

# RSC LAW GROUP NEWSLETTER



April 2015

## *Message from the editor*

Dear all,

A number of events took place last year including the hugely popular case law seminar, which was held on 20 November at Burlington House. This year's case law seminar is scheduled to take place at the same venue on Wednesday 18<sup>th</sup> November.

The Law Group is busy planning further events for this year. The financial information regarding the Unitary Patent is due to be issued in the next couple of months, and a flash seminar to discuss the implications is to be held shortly thereafter. A live patent debate is being planned for the autumn. The debate is to include a number of high profile industry figures and academics, both for and against the patent system. Details of these events will be circulated shortly.

In this issue guest articles have been submitted by the Law Group members Sophie Maughan of Scott & York, Darren Smyth of EIP and Robert Barker of EIP. On behalf of the committee I would like to thank Sophie, Darren and Robert for their contributions. I would also like to take this opportunity to remind members that guest articles are always welcome.

Unfortunately, we have also lost two of our committee members: Richard Toon and Alex Rogers. The law group would like to thank Richard and Alex for their valuable contributions and we hope to see them at our future meetings.

In place of Richard and Alex, myself and Sophie Arrowsmith have become members of the committee, and our profiles are detailed on page 2. Both Sophie and I look forward to serving on the committee.

*Oliver Rutt*

## Recent Event Reviews

### **Annual Case Law Seminar, 20 November 2014**

The case law seminar has enjoyed a high attendance in previous years, and this year was no exception.

The seminar focused on recent, high profile case law developments in the UK, Europe and the US, relevant to the field of chemistry. The seminar was chaired by Jennifer Harris of Kilburn & Strode LLP. Speakers included:

Joseph Lenthall (Mewburn Ellis LLP)  
James Horgan (Merck Sharp and Dohme Ltd)  
Rob Jacob (Stephenson Harwood LLP)  
Stuart Jackson (Kempner and Partners LLP)  
Darren Smyth (EIP)  
Leythem Wall (Finnegan Europe LLP)

The talks were well received, and encouraged lively discussion. A drinks reception followed the talks.

*Oliver Rutt*

## *Profile of new members*

### **Sophie Arrowsmith**



Sophie joined Hamblins as a solicitor in 2014 having qualified in IP, IT and Commercial law

in 2012. Sophie works with Matthew Pryke in advising clients on general commercial issues, protection and enforcement of IP rights, IP exploitation, collaboration agreements, websites and e-commerce, marketing, consumer law and data protection, as well as providing support to the corporate team in commercial and IP matters.

Sophie also has an MSci in Chemistry from Imperial College London. She obtained experience in the science and technology sector businesses when conducting two internships with the pharmaceutical giant, Pfizer Inc. Sophie trained as a solicitor at a specialist IP and technology firm.

### Oliver Rutt



Oliver is a Chartered Patent Attorney and European Patent Attorney in the Chemical and Materials Group of Boulton Wade Tennant, and has experience in the drafting and prosecution of Patent applications in the chemical and materials science fields. He joined Boulton Wade Tennant in 2009 after working elsewhere in private practice.

Before entering the Patent attorney profession in 2007, Oliver carried out academic research in the areas of solid state chemistry and lithium-ion battery technology, and has co-authored a number of scientific journal publications. During his research, he gained practical experience of the synthesis and characterisation of non-oxide anion and mixed-anion solid compounds, including the use of techniques such as diffraction and NMR.

He also gives tutorials to candidates for the UK and European qualifying examinations.

Oliver has a MChem and DPhil (Inorganic Chemistry) from Oxford University. He also holds a postgraduate certificate in Intellectual Property Law from Queen Mary, University of London.

