marketing authorisation for Synflorix. As a consequence, it would be contrary to the aims of the SPC Regulation to grant an SPC to Mr Forsgren as there had been no delay caused by the grant of the marketing authorisation for Synflorix to the commercial exploitation of Mr Forsgren's patent. There was no nexus between the patent and the data required for the marketing authorisation.

9. **Advocate General recommends dismissal of latest Spanish challenge to the Unitary Patent**

*Kingdom of Spain v European Parliament and Council of the European Union*, Cases C-146/13 and C-147/13, AG's Opinion, 18 November 2014. At the time of writing, the opinion is not yet available in English. The press release announcing the Advocate General's opinions can be found [here](#).

Spain’s latest challenge to the legitimacy of the unitary patent and the use of enhanced cooperation to establish it within the European Union, has met with a recommendation of dismissal by the Advocate General of the Court of Justice of the European Union. If the CJEU implements the Advocate General's opinion, this will remove one of the final obstacles in the way of establishing unitary patent protection.

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10. **Final oral hearing on the draft UPC Rules**

The final oral hearing on the draft Rules of Procedure for the Unified Patent Court (UPC) took place in Trier, Germany on 26 November 2014. The hearing did not confirm the changes that will be effected in the final UPC Rules of Procedure (we will provide a further update when the 18th (final) draft is released), but the key points made at the hearing were:

- **Opt-Out (r 5):** The amendments included in the 17th draft Rules relating to the sunrise regime received mainly positive feedback. The regime allows parties to apply to opt-out of the jurisdiction of the UPC before the UPC Agreement enters into force, to prevent any possibility of parties being brought into UPC proceedings before their opt-out becomes effective.

- **Language (r 14.2(c)):** The 17th draft Rules allow a designated additional language to be used for a separate part of a proceeding. For example, the proceeding could be carried out in English while the judgment is issued in the national language. The rationale for the amendment is to provide flexibility of choice for litigants. However, the expert group has not yet agreed whether this provision should be included in the final Rules of Procedure.

- **Bifurcation (r 37.5):** To deal with bifurcation, the 17th draft Rules provide that a Local or Regional Division hearing an infringement action must communicate the dates for the interim conference and oral hearing to the Central Division hearing a corresponding revocation action. The Central Division must then accelerate its proceeding and endeavour to hold the hearing on validity prior to the hearing on infringement in the Local or Regional Division. It is hoped that this will mitigate the concerns expressed about bifurcation leading to the possibility of an injunction being granted while the issue of validity is still pending.

- **Injunctions (r 118.1):** There was general approval of the clarification in the 17th draft Rules that award of injunctions would be at the discretion of the Court, compared to the previous draft in which it seemed injunctions would be practically automatic on infringement.

- **Appeals (r 220):** The 17th draft Rules clarify which court is required to grant leave where leave to appeal from a particular order is required. The 17th draft Rules provide that in the event of a refusal of the Court of First Instance to grant leave to appeal, the applicant may make a request to the Court of Appeal for a discretionary review.
### Key points from featured United Kingdom judgments

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Injunction stayed on conditions that BT pay Adaptive 10% of BT's estimated revenue for period of the stay; and BT confirms steps taken to render its products non-infringing.
12. Contacts

Jonathan Turnbull (Senior associate, London)
T +44 20 7466 2174
Jonathan.Turnbull@hsf.com

Grace Pead (Associate, Australia)
T +44 20 7466 7518
Grace.Pead@hsf.com

Anna Vandervliet (Associate, Australia)
T +44 20 7466 2842
Anna.Vandervliet@hsf.com

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