A new UK approach to infringement: equivalents infringe a patent, but do not anticipate it?

In Actavis UK Limited v Eli Lilly and Company [2017] UKSC 48, the UK Supreme Court redefined the UK approach to patent infringement, making it more permissive and seeking to align it with that taken in other European countries. As we reported in detail here, the Supreme Court held that a product or process will infringe a patent claim, even if it does not fall within the proper interpretation of the wording of the claim, if it differs from the claimed invention in a way or ways that are immaterial. In considering whether this is the case, the Supreme Court held that “helpful assistance” is provided by the so-called Improver or Protocol questions, which it revised as follows:

1. Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention (i.e. the “inventive concept” revealed by the patent)?
2. Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
3. Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

Importantly, the Supreme Court revised the second of these questions such that the skilled addressee is taken to know that the variant works to the extent that it does work. This means that the second question is capable of covering all variants, whether they were obvious, inventive or unknown at the priority date.

On this basis, the Supreme Court held that Actavis’ pemetrexed products directly infringed Eli Lilly’s patent claims, even though the claims were limited to the disodium salt, because:

- it was obvious to a skilled addressee (once they knew that Actavis’ products in fact worked) that they worked in “precisely the same way” as pemetrexed disodium; and
• the skilled addressee would have understood that the claim was limited to pemetrexed disodium because that was the only pemetrexed salt on which experiments described in the specification had been carried out, and not because the patentee did not intend any other pemetrexed salts to infringe.

As we noted in our report, this left open the question of whether equivalents are relevant when assessing the novelty of a patent. This was considered by Arnold J in Generics (UK) v Yeda Research [2017] EWHC 2629 (Pat), which we reported on here. After considering the previous case law, the EPO Boards of Appeal jurisprudence and the legal basis of the Supreme Court’s decision in Actavis, Arnold J expressed the view that a claim would only lack novelty if the prior publication disclosed subject matter which fell within the claim on its proper interpretation, i.e. without applying the doctrine of equivalents to the claim. On this basis, the disclosure of a 40 mg QOD (every other day) dosing regimen in the prior art was held not to anticipate the claim to a 40 mg TIW (thrice weekly) regimen, even though the skilled person would have considered these to be equivalent in terms of efficacy.

Practically, as the Claimants in Generics (UK) v Yeda submitted, this approach means that it is possible for a claim to be infringed, but not anticipated, by someone who performs what is taught by a prior art publication. However, it must be noted that Arnold J expressly did not consider the matter at length, as he had found that the claim lacked an inventive step over the same prior art, and considered that “[i]t will require another decision of the Supreme Court to supply a definitive answer to the question”. As such there will undoubtedly be further developments in this space in the coming months.

Aaron Hayward, Senior Associate (Australia)

2. Plausibility before the EPO and reliance on post-published evidence

The Board of Appeal’s reasons for revoking Bristol-Myers Squibb’s patent for the anticancer drug, dasatinib (EP 1169038), were published in July. The Board upheld the decision of the Opposition Division on the grounds of lack of inventive step: it was not plausible from the application as filed that the technical problem was solved, and it was impermissible for the patentee to rely on post-published evidence as support for the technical effect not made plausible in the application. The technical problem to be solved was therefore defined as merely the provision of further chemical compounds, which is non-inventive.

In October 2017, the patentee filed a petition for review to the Enlarged Board of Appeal, seeking that the Board’s decision be set aside on the ground that the Board failed to observe the patentee’s right to be heard.

Patent

EP 1169038 described a broad number of structurally diverse chemical compounds useful as protein kinase (PTK) inhibitors. Although the claims originally filed included a broad Markush formula, the patentee narrowed its request before the Board from a broad Markush formula to a one compound claim for dasatinib (and its salts).

Plausibility

The Board found that it was not plausible from the patent application as filed that the technical problem of providing alternative PTK inhibitors was solved. The application did not disclose any activity data other than a statement that “Compounds described in the following Examples have been tested in one or more of these assays, and have shown activity.” There was no identification of which compounds were tested in which assays, and no guidance provided as to the threshold level for a compound to be considered active. It was therefore not credible from the vague indication of “activity” that the compounds of the patent, dasatinib included, would exhibit the claimed activity.

Inventive step

It is established EPO case law that post-published evidence can be relied upon to support or confirm that the technical problem proposed to be solved has indeed been solved.

However, the Board concluded that the post-priority journal articles established the technical effect of the patent for the first time, rather than merely confirming or supporting it. Therefore, it was impermissible for the patentee to rely on the post-published evidence.