## Guest Articles

### Leo's psoriasis patents found to be obvious in the Patents Court

*In Teva v. Leo Pharma<sup>1</sup> Mr Justice Birse's judgement provides further insight into how the UK courts consider inventive step with regard to so-called "incremental" pharmaceutical inventions, i.e. those relating to the optimisation of known drugs. Interestingly, the case centred on an inventive step attack starting from the common general knowledge, and considered the weight of commercial factors when addressing obviousness.*

#### Background

Leo Pharma owned two patents (EP1178808 and its divisional EP2455083) relating to a treatment for psoriasis. The claims were directed to an ointment comprising a combination of a corticosteroid (e.g. betamethasone) and a vitamin D analogue (e.g. calcipotriol), together with a particular solvent (polyoxypropylene-15-stearyl ether). It was known to administer betamethasone and calcipotriol individually in order to treat psoriasis, and the compounds had also been prescribed together for separate administration. However, the compounds had never been combined in a single formulation, since they were stable at different pH values. Use of the non-aqueous solvent polyoxypropylene-15-stearyl ether (Arlamol E) was found to result in a stable composition.

Leo's product, Dovobet ointment, which was covered by both patents, enjoys a high volume of sales in the UK. Teva wished to start selling a generic version of the ointment, and applied to have the patents revoked on the basis of a lack of inventive step, insufficiency and added matter.

#### The Decision

Teva's sole inventive step attack started from the assertion that it was common general

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<sup>1</sup> Teva UK Limited & Teva Pharmaceuticals Limited v Leo Pharma A / S & Leo Laboratories Limited [\[2014 EWHC 3096 \(pat\)\]](#)

knowledge to treat psoriasis using a combination of both compounds, and that it would be clearly beneficial to provide both compounds in a single formulation for reasons of patient compliance. Teva asserted that it would be obvious that such a combination would be stabilised by use of the solvent polyoxypropylene-15-stearyl ether in view of US 4,083,974 (Turi), which disclosed a non-aqueous composition containing polyoxypropylene-15-stearyl ether and betamethasone. Teva's case was unusual since it started from the common general knowledge and then involved adding information from a document (Turi) which is not part of the common general knowledge and which Teva did not submit would be found on a literature search. Leo did not contest this approach to obviousness in principle.

Mr Justice Birse considered that the skilled person was a team consisting of a skilled clinician and a skilled formulator of pharmaceutical formulations. Starting with the skilled clinician, it was considered to be obvious to incorporate both drugs into a single formulation in view of the fact that both drugs were known to be administered separately, and that it would be obvious that their combination in a single formulation would aid patient compliance. Moving on to the skilled formulator, Birse went on to consider whether it would be obvious for the skilled formulator to try the solvent disclosed in Turi. Leo argued that such a solvent was not regularly used, and therefore would not be an obvious solvent to try in view of the added uncertainty and cost, for example due to the need for additional regulatory trials.

After taking evidence from a number of expert witnesses on both sides, Mr Justice Birse concluded Teva's arguments were more persuasive. In particular, he considered that the skilled person, when presented with the Turi document, would proceed to attempt to stabilise the formulation using polyoxypropylene-15-stearyl ether. Specifically: "*The notional skilled formulator would test some familiar compounds but...would not be put off from including unfamiliar compounds merely because of their unfamiliarity...[t]he fact that unlike many other possible solvents, this compound did not have a well-established track record in pharmaceutical formulation, would not be sufficient to put the formulator off including it in the test*". Accordingly, the invention was considered obvious.

## Effect of the Decision

This case is a further example of a so-called "incremental" pharmaceutical invention being found obvious by the UK courts.

It also suggests that the weight afforded to commercial factors when assessing obviousness is low. In particular, in paragraph 82 of the judgement, Birse states "*in my judgement commercial considerations, such as the uncertainties surrounding the regulatory process relating to an invention in the pharmaceutical field, are capable of playing a role in the thinking of the notional skilled person as a matter of principle. However, first, like any other factor their significance will vary from case to case; and second, given that they are commercial rather than directly technical in nature, these factors are unlikely to outweigh technical considerations in any but the strongest cases*".

