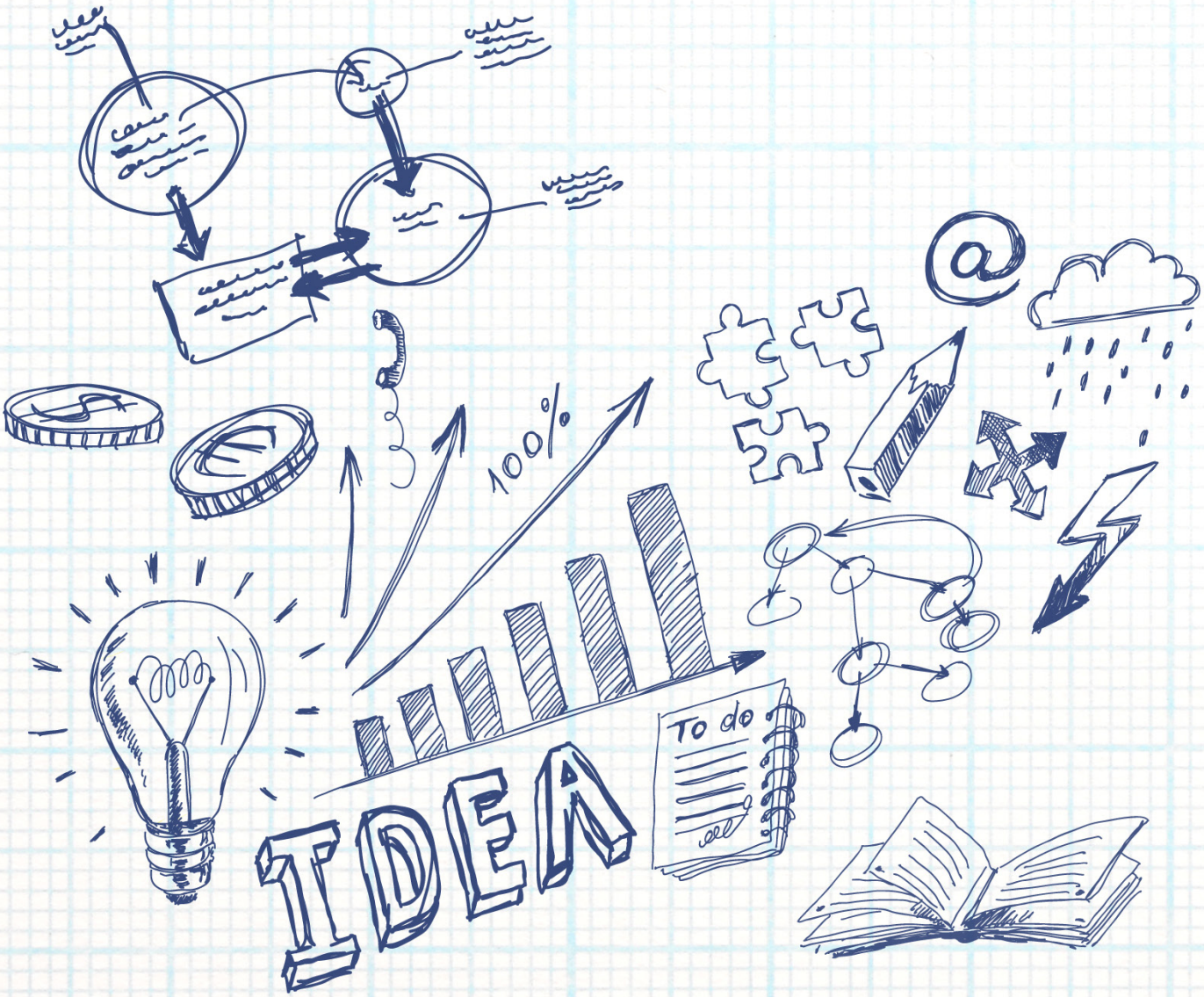
ALLEN & OVERY

Back to school – the last year in patents

September 2015

A pocket guide to 2014/15

As the children settle into school after the summer holidays, many of us still feel that sense of new beginning that comes with a new academic year. To help keep us on our toes in the new term we have compiled a short update on some of the main cases and issues arising over the last twelve months.



