RSC LAW GROUP NEWSLETTER

January 2014

Message from the editor

Dear all,

This is the first newsletter of the year and provides an update on our activities over the last twelve months. The group organised three events last year. A seminar entitled, IP Enforcement around the World in the Chemical Arts, was held on the 28th October, at Burlington House. In addition, the now annual Case Law event was held on the 28th November, again at Burlington House.

Other events throughout last year included, a Chemistry in Law Enforcement talk, which was part of our offering for the International Year of Chemistry. A tour of Parliament was also organised.

In this newsletter, we have three guest articles. Two have been kindly submitted by Simon Llewellyn and the other has been kindly submitted by Jennifer Harris. On behalf of the committee, I would like to thank both Simon and Jennifer for their hard work in preparing these articles.

We aim to offer an attractive series of seminars this year and the details will be circulated, to all of our members, prior to the event.

We would welcome any suggestions from our members.

Richard Toon

Recent Event Reviews

Chemistry in Law Enforcement

RSC ChemNet and Law Group event, Tuesday 20 November 2013

On a chilly evening in November, around 80 spritely 16-18 year old students flooded the library in RSC's headquarters, Burlington House, London. They had eagerly gathered to hear all about Chemistry in law enforcement. The talks were co-organised by the RSC Law Group and ChemNet.

The evening was filled with two excellent talks: first, a talk on the techniques used in fingerprinting from Senior Fingerprint Expert, Katie Venus-Bishop of the Kent and Essex Police Serious Crime Directorate; then, a talk from Julia Mills of the Forensic Explosives Laboratory, DSTL.

Katie delighted the audiences with some of the history of fingerprinting before explaining some of the techniques used now. Most members of the audience spent time inspecting their own fingertips during the talk. The talk concluded with a look at how fingerprinting had also been used to identify victims of the 2004 Tsunami in Thailand.

Julia then gave an explosive (almost literally) presentation on the forensics of explosives. The difference between low and high explosives was explained, along with real-life examples of chemicals used and devices sent to their laboratory for analysis. The talk came to a conclusion before the rather gruesome picture was shown of a man who had failed to make his home-made device safe.

Both speakers provided details of how the audience members could follow in their

footsteps and pursue a career in forensic science. The speakers were inundated with questions about their chosen career, and many students went home after an informative yet entertaining evening of forensic science.

Joseph Lenthall

Guest Articles

Preliminary Injunctions can now be granted in respect of patents held invalid at first instance

In Novartis AG v Hospira UK Limited[1] the Court of Appeal has, for the first time, granted a preliminary injunction in respect of patents that were held invalid at first instance by the High Court. This decision represents a favourable development for patent holders.

Background

This case concerned an appeal against the refusal of the High Court to grant a preliminary injunction (PI) on the basis of two patents for the use of zoledronic acid administered intravenously and intermittently (with a period between administrations of about a year) for the treatment of osteoporosis. In a separate, earlier case between the same parties, the High Court had held both patents invalid for lack of entitlement to priority (and if priority was lost, it was accepted that intervening prior art would invalidate the patents) and (for certain claims) lack of sufficiency. Permission to appeal this finding of invalidity was later given. Following this permission, Hospira's solicitors wrote to Novartis informing that Hospira intended to launch its generic zoledronic acid medicine for the treatment of osteoporosis following the expiry of a different patent (and related Supplementary Protection Certificate) which covered zoledronic acid itself. Novartis then commenced infringement proceedings (on the basis of the patents that had earlier been found invalid) and made an application for a PI. The High Court refused to grant the PI, and Novartis appealed this refusal.

The Decision

Reversing the High Court's refusal, the Court of Appeal accepted Novartis' appeal and granted a PI. In reaching its decision, the Court of Appeal accepted that to grant a PI in circumstances where the patents on which the PI application were based had been held invalid at first instance: first, the appeal must have a real prospect of success; and secondly, the balance of hardships must be in the patentee's favour. Once it had been established that there was a real prospect of success, it was not usually necessary to consider the merits of the appeal, which should not be taken into consideration when assessing the balance of convenience. However, the fact that a PI would have been granted before trial did not mean that a PI should necessarily be granted pending appeal. Rather the court must assess all the relevant circumstances following the first instance judgment, including the amount of time to the appeal and the balance of hardship if an injunction were granted or refused. The Court emphasised that the grant of a PI was not limited to circumstances where its refusal would render an appeal nugatory.