*Oliver Rutt  
Patent Attorney, Boulton Wade Tennant*

## **"An innocent party who is mixed up in the wrongdoing of others": NHS England are dragged in to break up Pfizer and Actavis.**

*Warner-Lambert claim that Actavis' skinny labelled product could infringe their second medical use patent. After an unsuccessful application for an unusual form of injunction against Actavis, Warner-Lambert apply for an unprecedented injunction compelling NHS England to issue guidance to prescribers to only prescribe pregabalin for the treatment of pain under their trade mark Lyrica®. Arnold J grants the injunction, with potentially far-reaching consequences.*

## Background

"Swiss-form" claims have been a staple of pharmaceutical patents in Europe since the decision *Eisai/Second Medical Use* G 5/83, but are now prohibited in favour of the EPC 2000 claim format following *Abbott Respiratory/Dosage Regime* G 2/08. Swiss-form claims will however still be present in patents for about two decades. Despite their

long use, there is surprisingly scant jurisprudence on the fundamental question of what this claim format actually means. Who infringes it by what acts, and, conversely, what is necessary in order not to infringe such a claim?

If a generic manufacturer wishes to launch a generic drug where some authorised medical indications are off-patent, but others are still the subject of patent rights, the regulatory system permits the generic manufacturer to employ a “skinny label”, by which only those indications that are free to operate are identified in the summary of product characteristics and patient information leaflet. Ostensibly the reason for this is to avoid infringement of the extant patent rights. However, again surprisingly, it has not been clear that a skinny label is of itself sufficient to escape liability for infringement. A doctor is permitted to prescribe, and a pharmacist to dispense, a medicine for an indication not listed in the label, and in fact about 95% of prescriptions do not state the indication for which the drug has been prescribed.

Warner-Lambert (part of the Pfizer group) market the drug pregabalin under the brand name Lyrica®, for use in the treatment of epilepsy, general anxiety disorder (GAD) and neuropathic pain. Their patent for the pregabalin product itself expired in 2013, and a subsequent Supplementary Protection Certificate has, for reasons which are unclear, been allowed to lapse for non-payment of fees. However, their second medical use patent, which features Swiss-form claims for the use of pregabalin for the preparation of a pharmaceutical composition for treating pain, is still in force.

Actavis had sought a marketing authorisation for a generic pregabalin product limited to the treatment of epilepsy and GAD. Once they obtained marketing authorisation, they intended to launch their product with a ‘skinny label’ (limited to the epilepsy and GAD indications only), under the trade mark Lecaent®. Other generic manufacturers have also shown interest in marketing generic pregabalin products, and at least one such manufacturer (Consilient) had already obtained marketing authorisation.

Warner-Lambert believe that Actavis’ skinny labelled Lecaent® product may, unless certain steps are taken, infringe the second medical use patent, and accordingly Warner-Lambert have brought proceedings against them.

Actavis in turn has filed for revocation of the patent.

### First Decision

In the first hearing relating to this case (*Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Ors* [2015] EWHC 72 (Pat)), Warner-Lambert applied for an interim injunction against Actavis. Unusually, the injunction sought was mandatory in character, and would require Actavis to take certain steps to minimise the chance of their generic product being used for the treatment of pain. Some of the steps were not in dispute, and Actavis had already fulfilled a number of these requests by the time of the hearing. Other steps, however, were more contentious – Warner-Lambert wanted Actavis to impose contractual obligations on pharmacies which they supplied with their product, requiring the pharmacist to not dispense the generic product to patients who had been prescribed pregabalin for the treatment of pain. They also wanted Actavis to add labels on the packaging of their product, indicating that Lecaent® should not be used in the treatment of pain.

At this stage, it was recorded as common ground between the parties that the best solution to the problem would be to ensure that prescribing doctors prescribe pregabalin for the treatment of pain by reference to the brand name Lyrica®, rather than by reference to its generic name. This could be achieved by NHS England issuing guidance along these lines.

Arnold J remarked that whilst they could ask NHS England to issue guidelines on the matter, Warner-Lambert and Actavis were in no position to mandate NHS England to take any action:

“Clearly, it is a matter for NHS England and NHS Wales to decide whether or not to issue such guidance, but for my part I would encourage them to consider do so as a matter of urgency”

It was at this hearing that Arnold J expounded his construction of Swiss-form claims: namely, that “for” in the claim “[X] for use as a medicament” should not simply be construed as “suitable for”, but should be understood to mean “suitable and intended for”. This construction is consistent with the caselaw, including the recent decision from Birss J in *Hospira UK Ltd v Genentech Inc.* [2014] EWHC 1094 (Pat).