Life sciences

Second medical use patents – a novel approach

The vexed question of how to enforce second medical use patents has dominated the headlines in the last half year. The case of **Warner-Lambert v Actavis**[1] in the English High Court highlighted the serious difficulties innovators face in enforcing these patents, which protect new uses for existing medicines. For example, in this case, the active ingredient pregabalin, originally developed for treating epilepsy and generalised anxiety disorder, was later found to be useful in treating neuropathic pain too. If, as here, a generic version of the medicine is available for the original use, cost-saving mechanisms within the National Health Service direct medical practitioners and pharmacists to cheaper generic versions and inevitably lead to these being supplied for the new use too. This happens despite the fact that the generic medicine is not authorised – or advertised – for the new use, because medical professionals know that it is equivalent. The patentee finds itself cut out of the loop.

In interim injunction proceedings the question arose as to what form of interim order would be appropriate in such a case. In a move he described as the "best solution to the problem" – Arnold J in the High Court turned to case law recently developed in relation to blocking orders against internet service providers and made a novel interim order requiring NHS England to arrange for guidance to be given to the effect that doctors and pharmacists should prescribe and dispense by reference to the brand name (Lyrica®) for the patented indication and generically for non-patented uses.

The practical approach represented by this order is certainly likely to be welcome to the parties involved and indicates a framework for a possible solution to the problem. However, it does not address the thorny, underlying question of what exactly constitutes infringement of these patents and whether infringement arises in the situation described above. At the time of writing the High Court judgment in the main proceedings has just been handed down. Warner-Lambert's patent was upheld on inventive step but foundered – at this stage – on an insufficiency point. The High Court also found infringement. However, there is clearly a difference of view between the High Court and the Court of Appeal on infringement, because in a preliminary judgment in the case Floyd J in the Court of Appeal appeared to indicate that infringement was indeed likely to arise. This is no doubt not the end of the story; it seems not unlikely that the Supreme Court will have its say.

1 Allen & Overy acts for Warner-Lambert

Cross undertakings – Court of Appeal upholds "largest award ever made"

If an interim injunction is granted in a case of patent infringement the claimant must give a "cross undertaking" to the court that it will compensate the defendant for loss suffered as a result of the injunction if it turns out that the injunction was wrongly granted.

In October 2009, based on its patent relating to esomeprazole, sold as Nexium, AstraZeneca obtained an interim injunction against KRKA preventing launch of KRKA's generic esomeprazole product Emozul. In July 2011 the injunction was discharged. Sales J in the High Court awarded the defendants more than £27 million on the cross undertaking, thought to be the largest award ever made by the Patents Court on an inquiry of this kind. This has now been upheld by the Court of Appeal (Lord Justice Kitchin giving the lead judgment). An important factor was KRKA's loss of "first mover" advantage – the court held that the defendants had lost the opportunity to enjoy almost a year as the only generic available on the market (**AstraZeneca v KRKA**, May 2015).

Obvious to try - the notional skilled person is not more open minded

Lord Justice Jacob, giving the lead judgment in the Court of Appeal in **Teva v Leo** (July 2015), held that the notional skilled person (in this case a formulator) would have the same prejudices and practices as a real one. He disagreed with the approach taken by Birss J in the High Court that the notional skilled formulator would be less conservative in his or her thinking and more open to considering unfamiliar compounds, illustrating this by reference to the case of Dyson v Hoover where "the 'bagridden' mindset of real vacuum cleaner designers" was attributed to the person skilled in the art.

This more grounded (and correct) approach to the skilled person is also reflected in the more realistic approach taken to the "obvious to try" test on appeal compared to at trial in this case. Where nothing is disclosed about a compound to suggest it is different from any other candidates the skilled person is unlikely to have a reasonably optimistic expectation that it will work, so finding it really does work is an invention. Lord Justice Jacob comments that in effect the Judge was saying that the idea of including the substance in a research project amounted to obviousness. However, this was incorrect. The "obvious to try" standard "requires a higher expectation of success than that."