The Court of Appeal upheld the High Court's finding that Novartis had a real prospect of success in its appeal on the validity of the patents and held that the balance of convenience favoured Novartis because the unquantifiable damage to Novartis would have outweighed that to Hospira. This was because the launch of a generic zoledronic acid product would have caused an immediate and irrecoverable downward price spiral. The Court of Appeal confirmed that to "clear the way", a generic company must first dispose of all arguable objections from the patentee, including a potential appeal decision.

[1] [2013] EWCA Civ 583; Bristows LLP acted for Novartis AG

Effect of the Decision

This decision confirms that PIs can be granted on the basis of a patent that is held invalid at first instance. The circumstances in which such a PI may be granted are limited to where the invalidity decision has been appealed, and it can be shown that the appeal has a real prospect of success. Nonetheless, this will be a welcome decision for patent holders particularly in sectors, such as pharmaceuticals, where the launch of what may ultimately prove to have been an infringing product, can cause immediate and irrecoverable damage.

Simon Llewellyn

Associate, Bristows LLP

When to stay patent infringement and revocation proceedings – the Court of Appeal issues revised guidelines

In IPCom v HTC[2], the Court of Appeal has revised its guidelines on when the English courts should stay patent infringement and revocation proceedings in circumstances where the validity of the same patent is also being challenged before the European Patent Office ("EPO"). While it remains to be seen if and how the current practice of the courts will change, the revised guidelines at least raise the possibility that stays may become more common.

Background

National courts have long been faced with the challenge of deciding whether or not to continue patent infringement or revocation proceedings where the validity of the same patent is also being challenged in opposition proceedings before the EPO. Parallel proceedings inherently bring the risk of inconsistent decisions, and as the EPO ultimately trumps national courts on questions of validity, faster moving national proceedings can be undermined by a subsequent opposite EPO decision. However, as EPO proceedings can move very slowly, taking at least several years (and in some cases a decade or more), staying the national proceedings may deny the parties a resolution in a meaningful timeframe. Given the very large financial sums at stake in modern IP disputes, the way in which the Courts handle this issue is hugely significant to patent holders.

The previous guidelines were set out in 2008 in *Glaxo v Genentech*[3], and the courts have developed a tendency to continue proceedings where it was thought the court would resolve the question of validity sooner than the EPO, which in practice was most of the time. However, in the recent Supreme Court decision *Virgin Atlantic Airway v Zodiac Seats*[4], this practice was criticised and the Court of Appeal was asked to reconsider the Glaxo guidelines, which it then did in *IPCom v HTC*.

The Decision

(For brevity, the Court of Appeal's revised 13-point guidelines are not reproduced here (they are given in full in the judgment, which is freely available from www.bailii.org). However, the key points are discussed in the following paragraph.)

Significantly, the Court of Appeal declined to make stays compulsory (which they are in a number of jurisdictions, such as Germany). It held that given the tensions inherent in the European patent system, judges should maintain the discretion to progress or stay a case depending upon its facts. However, the revised guidelines state that in the absence of any other facts, a stay should be granted as there is no point in pursuing parallel

[2] [2013] EWCA Civ 1496; Bristows LLP acted for IPCom

[3] [2008] EWCA Civ 23

[4] [2013] UKSC 46

proceedings, just because it is possible to do so. This arguably represents a change of emphasis to the previous guidelines, which noted that fact of duplicative proceedings, was not, of itself, a ground for granting a stay. Nonetheless, the length of time taken by respective proceedings remains a significant factor in deciding whether to grant the stay under the revised guidelines.

The guidelines also state that one new factor in favour of granting a stay would be if the patentee were likely to irrevocably gain some compensation from the defendant which might later be found to have been wrongly awarded. However, if the patentee is prepared to give an undertaking to return any such money, then allowing the proceedings to progress in parallel could achieve at least some certainty as between the parties in a sensible timescale.

Effect of the Decision

The effect of the revised guidelines on the practice of the Courts remains to be seen. While on the face of it there will now be more occasions on which the Court may consider granting a stay appropriate, if it becomes common practice for the patentee to give an undertaking to return money if the patent is later revoked, this could well ensure that the refusal of stays remains the norm.

Simon Llewellyn
Associate, Bristows LLP

Evolving Indian Patent Trends in the Pharmaceutical Field

Extracts from an article originally written by Pravin Anand and Archana Shanker of Anand & Anand, re-published here with their kind permission.

Intellectual Property cases in India have witnessed an exponential growth in the last 10 years, especially with respect to pharmaceutical patents. It is becoming increasingly clear that a top-down reform of the entire system is necessary and that to protect the intellectual property of innovators, India's patent system must begin to reflect established international norms.

