RSC | Advancing the Chemical Sciences

RSC Law Group Newsletter

Issue 8

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Message from the Editor

Dear members,

This is the first newsletter of the year. I would like to take this opportunity to congratulate the organisers and speakers for the case law seminar, held towards the end of 2011. We had some very good feedback about the event and this will be followed by another update towards the end of the year.

There are numerous events planned for the year. The first event will be a basic intellectual property seminar for researchers on the 22nd May

May I also take this opportunity to thank all the contributors to this issue and again, I would encourage our readership to submit articles for the newsletter. A special thank you must go to Steve Jones and Katherine Wright, both non-committee members, who have contributed to this newsletter.

For those of you who missed it, the RSC hosted a webinar on the exploitation of intellectual property last year.

An article appeared in February's edition of Chemistry World, which detailed a brief career biography of Stuart Jackson, (the chair of the Law Group).

I hope to see many of you at our next seminar in May.

Richard Toon.

Case Law Seminar—November 2011

The RSC Law Group held its, now annual, seminar on IP case law in November last year. The speakers included the following members of the Law Group:

Joseph Lenthall
Will James
Stuart Jackson
Jennifer Harris
Leythem Wall
Don Lewis

This seminar focussed on recent high profile patent law developments in the UK, Europe and the US relevant to the field of chemistry. In particular, the seminar covered a European Patent Office Board of Appeal decision relating to disclaimers in European patents, the UK Supreme Court decision in the *Lilly vs HGS* case, an update on supplementary protection certificates in Europe, some of the differences between national case law in Europe, and developments in the US.

The talks were well received, and it showed how much development there can be in a year in the field of chemical IP. We would like to thank all the speakers for giving up their time and preparing excellent presentations, in some cases within days of legal decisions being published!

Alex Rogers

Basic Intellectual Property for Researchers

This seminar will be held on **22 May 2012** at The Chemistry Centre, Burlington House, London. Registration will begin at 1.30 pm, with the talks starting at 2 pm.

The seminar will give an overview of what researchers need to know about IP. As well as a general introduction to the various types of IP, it will also give more a more in-depth guide to patents, including the meaning of 'novelty', 'inventive step', and special considerations for patents in the chemistry and pharmaceutical fields. There will also be a talk on non-patent intellectual property that can be relevant to researchers, including confidentiality, database rights, software copyright, and designs.

The seminar will conclude with a talk on IP in collaborations and licensing. This will give a guide to ownership of inventions resulting from joint projects, the considerations when negotiating and drawing up a license.

The seminar will be of particular interest to researchers who would like to know more about how to protect their inventions and how to commercialise them.

The talks will be practical guides from patent attorneys and solicitors with many years of experience dealing with chemistry IP. There will be opportunities to ask questions on all the topics covered.

The speakers will include Joseph Lenthall and Sean Jauss of Mewburn Ellis, Jenny Harris of Kilburn and Strode and Alex Rogers of Haseltine Lake .

To book or for further details, please contact Maggi Churchouse (maggi@maggichurchouseevents.co.uk, tel: 01359 221004).

Licensing—A Practical Guide

This seminar will be held in the afternoon on **21 June 2012** at The Chemistry Centre, Burlington House, London.

This seminar will provide an overview of the licensing process, from the very beginning when projects are in their infancy to finalising licensing negotiations. It will include talks on how to decide on which projects are suitable for licensing and how to go about finding a potential licensee. The seminar will also cover the considerations when negotiating a licence, the various types of licence, and the key clauses that should be included. The seminar will also include case studies on successfully licensed projects.

This seminar would be of interest to any company or organisation who is considering licensing their technology. The attendees should come away with a good idea of the key questions to ask when getting involved in licensing. It will be suitable for researchers or technology managers, and no legal knowledge will be expected.

The speakers will include legally qualified professionals and licensing executives who have considerable experience in technology licensing.

Further details will follow soon.

To book or for further details, please contact Maggi Churchouse (maggi@maggichurchouseevents.co.uk, tel: 01359 221004).

Are gene sequences capable of Industrial Application?

In its first decision in a patent case, the UK's new Supreme Court (formerly the House of Lords) has handed down its judgement in the case *Eli Lilly v HGS,* overturning the decision of the lower courts that the patent in question lacked industrial applicability.

The Patent

Human Genome Sciences (HGS) had a European patent containing claims to the nucleotide sequence of the gene which encodes for the protein Neutrokine-α.

At the time of filing the patent application, Neutrokine-α had been identified as a member of the TNF (Tumour Necrosis Factor) superfamily of proteins. Though displaying some diverse functions, members of this superfamily were all known to be involved in the immune system. Other than this, the patent application simply listed a large number of speculative uses for the protein.

Background to the case

Eli Lilly opposed the patent, bringing parallel proceedings at the European Patent Office (EPO) and in the UK courts. Among other things, they claimed that the patent fell foul of Articles 52 and 57 EPC which state that an invention cannot be patented unless it is *"capable of industrial application"*, and that this is true *"if it can be made or used in any kind of industry, including agriculture"*.