Product-by-process claims explained and updated

Hospira v Genentech (November 2014) was one of a number of cases this year relating to "follow-on" patents for Genentech's well-known breast cancer drug Herceptin (trastuzumab). Birss J in the High Court rejected amendments to two formulation claims. He considered the UK and EPO approaches to product-by-process claims, holding that the effect of s.75(5) of the UK Patents Act was that the court should follow the principles applied by the EPO when considering whether to permit amendments to include such claims. This means, among other things, that a product-by-process claim is only allowable where the product cannot be defined in any other way – the reference to the process in the claim serves to define characteristics of the product.

The key point in understanding the scope of such claims seems to be that validity and infringement should be considered separately. Birss explains that there are two kinds of product-by-process claim, a product 'obtained by' and a product 'obtainable by' a process. However, in both cases, in the context of validity, the product must be novel – to be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product. On the infringement side, however, the scope of the two sorts of claim is different. A claim to a product "obtained by" a process is infringed only by a product which has actually been made using the process.

Contributory infringement

Contributory infringement arises where a person (the infringer) supplies a third party with means for putting the invention into effect knowing, or it being obvious, that these "means" will be used for this purpose; the means must relate to an "essential element of the invention" (S.60(2) UK Patents Act). The issue arose in **Actavis v Lilly** (June 2015). The patent was for a cancer treatment using pemetrexed disodium (among other things). The substance (the "means") supplied by the alleged infringer (Actavis) did not contain pemetrexed disodium as such, but consisted of different pemetrexed compounds. In the High Court Arnold J concluded that in these circumstances there was no contributory infringement, but the Court of Appeal disagreed. The substances were supplied to third parties who would reconstitute them with saline and the resulting solution would fall within the patent claim because it would include both pemetrexed and sodium ions, so completing the invention.

Supplementary protection certificates

An SPC extends the life of patent protection for a medicine to compensate the patentee, at least in part, for the delay in bringing the product to market caused by the need to obtain marketing authorisation. An SPC may only be obtained for active ingredients or combinations of active ingredients.

In Arne Forsgren v Austrian Patent Office (Case **631/13**) the CJEU held that, in principle, the fact that an active ingredient is covalently bonded to another active ingredient contained in the medicine does not preclude the grant of an SPC for that active ingredient. The essential points are whether it genuinely has an independent therapeutic effect and whether this effect is covered by the marketing authorisation. The case involved a carrier protein present in a pneumococcal vaccine for paediatric use. The extent to which this carrier protein actually had a separate therapeutic effect is not clear from the case, but it does seem clear that no such effect was described in the authorisation.

In Actavis v Boehringer (Case C-**577/13**) the CJEU held that where the patentee has already obtained an SPC for an active ingredient which is the "sole subject-matter of the invention" it cannot obtain a second SPC for a subsequent claim to a combination of that active ingredient and another substance. The case involved a combination of Telmisartan, which is used in the treatment of hypertension, and a second active ingredient, hydrochlorothiazide, a prior art substance. It was common ground in the main proceedings that, in that combination, Telmisartan, as the innovative active ingredient of Boehringer's patent, was the "sole subject matter of the invention". The CJEU indicated that allowing patentees to obtain "multiple SPCs" on such combinations would tip the scales too far in favour of the pharmaceutical industry. An additional point was that the claim in the patent to the combination had, in fact, been added by amendment at the suggestion of the UK IPO in order to obtain the second SPC. Although it is clear that the second SPC should not have been granted in this case, the CJEU unfortunately does not answer the High Court's questions about the legitimacy of post grant amendment in order to satisfy the conditions for an SPC.

Patents for plants bred by conventional means – tomatoes and broccoli II

In March 2015 the Enlarged Board of the EPO gave its second **ruling** in the (in)famous tomato and broccoli cases. The tomato case relates to a method of breeding wrinkly-skinned tomatoes with reduced water content and the broccoli case to a breeding method that increases the level of anticarcinogenic glucosinolates in brassica species. Both methods are essentially conventional plant breeding methods based on crossing and selection. They had already been held by the Enlarged Board to be excluded from patentability by Article **53(b) EPC** as "essentially biological processes for the production of plants". The patentees had, however, now limited the claims to product and product-by-process claims and were trying again.