Inconsistencies with established international norms

Some Indian Court and the Intellectual Property Appellate Board (IPAB) decisions changing patent jurisprudence in contrast with other countries include:

In the Novartis (Gleevac) case, the Supreme Court diluted the well-acknowledged distinction between "Coverage" and "Disclosure" for the purpose of anticipation and infringement, thereby affecting an applicant's ability to formulate broader claims than the invention itself. In this case, the patent owner had claimed that a salt was covered by a basic patent and the court then deemed that it was disclosed therein.

The IPAB, in invalidation proceedings, analyzed the elements of a claim not as a whole but taking only those elements after transition terms like "comprising" and comparing them with the prior art, both for the purpose of anticipation and obviousness. This led to a new concept for anticipation which the IPAB evolved called "partial anticipation" which is contrary to the "all the elements rule".
For secondary inventions (i.e. salts, ethers, esters, polymorphs etc.), applying the Novartis Supreme Court findings, for pharmaceutical patents, the provisions of section 3(d) were added as a fourth element to novelty, utility and non-obviousness. The Supreme Court held that the Indian test for patentability particularly for pharmaceutical patents has a higher threshold.

On amendment, the IPAB seems to have developed jurisprudence totally contrary to the intent and provisions of the Indian Patents Act. While the Act empowers the courts and

IPAB to grant relief in respect of any valid claim in infringement proceedings or to allow amendments once an invalidation determination has been made, the IPAB in a large number of cases has disallowed amendments on the ground of "delay". Besides disallowing amendments, the IPAB revoked patents if the parent claim was held as being invalid. This is contrary to the Act which contemplates relief on valid claims despite some claims being held invalid.

The IPAB, in a number of cases, held that the test of obviousness is different than the one in USA and UK and would not specify what the test is. The IPAB in several invalidation cases held that unlike the law in other countries, where for the purpose of obviousness, the hypothetical construct is a person of ordinary skill in the art, in India, the standard for obviousness is higher as this hypothetical construct is not an "ordinary" person. The IPAB attributed special skills to the person skilled in the art and held that for the purpose of obviousness, this hypothetical construct has a creative imagination. For insufficiency, however, this person is a person with average skill.

Silver linings and opportunities for reform

Despite the aforesaid trends, there are several indicators which demonstrate that the law is in a state of flux and may yet yield positive reforms on the side of innovators, examples of which are listed below:

The Pfizer cases relating to Sunitinib and the BMS cases relating to Dasatinib have successfully upheld the right of the innovator to keep infringers out of the market via the grant of interim injunctions. A large number of ex parte injunctions have been granted in the nature of status quo orders when generic companies have applied for manufacturing or marketing approval before the drug regulatory authorities and before the product is launched.

In Roche vs. Cipla, the plaintiff lost on infringement due to a claim construction that limited the claim to a mixture of polymorphs as against the defendant's single polymorph despite being a new chemical entity claim. But on the positive side, the Court upheld the patent.

In the Glaxo Lapatinib case, the IPAB upheld the patent for the basic compound although it annulled the patent for its ditosylate salt and held that in an obviousness analysis, the challenger of a patent cannot do a *"hip-hopping"* over prior arts unless the *"Hopscotch -outline"* of the invention was before the person skilled in the art.

Patent trials have been expedited on a fast track to be disposed of within a year or so.

Conclusion

While there have been a few bright spots in India's evolving patent laws, the trend against foreign innovators in favor of domestic companies (who did not contribute at all to the underlying intellectual property) cannot be ignored and remains a cause for concern.

On 20th of September 2013, the Madras High Court set aside 12 orders of the IPAB (which had cancelled 12 patents in the Wind Energy Field) on the ground that the IPAB had not decided whether the revocations were validly instituted. This order demonstrates that the IPAB orders referred to above are "stage one" and writs/appeals may be filed before higher courts. The law is therefore in a state of flux and the principles will shape up over the next few years. While there remains hope that recent trends may be reversed in favour of innovators, much work remains to be done to educate all levels of the Government of India on the enormous value and potential of intellectual property.

Edited by Jennifer Harris, Kilburn & Strode LLP.

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Find us on online:www.rsc.org/law

We will be posting details of future events on the web. You can also find handouts from past seminars on our webpage.

This newsletter was produced by Richard Toon, publicity chair of the Law Group

If you would like to include short articles that may be of interest to Law Group members, please let Richard know. We aim to send the next issue out in Summer 2014.
Richard would like to thank everyone for their contributions to this issue. The views of individuals contained in this newsletter are not necessarily those of the Law Group or of the Royal Society of Chemistry.