Since post-published evidence could not be taken into account, the patentee was unable to establish that the activity of dasatinib was superior to that of the closest prior art. The technical problem to be solved could not be formulated by reference to activity and was defined as merely the provision of further chemical compounds. As none of the compounds of the application were disclosed to have any particular valuable property or advantage, the contribution of the patent was to merely enrich the pool of chemical compounds, which is non-inventive.

Comment

The Board’s decision to revoke the patent appears to elevate the threshold for plausibility, at least in the context of inventive step. It is true that the EPO does not require a patentee to include experimental results or raw data in a patent application.
However, the Board concluded that since the present invention relied on a "technical effect, which is neither self-evident nor predictable or based on a conclusive theoretical concept, at least some technical evidence is required to show that a technical problem has indeed been solved". It therefore appears that it is a question of degree as to what and how much data should be included in a patent application in order to satisfy the requirement of plausibility.

Patentees must strike a balance between being the first to file and accumulating sufficient data to disclose in the patent to ensure it is credible that the problem has been solved. Notably, this issue was raised by the European Federation of Pharmaceutical Industries and Associations (which represents the pharmaceutical industry operating in Europe) in Third Party Observations filed during the appeal procedure.

Julie Chiu, Associate (Australia)

3. Further References to the CJEU on Supplementary Protection Certificates ("SPCs")

In our last Patent and Pharma update we reported on two references to the CJEU in relation to the SPC Regulation (Regulation 469/2009) by the Courts of England & Wales:

1) On Article 3(a) in Teva UK Ltd & Ors v Gilead Sciences Inc [2017] EWHC 13 (Pat); and

Since these references, two further references have been made by the German Federal Patent Court to the CJEU concerning the SPC Regulation.

In its decision 14 W (pat) 13/16, the German Federal Patent Court essentially asks the CJEU: can an SPC be obtained for drug device combination products and, if so, in what circumstances? The question itself concerns Article 2 of the SPC Regulation, which defines the scope of the SPC Regulation as relating to medicinal products that have been approved to be marketed under Directive 2001/83/EC for human use or Directive 2001/82/EC for veterinary use. The question the German Court asks is whether the correct interpretation of Article 2 of the SPC Regulation permits SPCs for drug device combination products for human use where the safety and efficacy of the drug part has been examined by the relevant authority in accordance with Directive 2001/83/EC.

In its decision 14 W (pat) 12/17, the German Federal Patent Court asks three further questions in relation to the correct approach to Article 3(a), which are more detailed than those asked by Arnold J in Teva v Gilead. These questions arose from a case concerning an SPC application for sitagliptin and ask:

1. Is a product only protected by a basic patent in force according to Article 3(a) if it belongs to the protected subject-matter as defined by the claims and is thus provided to the skilled person as a specific embodiment?
2. Is it therefore insufficient for the requirements of Article 3(a) if the product in question meets the general functional definition of a class of active substances as mentioned in the claims, but apart from that is not individualized as a specific embodiment of the teaching protected by the basic patent?
3. Is a product not protected according to Article 3(a) of the SPC Regulation by a basic patent in force if it is covered by the functional definition contained in the claims, but was only developed after the filing date of the basic patent with independent inventive activity?

Jonathan Turnbull, Senior Associate

4. New Unjustified Threats Regime in force from 1 October 2017 - encompassing unitary patents and European patents under UPC jurisdiction

Threatening proceedings for intellectual property right infringement can sometimes backfire. In relation to patents, trademarks and designs, there is a right for any person aggrieved by the threat to bring an action against the threatener. The "aggrieved" person may not necessarily be the person directly threatened with proceedings, it could be anyone whose commercial interests are damaged by the threat – such as a manufacturer whose suppliers or distributors are threatened. Not only does the threats action expose the IP rights-holder to the risk of damages, it also turns the potential claimant into a defendant. This in turn creates a tension with the requirements of the Civil Procedure Rules to communicate a litigant’s case early before issuing proceedings, with rights holders more likely to sue first than to threaten first.

The Intellectual Property (Unjustified Threats) Act 2017, which came into force on 1 October 2017, attempts to encourage more pre-action communication by detailing what an actionable threat is, whilst providing for "permitted communications" or communications for "permitted purposes" which cannot amount to an actionable threat. It harmonises the position across patent, trade mark and design rights (including providing for unitary patents and European patents under the proposed Unified Patent Court jurisdiction) and allows pursuit of information on primary infringers from secondary parties where reasonable efforts have been made to find the primary infringer already.