He went on to state that, with regard to “intended for”, it is the manufacturer of the medicament whose intention should be considered. Warner-Lambert contended that it should be the intention of the person dispensing the product. However, as Arnold J stated, the Swiss-form claim is fundamentally taken to be a process claim, rather than a product claim. He elaborated on Jacob LJ’s statement in *Actavis v Merck* [2008] EWCA Civ 444 – “[a Swiss claim] is not aimed at and does not touch the doctor – it is directed at the manufacturer” – to add at paragraph [96] of this decision:

“Nor does such a claim touch the pharmacist (except in the case of extemporaneous preparation by the pharmacist). Thus the process will be carried out by Actavis (or their manufacturer), not by the prescriber or the pharmacist”.

It then follows that it is the manufacturer’s intent which is relevant. In the later judgment discussed below, he expanded upon this point, stating that the word “manufacturer” should be interpreted broadly, but it still does not touch the pharmacist:

“[I]n this context, manufacture (or, more strictly, “preparation”) should be broadly interpreted as extending to, for example, a person who packaged and labelled the product (if different to the manufacturer of the pharmaceutical composition). It is also worth pointing out that the fact that a generic supplier subcontracts manufacture will not necessarily cause any difficulty.”

Furthermore, the manufacturer’s intent must be “subjective intent” in order for them to be found to infringe. That is, in order to infringe, the manufacturer must subjectively intend for the product to be sold for the purpose of treating the condition still under patent protection, rather than simply being aware that it is likely that pharmacists may prescribe the skinny labelled product for the protected condition. At the time of this first hearing, Warner-Lambert had not pleaded any case based on Actavis’ subjective intent.

In order to settle the application for this interim relief, Arnold J turned to the *American Cyanamid* principles (*American Cyanamid Co v Ethicon Ltd* [1975] AC 396), namely whether there was a serious issue to be tried, and assessing the relative harm to each party if the relief were to be wrongly granted or wrongly

refused. In both these criteria Arnold J found in favour of Actavis, and therefore did not grant the injunction that was sought. In particular, he determined that, since the requisite subjective intent had not been pleaded, there was no serious issue to be tried.

## Second and Third Decision

In the second hearing relating to this case ([2015] EWHC 223 (Pat)), Actavis applied to strike out Warner-Lambert’s claim for infringement, and Warner-Lambert applied to amend its Particulars of Infringement to plead a case of subjective intent. They alleged infringement under section 60(1)(c) and 60(2) of the Patents Act 1977.

Although Warner-Lambert presented many arguments as to why Actavis’ actions indicated existence of subjective intent, Arnold J was not convinced that the Amended Particulars of Infringement disclosed reasonable grounds for alleging Actavis’ subjective intent.

Despite the judge’s negative view of Warner-Lambert’s arguments, he did not strike out their claim for infringement under section 60(1)(c). Arnold J accepted that an appellate court may disagree with his construction of the words “for treating” in a Swiss-form claim, and this was an important factor in allowing the case to proceed to trial.

Furthermore, he accepted that this is a developing area of law, and so the correct course of action was that the facts of the case should be determined at trial before any appeal. The refusal to strike out the claim for infringement was also a pragmatic one: Warner-Lambert had already made it clear that they would appeal such a decision. Such an appeal, regardless of outcome, would probably be further appealed. As such, the case would likely reach the Supreme Court. As the trial was already scheduled for the end of June 2015, it is unlikely that the appellate courts would have had chance to reach a decision before the trial. The overall effect would be a delay in proceedings.

In arguing that the case should be heard at trial (and later arguing their case for indirect infringement under 60(2)), Warner-Lambert relied on a recent Dutch decision from the Court of Appeal of the Hague in *kort geding* proceedings, which at first blush appears to have found a generic manufacturer to be infringing a second medical use patent in an

analogous case (*Novartis AG v Sun Pharmaceutical Industries (Europe) B.V.* 200.1 50.713/01). However, there were important factual differences between the cases which justified a different outcome. For instance, unlike Actavis, Sun had not taken several steps which would have helped them to avoid infringement. More importantly, Sun had won a tender to be the exclusive supplier of the drug in question to a large healthcare insurer: this would inevitably result in pharmacists dispensing the generic product for on-patent indications.