In Europe the patent was initially revoked, but this decision was overturned on appeal. It was considered that a person skilled in the art would, in the light of common general knowledge of the TNF superfamily and its properties, appreciate that Neutrokine-α would be involved in the immune system, and that this was sufficient to satisfy the requirement of industrial applicability.

In the UK courts, the patent was initially revoked, a decision which was upheld by the Court of Appeal. HGS then appealed to the Supreme Court.

In their arguments, Eli Lilly stated that membership of the TNF superfamily did not in itself provide any useful information about Neutrokine-α, and that no data had been provided to demonstrate that Neutrokine-α was involved in the immune system. On the other side, HGS argued that the predictions made in the patent were reasonable, and that subsequent research has shown Neutrokine-α to play an important role in the development of auto-immune diseases and B -cell cancers.

The BioIndustry Association (BIA) also submitted comments to the court pointing out that, after a gene has been discovered, it takes considerable research, time and investment to transform the discovery into a commercially exploitable product. Intellectual property is a key way of attracting investment, and making it more difficult to obtain patent protection for new discoveries would risk slowing early stage investment in the bioscience sector.

The Decision

As it was a European patent in issue, the Supreme Court looked to the corresponding European case and the principles of the European Patent Convention for guidance. In doing so, they summarised the following guidelines:

- The patent in question must demonstrate a real possibility of commercial exploitation; merely identifying the structure of a protein without indicating any practical use is not sufficient.
- A "plausible" or "reasonably credible" claimed use, or an "educated guess" can suffice. Such plausibility can be assisted by later evidence (though such evidence on its own is not enough).
- If all known members of a family or superfamily have a common role, assigning a similar role to the protein may be sufficient.

Though the patent itself simply contained speculation as to potential uses of Neutrokine-α, the Court considered that the protein had nevertheless been plausibly identified as a member of the TNF superfamily. That family had known functionality, and the fact that further work was required in order to determine the therapeutic benefits of Neutrokine-α did not in itself render the patent invalid. This "plausible" use was enough to satisfy the requirements of Article 57 EPC.

(cont.)

Are gene sequences capable of Industrial Application (cont.)?

In considering the issues raised by BIA, Lord Neuberger stated that: "*Just as it would be undesirable to let someone have a monopoly over a particular biological molecule too early, because it risks closing down competition, so it would be wrong to set the hurdle for patentability too high".*

What Next?

The case will now be returned to the Court of Appeal to deal with the remaining issues of obviousness and insufficiency.

Effect of the Decision

This decision has brought the UK courts into closer alignment with the EPO, providing greater legal certainty for those seeking to protect their discoveries. This decision means that, though there may be gene sequence patents which do not meet the requirements for industrial applicability, it will not be the default position that a claim to a newly discovered sequence will fall foul of this requirement. As this is the first case of a bioinformatics gene sequence patent being litigated in the UK, it sets a strong precedent for future rulings.

The bioscience sector can therefore breathe a collective sigh of relief. For legal practitioners, the case is also of interest because of the manner in which the judges were clearly influenced by policy considerations, and their evident misgivings in doing so.

In his leading Judgement, Lord Neuberger clearly paid heed to the desirability of achieving harmonisation between the case law of the EPO's Boards of Appeal and the UK courts, and to the submissions of the BIA. He found in favour of the appellant, but commented *"there is good sense in the contrary conclusion reached by the judge [at first instance] and the Court of Appeal"*. Lord Walker agreed with Lord Hope that *"this is a difficult and troublesome case"*, but also noted that it is *"an important case: not only for the parties, but also for the bioscience industry generally … and, in some measure, for the future course of patent law in the United Kingdom"*. He went on to say that *"all my instincts … are for dismissing this appeal"* but he was nonetheless persuaded *"against my inclination, that this appeal must be allowed"*.

Katherine Wright (Senior Patent Assistant) and Steve Jones (MD/Principal Patent Attorney) of Adamson Jones, Nottingham.

Expert Witnesses: Jones v Kaney

In March 2011, it was held by the Supreme Court, that a client may sue their own expert witness for negligence.

The case involved an expert clinical psychologist who had given an opinion that a claimant, for whom she was acting, was suffering from post-traumatic stress disorder, after a road traffic accident. However, the defendant's expert disagreed, and both experts were ordered to discuss the case. The defendant's expert then prepared a report, which stated that the claimant was exaggerating and this was signed by the claimant's expert, without amendment. The case was settled for a relatively small sum.

The claimant's expert later claimed that she had signed a statement, which she did not agree with, and the claimant then sued her, stating that the case could have been settled for more, if his expert had not negligently signed the joint statement. At first instance the claim had been held inadmissible in accordance with accepted precedent that experts are immune from liability, but the Supreme Court decided to change the law, thus making negligent expert witnesses liable to their clients.

The repercussions from *Jones v Kaney* have yet to filter through. The main issues with this case are believed to be the additional costs of insurance, vexatious litigation and issues related to single joint experts.