The Enlarged Board ruled that the exclusion of essentially biological processes in Article 53(b) does not extend to product and product–by–process claims even if the only method available for generating the product is an essentially biological process. As a result, patent protection is in principle available for plants and plant material produced by conventional breeding methods even though patents are not available for the methods themselves. The Enlarged Board acknowledged that there might be an argument that the purpose of the exclusion of the method claims in Article 53(b) would be frustrated if a patentee is able to claim the product obtained by such a method. However, it said that interpreting the exclusion to include products would introduce an inconsistency as plants and plant material (other than plant varieties) are generally eligible for patent protection. Policy issues might also arise, for example, out of the fact that patent protection extended to using as well as producing the product, but the Enlarged Board emphasised that the point of law referred to it had not included the scope of protection – the ethical, social and economic issues were not for the Board to decide.

Patents and standards

What price FRAND?

The developing relationship between competition law and standard essential patents continued to steal the limelight. However, despite a number of important decisions, we still do not have a clear answer to the most important question – how much is a Fair, Reasonable and Non-discriminatory (FRAND) rate, and how should it be calculated? The English High Court may give some indication if and when judgments in the on-going dispute between Unwired Planet and Huawei are delivered, probably in 2016.

FRAND licensing commitment does not rule out injunctions

Meanwhile, in April 2015, the decision of the Court of Justice of the European Union (CJEU) in **Huawei v ZTE** made it clear that the proprietor of a standard essential patent (SEP) may seek injunctive relief against infringers despite its undertaking to the standard-setting organisation that it will grant licences on FRAND terms. Before seeking an injunction the SEP owner must, however, alert the infringer to the infringement and make a specific, written offer of a licence on FRAND terms. Only if the alleged infringer does not "diligently" respond to the offer "in accordance with recognised commercial practices in the field and in good faith" – for example if it employs delaying tactics – may the SEP owner seek an injunction. The FRAND licence will be a matter for negotiation between patent owner and licensee, but the important question of the circumstances (if any) in which the potential infringer is entitled to refuse an offer which qualifies as FRAND remain unclear. Read our eAlert **here**.

Can the patentee insist on a portfolio licence?

A major question is whether the patentee can insist on the licensee taking a FRAND licence covering a worldwide portfolio rather than licences under single patents in single countries. Such portfolio licences are standard in the industry, often allowing the issues between the patentee and licensee to be settled once and for all. A potential objection – referred to by Mr Justice Birss in the High Court – is, however, that they could allow a patentee to force the licensee to take licences under a wide range of patents in many countries based on the threat of an injunction in one country. The issue arose in preliminary applications made in the English High Court in the cases of **Vringo v ZTE** (January 2015) and in **Unwired Planet v Huawei** (April 2015). In both cases Mr Justice Birss rejected arguments that the FRAND licensing issues should be heard in advance of other issues. The question of portfolio licences is likely to be addressed in the decisions in Unwired Planet v Huawei expected next year.

Read our eAlert here

Claim construction

About-turn on use of the prosecution history in construing a claim

Floyd LJ, giving the lead judgment in the Court of Appeal in Actavis v Lilly (June 2015), strongly discouraged the use of the prosecution history in construing patent claims. In so doing he rejected the reasoning of the trial judge (Arnold J) and reasserted the traditional approach of the English courts – that it is not prohibited but generally discouraged. Floyd remarked that it would be "a very rare case indeed" in which the prosecution history would assist the court in preventing abuse of the system as Arnold had suggested.

Rounding up to infringement

In **Smith & Nephew v Convatec Technologies** the Court of Appeal held that the approach to construction set out by the House of Lords in Kirin Amgen applied just as much to numerical ranges as it did to descriptive words and phrases. The basic question was what the skilled person would understand the patentee to be using the numbers to mean.

Scientists expressed numerical values with various degrees of precision. In this case the correct construction was a "whole numbers approach" with the result that a range of 1% to 25% was to be understood as including anything from 0.5% to 25.5%, and the disputed product (at 0.77%) infringed. This contrasted with the "significant figures" approach incorrectly applied by Arnold J in the High Court. At the time of writing the injunction in this case had been stayed pending the Supreme Court's decision on whether to grant permission to appeal and also the decision of the European Patent office on an appeal by Convatec in opposition proceedings.