These factual discrepancies notwithstanding, Arnold J also considered the Dutch Court to have been wrong in accepting *indirect* infringement of a Swiss-form claim. He considered that the Dutch decision relied on interpreting a Swiss-form claim as a product claim, which is completely at odds to Arnold J's assertion that such a Swiss-form claim should be construed as a process claim (that is, a claim which is directed at the manufacturer). In the view of Arnold J, for the manufacturer to be found guilty of indirect infringement, there must be a party capable of infringement further downstream. As discussed above, the Swiss-form claim does not touch doctors or pharmacists, so in a case such as this there are no parties aside from the manufacturer capable of infringement. Therefore, in relation to a Swiss-form claim, a manufacturer must be found to have directly infringed the patent, or to have not infringed at all.

In a short, separate hearing later on the same day ([2015] EWHC 249 (Pat)), Arnold J *did* strike out Warner-Lambert's claim under section 60(2). The judge rejected their submissions, stating that their arguments were essentially premised upon interpreting a Swiss-form claim as an EPC 2000 claim, and were contrary to settled jurisprudence both in this country and in the EPO Boards of Appeal. Furthermore, the mental element required for indirect infringement has been considered in previous cases much more than the mental element required for infringement of a Swiss-form claim, and as such there was a less compelling reason to hear this part of the case in full at trial.

### **Most Recent Decision**

The last of the four decisions ([2015] EWHC 485(Pat)) concerned an application from Warner-Lambert for an injunction requiring

NHS England to issue guidance to Clinical Commissioning Groups. This guidance would inform prescribers that "pregabalin should only be prescribed for the treatment of neuropathic pain under the brand name Lyrica®".

Warner-Lambert had exchanged correspondence with NHS England before issuing this application, requesting them to provide this guidance of their own volition. NHS England refused though, stating that they were innocent bystanders in the present dispute, and that they were unwilling for various reasons to issue guidance of their own motion. However, they also stated that they would not oppose an application by Warner-Lambert for an order requiring them to issue guidance, providing certain conditions were met, and provided that the Court was satisfied that it was appropriate to make the order.

In considering the Court's jurisdiction to make such an order, both Warner-Lambert and NHS England observed that the present situation was comparable to *Norwich Pharmacal*, with Warner-Lambert saying that "NHS England is an innocent party who is mixed up in the wrongdoing of others".

Arnold J considered the purportedly analogous *Norwich Pharmacal* case, and whilst he noted that the present situation differed from the usual *Norwich Pharmacal* circumstances where disclosure is necessary in order for the applicant to determine whether a tort has in fact occurred, he seemed to be persuaded by Warner-Lambert's submission that *Norwich Pharmacal* relief is available where there is an arguable case of wrongdoing based on the evidence available at the time of the application, and as such was relevant to this case.

Arnold J granted the injunction, stating:

"I consider that the issuing of guidance by NHS England is the most efficacious, dissuasive and cheapest solution to the problem which confronts Warner-Lambert. Furthermore, it is the least onerous solution in the sense that the only other alternative open to Warner-Lambert is to pursue its applications for interim relief against the generic suppliers."

Warner-Lambert offered to give a cross-undertaking in damages in favour of NHS England and the Department of Health, but after submissions from Actavis and Teva, the benefit of the undertaking was extended to them as well. Warner-Lambert are also

responsible for the costs of all parties to this hearing, and the costs incurred by NHS England by complying with the order, regardless of the outcome at trial.

### Commentary

Does this most recent decision indicate a dilution of Arnold J's stance? In his first judgment, he determined that Actavis had taken enough action to avoid infringement. In this most recent judgment, though, it is implied that the NHS injunction is required to ensure that Actavis don't infringe.