For a detailed analysis – see here.

Rachel Montagnon, Professional Support Consultant
5. Further information ordered to be provided in an enquiry as to damages under a cross-undertaking

_Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories [2017] EWHC 1433 (Pat)_

Napp obtained an interim injunction against Sandoz (among others) in relation to buprenorphine transdermal patches and in doing so provided a cross-undertaking in damages, which also entitled other companies in Sandoz's group to join a claim if appropriate. Thereafter Napp lost at first instance and on appeal (the patent found not to be infringed) and, consequently, Sandoz commenced an inquiry into its damages. In the course of this inquiry, Birss J heard an application for further information made by Napp in relation to the damages claim set out by Sandoz in its Points of Claim.

In its Points of Claim, Sandoz (along with three additional Sandoz group companies) claimed a substantial sum of £100 million for being kept out of the market for six months, with this representing more than the annual value of the relevant market to Napp. Sandoz argued before Birss J that the effect of being kept out of the market for that six month period led to permanent effects on the market and losses which ran into the future. Birss J accepted that there is nothing inherently wrong with such an argument in principle, but it will depend on the facts.

Birss J found the Points of Claim to be entirely lacking any explanation of how the damages claimed were derived from the figures for sales volumes, with no specific profit margins being disclosed. As a consequence, Birss J held that the Points of Claim were fundamentally lacking in critical information which should have been provided to Napp. In doing so, he held that it was insufficient for Sandoz to provide a blended lost profit figure and rejected Sandoz’s concerns about providing price information to a competitor because confidentiality arrangements had been agreed between the parties.

In addition, Napp also requested further information as to how the losses were suffered by each of the Sandoz entities claiming damages. Although Birss J noted that in _Gerber v Lectra_ it was accepted that in principle it is possible for a parent company to claim damages on a one-for-one basis even if the loss was suffered by a subsidiary, this has to be pleaded and proved. Therefore, he held the claim could not proceed simply on a group basis and that Sandoz’s profit flows needed to be explained.

Laila Beynon, Senior Associate

6. UK Court strikes out a claim for loss suffered as a result of the tort of unlawful deceit

_Secretary of State for Health and Others v Servier Laboratories Limited and Others [2017] EWHC 2006 (Ch)_

An interim decision where the English Court struck out a claim based on the tort of causing loss by unlawful means represents the latest instalment in the fall-out from Servier’s actions concerning perindopril. The decision is part of ongoing proceedings where the English Health Authorities are seeking damages from Servier for delaying entry of cheaper generic versions of perindopril (used to treat hypertension and cardiac insufficiency), based on the following causes of action:

(i) infringement of EU and UK competition law by entering into a series of agreements with generics/suppliers not to enter the market and/or to withdraw their patent challenges;

(ii) abuse of a dominant position by making misleading or dishonest representations to the EPO/UK Court leading to the grant of a patent blocking generic entry; and

(iii) the tort of causing loss by unlawful means as a result of making misleading or dishonest representations to the EPO/UK Court as to the validity of a patent.

The last of these was the subject of Servier’s strike out application.

The relevant patent relates to a crystalline form of the perindopril salt. Before the present proceedings were commenced, Servier obtained an injunction against Apotex for infringement of this patent, which was subsequently overturned when it was found invalid by the English Court (and later by the EPO Board of Appeal). The English Health Authorities now claim that Servier made dishonest representations before the EPO/English Court that the crystalline form was novel and not obvious, when in fact the crystalline form was part of the state of the art and/or would have been obvious to a person skilled in the art, and the servants or agents of Servier knew or were reckless as to these matters.

Roth J held that the test for the tort of unlawful means is as set out in the dicta of Lord Hoffmann in the landmark decision of _OBG Ltd v Allan [2007] UKHL 21:_ "acts intended to cause loss to the claimant by interfering with the freedom of a third party in a way which is unlawful as against that third party and which is intended to cause loss to the claimant", but, critically in this case, not including "acts which may be unlawful against a third party but which do not affect his freedom to deal with the claimant".

Roth J assumed that the allegation of deceit, and therefore the unlawful means, was made out (as Servier did not suggest that it was unarguable). However, he held that the "third party" were the EPO and the English Court, and there was no question of interference with their "freedom to deal" with the English Health Authorities, therefore this head of claim was bound to fail and should be struck out.
His decision was influenced by various legal dicta and commentary seeking to confine the tort within a narrow ambit. He held that "the statutory regime governing patents prescribes rights and remedies in a manner that reflects the legislative assessment of the policy issues involved", and where a third party suffers economic loss as a result of a patent being obtained by dishonest or reckless misrepresentations as to novelty or obviousness, any remedy should be found in the field of competition law. This is indeed the basis for a separate claim in these proceedings for abuse of a dominant position (at (ii) above).