Priority issues

Idenix Pharmaceuticals v Gilead Sciences (December 2014) in the English High Court served as a timely reminder that priority under the Paris Convention can only be claimed by the person who filed the original application himself or his legal successor. It is particularly important to bear this issue in mind within groups of companies, because if a different group company makes the later application (for example for tax reasons as here) rights in the invention must be assigned to it before that application is made as it cannot be remedied by a later assignment. The defendant's novelty attack depended on it establishing priority for its PCT application from a previous US application; in this case it was able to establish an effective assignment on the balance of probabilities despite the fact that no signed copy of the relevant agreement could be found.

Tactics

Bifurcation possible but "not normal" in the English High Court

In British Gas Services v Vanclare, a case involving the largest smart metering utilities contract in the world, British Gas Services (BGS) argued that validity should be tried before infringement as this would be quicker, its validity attack being "simple, straightforward and strong". Inevitably the patentee did not think the issues were that simple, and nor did Mr Justice Arnold. (Arnold J was sitting in the IPEC from which the revocation claim was being transferred to the High Court.) He took the opportunity to set out the High Court's approach to bifurcation: the starting point is that trying validity and infringement together is the normal practice, although the court has power to order them to be tried in "whatever order may be convenient". However, he thought that if the court is to depart from the normal practice "some good reason needs to be shown", although the onus is not necessarily a heavy one. The disadvantages of bifurcation included that the court has potentially to address the patent twice over with a risk of divergent interpretations and delays whilst an appeal on validity was heard. There was no good reason for bifurcation in this case.

You suggest we need a licence under your patent? Send us copies of your other licences please

Big Bus, which ran open-top bus sightseeing tours, found itself pursued by patent licensing company Ticketogo to take a licence under a patent relating to an online ticketing system. Big Bus countered by applying for pre-action disclosure of Ticketogo's other licences under the patent. It argued that this would allow it to establish the value of Ticketogo's claim and put it in a better position to evaluate whether it made sense to settle. It was successful in obtaining disclosure of Ticketogo's licences in the transport field.

Whereas some have regarded this as a useful tool in dealing with potential "trolls", others have seen a wider risk that patentees may be obliged to disclose their licences in licensing negotiations more generally. We believe that the judgment is currently subject to appeal, which may establish more clearly the circumstances in which such orders are likely to be granted in future. (**Big Bus v Ticketogo**, April 2015)

Jurisdiction

Things go wrong under the Brussels Regulation

Under the Brussels Regulation (No 44/2001) judgments given in one Member State must be recognised in other Member States and "under no circumstances may a foreign judgment be reviewed as to its substance". An exception applies if recognition of the judgment would be "manifestly contrary to public policy in the Member State in which recognition is sought".

The case of **Diageo v Simiramida (Case C-681/13)** concerned a consignment of Johnny Walker whisky brought into Bulgaria by a parallel importer from outside the EU and seized at Diageo's request. The Bulgarian courts, misapplying trade mark law, held that the seizure was unlawful, although some of them had also acknowledged that there had been an error. Pressing its advantage, the alleged infringer then sued Diageo in the Netherlands, its home court, for damages arising out of the "unlawful" seizure. The Dutch court referred a question to the CJEU. The CJEU held that a trade mark judgment that was contrary to EU law did not qualify as "manifestly contrary to public policy". As a result the incorrect judgment will have to be recognised in the Netherlands. In order to come within the exception the judgment would have had to constitute a "manifest" breach of a rule of law "regarded as essential in the EU legal order and therefore in the legal order of the Member State in which recognition is sought or of a right recognised as being fundamental in those legal orders".

The Unified Patent Court comes closer

Slowly but surely the remaining pieces are being put into place. On 5 May 2015 the CJEU finally removed the last legal obstacle when it dismissed Spain's legal challenge. Eight Member States have now ratified the UPC Agreement, and others, including Germany and the UK, are in the process of producing legislation to achieve this – the UPC Agreement will enter into force after 13 Member States including Germany, France and the UK have ratified it. On 11 August 2015, in a burst of **purple prose**, the UK Government announced that a lease for the central London premises of the London section of the central division in the Aldgate Tower has been signed. Current estimates are that the court will open its doors in late 2016 or early 2017. To read more about the UPC, please see our **UPC Microsite**.

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