It is important to note that the relief granted in this decision appears not to be an interim measure only, and has final character: paragraph 1 of the annex to the judgment compels NHS England to send guidance to the CCGs, stating that only Lyrica® should be prescribed for pain, by 3 March 2015. The annex only instructs NHS England to rescind these guidelines in the event that the patent is revoked, or that the patent expires. It then follows that if at trial the patent is found valid but Actavis is found to not infringe (i.e. there has been no wrongdoing by any party to the proceedings), NHS England will still be bound by this injunction (unless separate steps are taken to vary or discharge it). If Arnold J's view is found to be right, in that Actavis do not infringe, how can it continue that NHS England must still restrict the actions of prescribers?

The majority of this fourth decision is spent grappling with whether the Court has the jurisdiction to issue such an order. It does not, however, directly address the apparent paradox of how the Court can compel doctors to take a particular course of action, when Arnold J has already stated that these Swiss-form claims do not touch doctors and pharmacists (see the first decision, paragraph [96], quoted above). The Court is happy to accept that such clinicians (and moreover, NHS England) are "innocent bystanders", but constraining their activity in this manner seems inconsistent with Arnold J's construction of the Swiss-form claim.

Whilst this case steadily marches to trial for one reason or another, Arnold J has indicated numerous times that it is unlikely that Actavis can be found to infringe. He has said that unless Warner-Lambert present some new and formidable evidence, or his construction of a Swiss-form claim is wrong, there is not a serious case to be tried. However, even if

either of these eventualities comes to pass, can there still be any case of infringement to try? Now that the NHS has issued their guidelines to prescribers, categorically instructing them to not prescribe generic pregabalin for patented indications, there seems no route by which Actavis could infringe with a skinny label product, however much they wanted to (leaving aside all arguments about "subjective intent"). If Actavis intended for their generic product to be sold for the treatment of pain, the guidelines now in place mean that they are precluded from marketing their generic product for patented indications, because now there is no market for such a product.

If the NHS England injunction is the only aspect of this ongoing case which will extend beyond the date of trial (which seems increasingly likely to be the case), seeking the type of relief granted in this decision could become routine in second medical use cases; both patent holders wishing to protect their interests, and generic manufacturers looking for a cast-iron means of avoiding infringement, may find the prospect of this sort of relief appealing.

*Darren Smyth, Partner at EIP*

*Robert Barker, Patent Scientist at EIP*

## **Idenix Pharmaceutical, Inc. v Gilead Sciences<sup>2</sup> – Stupendously broad patent knocked out**

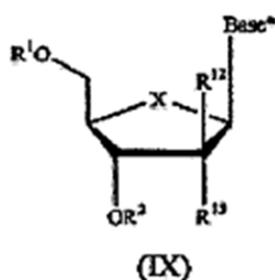
This case related to alleged infringement of Idenix's European Patent (UK) No. 1 523 489. Idenix issued a claim for infringement against Gilead on the day of grant, 12 March 2014. Idenix argued that compound claims in the patent were infringed by Gilead's sale of sofosbuvir, a drug for the treatment of the hepatitis C virus, marketed under the trade mark Sovaldi. Gilead denied infringement and counterclaimed for invalidity, and additionally filed an opposition against the patent on the date of grant (to be followed by oppositions

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<sup>2</sup> *Idenix Pharmaceutical, Inc. v Gilead Sciences, Inc. & Others* [2014] EWHC 3916 (Pat), Patents Court, England and Wales, 1 December 2014.

from four more opponents before the expiry of the opposition period). On request by Gilead, Mr Justice Arnold agreed to expedite proceedings before the High Court, and the hearing was held in October 2014, prior to the expiry of the opposition period at the EPO. The hearing was held over 11 days with evidence from four technical experts, four experts on US law, and five witnesses of fact. The patent was found to be infringed but invalid.

Claim 1 was directed to a compound of Formula (IX)



or a pharmaceutically acceptable salt thereof, wherein  $R^1$  and  $R^2$  are independently H; phosphate; straight chained, branched or cyclic alkyl; acyl; CO-alkyl; CO-aryl; CO-alkoxyalkyl; CO-aryloxyalkyl; CO-substituted aryl; sulfonate ester; benzyl, wherein the phenyl group is optionally substituted with one or more substituents; alkylsulfonyl; arylsulfonyl; aralkylsulfonyl; a lipid; an amino acid; a carbohydrate; a peptide; or a cholesterol;

X is O;

Base\* is a purine or pyrimidine base;

$R^{12}$  is  $C(Y^3)_3$ ;

$Y^3$  is H; and

$R^{13}$  is fluoro.