In 2014, the European Commission fined Servier a very substantial sum for delaying generic entry of perindopril by virtue of the agreements referred to in (i) above (currently on appeal to the General Court), thus this part of the UK case is now a follow-on claim from that EC decision.

Laila Beynon, Senior Associate

7. Judicial consideration of a collaboration agreement in Astex Therapeutics Limited v AstraZeneca AB [2017] EWHC 1442 (Ch), ("Astex")

Astex Therapeutics Limited v AstraZeneca AB [2017] EWHC 1442 (Ch)
The Astex case concerned a lengthy (67 page) 2003 collaborative research agreement between Astex and AstraZeneca AB ("AZ") for the development of Beta-site Amyloid precursor protein Cleaving Enzyme Inhibitors ("BACE Inhibitors") for the treatment of Alzheimer's Disease. The collaboration continued under the agreement for a Collaboration Term of two years until 2005 after which AZ continued the project alone. Arnold J had to consider whether under the terms of the agreement Astex was entitled to additional payments for AZ reaching specific milestones relating to a candidate drug (AZD3293, "CD2") that is currently in Phase III clinical trials and whether AZ was entitled to recover certain milestone payments made in relation to another candidate drug (AZD3839, "CD1"). This required Arnold J to consider, inter alia, whether CD1 and CD2 fell within the definition of Collaboration Compounds to which the agreement applied and whether payments were owed as the research "Program" for these products continued beyond the Collaboration Term.

Arnold J, having considered the totality of the evidence before him, concluded that neither CD1 nor CD2 fell within the meaning of a Collaboration Compound as neither were the direct result of "AFFIT Optimisation, Hit Optimisation or Lead Optimisation", as required by the definition of collaboration compound. Further, Arnold J held that the research Program ended at the end of the Collaboration Term, such that neither CD1 nor CD2 could in any event be a Collaboration Compound. Arnold J applied Jazztel Plc v Revenue and Customs Commissioners [2017] 4 All E.R. 470, which held that any causative mistake of fact or law can qualify as a relevant mistake, such that AZ was entitled to restitution of the two milestone payments of $1 million made in relation to CD1.

In his judgment, Arnold J also commented on the amount of witness evidence before him concerning events that happened between 10 to 15 years ago. Arnold J emphasised that in such circumstances considerable weight will be placed on contemporaneous documentary evidence. On factual witnesses, Arnold J agreed with the observation of Leggatt J in Gestmin SGPS SA v Credit Suisse (UK) Ltd [2013] EWHC 3560 (Comm) that such witness could be perfectly sincere, but mistaken, in their recollections and he refused to draw any adverse inferences against a party that did not seek to apply for letters rogatory to be sent to foreign courts to compel witnesses resident in those countries to give evidence. On expert evidence, Arnold J highlighted the need for relevant issues to be clearly identified on which experts can assist to avoid unnecessary disproportionate costs. In the Astex case he concluded that neither party's expert was in a position to give any evidence of real weight on the points which matter.

Jonathan Turnbull, Senior Associate & Imogen Kelso, Trainee Solicitor

8. Developments in Europe

EU Commission consultation on SPCs

On 12 October 2017, the European Commission launched a public consultation on SPCs and patent research exemptions. The consultation forms part of the Single Market Strategy, one aim of which is to improve the patent system in Europe, notably for pharmaceuticals and other industries whose products are subject to regulated market authorisations. The consultation focuses on three main elements: (i) the creation of a European SPC title; (ii) an update of the scope of EU patent research exemptions; and (iii) the introduction of an SPC manufacturing waiver.

The pharmaceutical research exemption, or the 'Bolar' exemption, has been updated in some EU countries to meet new pharmaceutical-related requirements, among other things, and this has led to inconsistent application of the Bolar exemption by the national courts. The Commission is therefore considering modifying the Bolar exemption to harmonise it in line with best practice.

All citizens and organisations are welcome to contribute by the end of the consultation period on 4 January 2018.
For more information, please see here.
Patentability of products obtained by essentially biological processes

Since 1 July 2017, plants and animals exclusively obtained by means of an essentially biological process are no longer patentable. This exclusion was initially proposed in a European Commission notice published on 3 November 2016 (the "Commission Notice") (for full text of the Commission Notice click here) and prompted by the decisions of the Enlarged Board of Appeal of the EPO. In those decisions the Enlarged Board held that although non-microbiological processes for the production of plants which are "essentially biological" cannot be patented, the products derived from using essentially biological processes could be patentable (G2/12; G2/13, also referred to as Tomatoes II/Broccoli II).