### Novelty

Gilead argued that the patent in suit lacked novelty over a PCT that had been acquired by Gilead. Gilead could only rely on the PCT to attack novelty if the PCT was entitled to priority from an earlier US application. The US priority application was filed in the name of the inventor and Gilead argued that the PCT applicant was entitled to priority as the successor in title to the inventor. The judgment included detailed analysis of

agreements between the parties involved in the filing of the US priority application and PCT application and evidence on US federal law and Georgia state law. Having weighed up the evidence, Arnold held that the PCT was entitled to priority and consequently that all the claims of the Patent other than claims 20 and 37 lacked novelty over the PCT.

### Inventive Step

Idenix argued that claim 1, a nucleoside compound claim (see above), was independently valid. Arnold noted the patent's claims were "stupendously broad" and claim 1 covered as many as a billion different compounds. Arnold held that the compound claims should not be assessed on the basis that they were pure compound claims, but rather as claims to compounds which had anti-Flaviviridae activity. If it were otherwise, the compound claims would lack inventive step on the basis that the only technical problem they solved was the provision of additional or alternative nucleoside analogues.

Gilead contended claim 1 lacked an inventive step, not in the conventional sense that the invention would be obvious from a specific item of prior art, but rather because it made no technical contribution to the art (following T 939/92 *Agrevo/Triazoles*). Gilead argued that it was not plausible that substantially all the compounds covered by claim 1 would be effective against Flaviviridae. Indeed, Idenix's own witness admitted that certain compounds falling within the scope of claim 1 would not have antiviral activity, and consequently Idenix applied to limit the scope of claim 1. In light of Idenix's evidence, Arnold unsurprisingly held that claim 1 as granted lacked inventive step because it covered compounds which the skilled team would not have considered to have anti-Flaviviridae activity and which therefore did not plausibly solve the technical problem of providing compounds which did have such activity.

Idenix sought to remedy the apparent deficiency in claim 1 by seeking to delete "straight chained, branched or cyclic alkyl" or "benzyl, wherein the phenyl group is optionally substituted with one or more substituents" from the lists of possible  $R^1$  and/or  $R^2$  substituents in claim 1 as these were the classes of compounds which their witness was of the opinion would not have plausible antiviral activity. Arnold held that the amended claim was not allowable as it added matter

because by deleting certain substituents from the list for R<sup>1</sup> and R<sup>2</sup>, Idenix was creating a narrower sub-class of compounds which was not disclosed in the Application and Idenix's own evidence was that it was plausible that this new sub-class was effective against Flaviviridae, whereas this was not the case for the broader class. Accordingly, the skilled team would learn something new about the invention and hence the amendment was not allowable. Even if claim 1 as amended was held to be allowable, Arnold found that it lacked inventive step, *inter alia* because the Patent contained no rationale for the assertion that the claimed compounds would be effective against Flaviviridae.

### **Insufficiency**

Unsurprisingly given the conclusions on inventive step, Arnold held that the disclosure of the Patent did not make it plausible that the invention would work across the scope of the claims (whether as granted or as proposed to be amended). Accordingly, all the claims were held invalid. He went on to consider whether the invention could be performed without undue burden either at all or across the breadth of the claims. Weighing up the evidence, Arnold concluded that the specification on its own neither enabled the skilled person to make the claimed compounds nor gave the skilled person any real assistance in doing so. Furthermore, he agreed with Gilead that the Patent did not enable the skilled team to perform the invention across the breadth of the claim without undue burden because it sets the skilled team a research project and claims the results.

### **Infringement**

In the case of sofosbuvir, the 5'-phosphate group is masked in order to assist the drug to permeate the cell membrane. It is then metabolised to give the active form of the nucleoside analogue – i.e. it is a prodrug. It was common ground that, subject to one point, the structure of sofosbuvir corresponds to the formula defined in claim 1. The dispute concerned the R<sup>1</sup> substituent. Idenix contended that the phosphorous-containing part of sofosbuvir is a "phosphate", which is one of the possible R<sup>1</sup> substituents prescribed by claim 1. Gilead disputed this, arguing that "phosphate" is limited to monophosphate only. Weighing up the expert evidence to consider how "phosphate" would be construed in the

context of the patent, Arnold concluded that, purposively construed, the skilled team would interpret the term "phosphate" to include a masked phosphate group of the kind found in sofosbuvir. Idenix had put forward evidence that leading scientists used "phosphate" as shorthand to describe phosphoramidate groups, therefore this is how the reader would understand the term "phosphate" in the context of the Patent.

Having held that the masked phosphate group in sofosbuvir was "phosphate" within the meaning of the claim, sofosbuvir fell within claim 1 and therefore directly infringed. Arnold also concluded that Gilead indirectly infringed claim 1 by supplying sofosbuvir even if sofosbuvir did not itself fall within claim 1, since metabolism of sofosbuvir results in the production of at least one compound falling within claim 1.

### **Conclusion**

This decision highlights, as per earlier case law, that a patent cannot simply provide instructions for a "research project" to select, synthesise and test a very large set of compounds to assess whether any have the target activity, as such claims will lack inventive step and be insufficient.

*Sophie Maughan  
Principal, Scott & York*

## **What's new in the Intellectual Property Act 2014**

The Intellectual Property Act 2014 has been in force for more than 6 months now. The Act modernises, simplifies and strengthens the UK's intellectual property legislation, particularly for design rights and patents thereby making the UK's intellectual property system more cost effective, clear and accessible. This should help SMEs better protect their rights by aiding innovation and investment.

### **What are the key changes for patents?**

- **Simplifying and improving protection of patented products**

Patent owners can mark patented products with an internet link at which the owner can provide the relevant patent numbers. As well as reducing cost, this public assertion of the product's patents increases protection and provides up-to-date information for competitors.

- **Reducing cost of applying for a patent and increasing strength of patents granted**

The IPO can provide non-binding opinions on more validity issues and on Supplementary Protection Certificates (which extend the life of a patent), and can revoke a clearly invalid patent. This means a wider range of disputes should be resolved earlier, reducing the cost of challenging a patent or a patent infringement and helping to ensure only valid patents are in force.

- **Power to implement the European wide Unified Patent Court (UPC)**

When introduced, businesses can use a single patent to protect their inventions across almost all the EU countries rather than applying for a patent in each country, which reduces patent costs.

### **What are the key changes for design rights?**

- **Simplifying and improving design protection**

To better protect designs, the following simplifications have been implemented: (i) protection is given to anyone living or economically active in the EU; (ii) the designer of a commissioned design will be the first owner of the design; (iii) registering a change in ownership is simplified; (iv) registered design files can be inspected on-line; (v) protection for trivial features of UK unregistered designs is more limited; and (vi) owners will be able to specify relevant EU territories when seeking international protection.

- **Rights to use a design**

Using a design right for experiments or teaching does not infringe an unregistered design. Also, a person may continue to use a design which has been registered provided they are acting in good faith.

Further, persons permitted to use a registered Community design (valid in the UK) do not infringe associated copyright. These measures reduce complexity (including for potential disputes) and the risk investments are jeopardised.

- **Introduction of the criminal offence of infringing design rights**

The new criminal offence of copying of UK registered designs in the course of business increases the consequences of infringement and helps designers protect and enforce their rights. This recognises designs as economically important as music (protected by copyright) and brands (protected by trade marks).

- **Facilitating the settling of design rights disputes using a design rights opinions service**

A non-binding design rights opinions service gives an impartial view on the strength of a potential designs litigation case. This should assist more disputes to settle earlier and/or focus any litigation which does take place.

### **When should I do something about it?**

Patent and design rights owners should mark new products with an internet link and redesign new packaging for the product. Additionally, if commissioning a product, you should ensure the agreement with the designer provides for assignment of the design rights in the product to you.

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Find us on online:[www.rsc.org/law](http://www.rsc.org/law)

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

This newsletter was produced by Oliver Rutt, 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 Oliver know. We aim to send the next issue out in Summer 2015. Oliver 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 RSC.