The Commission Notice provides the Commission's reasoned view as to why patenting plants or animals exclusively obtained by means of an essentially biological process could not have been the intention of the EU legislator. The Commission Notice provides no guidance on how to categorise products obtained from processes which are essentially biological, but contain additional step(s) introducing or modifying traits of the genome.

In reaction to the Commission Notice, the EPO had stayed all relevant proceedings until issuing a notice at the end of June (the "EPO Notice") which followed the guidance in the Commission Notice (click here to read the EPO Notice in full). The EPO Notice adopts the Commission's proposal with the aim of safeguarding uniformity in harmonised European patent law. The new provisions were implemented in July 2017.

It is clear that further EPO and national jurisprudence will be needed to understand and define the extent of this patentability exclusion.

Please see here to read our full report.

GDPR

Data has evolved in our digital economy to become the lifeblood of global trade. It affects all businesses and industries and dealing with it is a "whole of business" issue, affecting each and every team within an organisation.

With innovation comes regulation and Europe is on the cusp of overhauling its data protection laws. Despite the outcome of last year's Brexit referendum, at least one constant remains – from 25 May 2018 organisations established in or providing goods or services to data subjects in the EU (including the UK) will need to comply with the enhanced regime under the EU General Data Protection Regulation (the "GDPR").

For more information, please see here.

Monika Klajn, Associate & Emily Thomas, Trainee Solicitor

9. UPC update

In June we gave an update on the progress of the UPC, including the announcement by the UPC Preparatory Committee that the 1 December 2017 start date could not be maintained. We reported on the need for ratification of the UPC Agreement, as well as the UPC Protocol on Provisional Application (the Protocol), by a number of states including the UK and Germany, which are mandatory signatories along with France.

UK

The UK has recently drawn closer to ratification as a result of the International Organisations (Immunities and Privileges) (Scotland) Amendment (No 2) Order 2017 being approved by the Scottish Parliament on 25 October 2017. This order will confer certain privileges and immunities on the UPC and its judges and other staff. As we have reported previously, the equivalent statutory instrument, the Unified Patents Court (Immunities and Privileges Order) 2017 was laid before the House of Commons on 26 June 2017 and is awaiting approval by both chambers of the Westminster parliament. Before this can occur, it must pass through three committees: the Joint Committee on Statutory Instruments (JCSI), the Secondary Legislation Scrutiny Committee and the Delegated Legislation Committee. The members of the JCSI were recently re-appointed (on 31 October 2017), following its dissolution prior to the general election in June this year. It is now up to the JCSI to report on any instance where legislative power has been exceeded or the drafting of the order is defective or requires further explanation.

Germany

There has been some delay to the German ratification of the UPCA, owing to a case pending before the German Federal Constitutional Court (FCC) regarding the law passed by German Parliament on its implementation. The German Court has asked for observations on the case and had previously set a deadline for any comment by end of October 2017 – though it has been reported that this has now been extended to the end of the year. The FCC will then determine whether or not to dismiss the complaint, a process which is expected to take until at least April 2018. If the complaint is dismissed, Germany will be able to ratify the UPCA soon after. There has, however, been talk of the possibility of the case being referred to the Court of Justice of the EU (CJEU), which would cause substantial delay to the case being decided and ultimately to Germany's ratification.
Overall, according to the latest update on the UPC website, published on 21 September 2017, while good progress has been made, "[i]t is now difficult to predict any timeline".

Katie Pryor, Associate (Australia)

For more on the UPC and unitary patent system, see our Hub here: www.hsf.com/upc.
10. Table of Recent UK Court Decisions on patents

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<td>disaggregated loss of profit information and the basis for Sandoz’s calculation of lost profits, despite this information being confidential. [2017] EWHC 1433 (Pat) (8 June 2017)</td>
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11. Contacts

Sophie Rich (Partner)
T +44 20 7466 2294
Sophie.Rich@hsf.com

Jonathan Turnbull (Senior Associate)
T +44 20 7466 2174
Jonathan.Turnbull@hsf.com

Monika Klajn (Associate)
T +44 20 7466 7604
Monika.Klajn@hsf.com

Rachel Montagnon (Professional Support Consultant)
T +44 20 7466 2217
Rachel.Montagnon@hsf.com

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