Richard Toon.

A TRIO OF CHEMICAL EPO BOARD OF APPEAL CASES

Clinical Trials Sink European Patent: EPO maintains broad interpretation of "made available to the public"

A Technical Board of Appeal of the European Patent Office (EPO) has issued a decision (T0007/07) revoking a European Patent because, in this case, the distribution of contraceptive pills during clinical trials destroys the novelty of the patent. The trials were conducted before the earliest filing date of the patent in suit.

Background

For a European patent application to be granted, it must be novel. In other words, the invention must not have been made available to the public before the earliest effective filing date of the application (Art. 54 EPC). The requirement is interpreted broadly by the EPO and an invention can be made publicly available, for example, by the sale or the distribution of a product (known as public prior use).

Enlarged Board of Appeal decision G1/92 deals with various aspects of public prior use. The decision established that the composition of a product forms part of the state of the art when the product is available to the public and can be analysed and reproduced by the skilled person, irrespective of whether or not particular reasons for analysing the product exist.

Patent in suit

The patent of the present decision relates to an oral contraceptive composition containing drospirenone and ethinylestradiol, where the drospirenone is in a micronized form. Following litigation in the US, a public prior use argument was raised in the opposition procedure by the opponent based on clinical trials carried out before the earliest effective filing date of the patent.

The patentee admitted that the patients in the clinical trial had not signed a confidentiality agreement and the patients had been told the two active ingredients: drospirenone and ethinylestradiol. The contraceptive pills were taken home with the patients and not all of the pills had been used.

However, the patentee failed to convince the Board of Appeal that there was an implied secrecy agreement because it would be unethical for the patients to sign a confidentiality agreement. Further, the patentee failed to convince the Board that it would not be able to determine the micronized property of the drospirenone because of the small sample amount available to each patient.

Accordingly, the disclosure was found to invalidate the patent, which has been revoked. The case emphasises the importance of filing a patent application before distributing a product (even during clinical trials).

Extension State Intervention

This case also has an interesting procedural point with respect to third party intervention at EPO opposition proceedings. Article 105 EPC states that a third party may intervene in opposition proceedings after the expiry of the opposition period if proceedings for infringement of the same patent have been instituted against the third party.

In this case, infringement proceedings were launched against a third party in Lithuania. However, Lithuania was only an "extension state" and not an EPC contracting state at the time of filing the patent application. The Board clarified that extension procedure generates legal effects exclusively under Lithuanian national law.

As a result, the infringement proceedings are based on a patent granted for a number of EPC contracting states that also has effects in Lithuania under Lithuanian law. In other words, the proceedings were not in fact brought against "the same patent" as referred to in Article 105 EPC.

As a result, the intervention could not be based on the infringement proceedings in Lithuania. This confirms the recent decision in T 1196/08.

Joseph Lenthall

A TRIO OF CHEMICAL EPO BOARD OF APPEAL CASE (cont.)

Use of Contraceptive Composition May Be Excluded from Patentability at EPO as a Method of Treatment by Therapy.

Continuing the theme of contraception, the EPO Board of Appeal issued a decision (T 1635/09) stating that use of a contraceptive oral dosage may be considered a method of treatment by therapy. Accordingly, such a claim may be excluded from patentability under Article 53(c) EPC.

Previous EPO case law established that pregnancy is not an illness and so the use of contraception is not considered a method of therapy (T820/92).

However, the patent in suit claimed use of a contraceptive composition containing an oestragen and one of a list of six gestagens, both substances being at a very low dose in order to prevent or reduce unwanted secondary side effects, such as the risk of cardiovascular or thrombolytic complications.

The Board considered the technical effect of the claimed use to be treatment of the patient's side effects and therefore to be treatment by therapy. This excluded the use from patentability as a method of medical treatment.

This is an unusual decision. In the author's mind, at least, there is a conceptual difference between use of a drug to treat or alleviate symptoms of a disease and use of a drug that will not produce the same (or as severe) side effects as comparative drugs.

However, the decision indicates that the use of contraceptive compositions where the technical effect is to reduce side-effects will not be considered patentable at the EPO. The patent did contain composition claims limited to the use as a contraceptive. Such claims are in principle allowable at the EPO as second medical use claims. However, the second medical use claims were dismissed for clarity reasons.

Polymorph Screening is Routine Says EPO

The final EPO Board of Appeal decision relates to the inventiveness of pharmaceutical polymorphs (T777/08). The opposed patent claimed a particular crystalline form of atorvastatin hydrate and was defined by its X ray powder diffraction pattern.
The Appeal Board addressed the issue of whether this new crystalline form was inventive in light of the amorphous form of atorvastatin hydrate.

The patentee argued that it was well known that amorphous forms were generally more soluble and bioavailable compared to crystalline forms. Accordingly, the skilled person would not be motivated to depart from the amorphous form at the cost of these properties. In addition, the skilled person would not have predicted that the specifically claimed polymorph would show the properties of improved filterability and drying characteristics demonstrated. The improved properties made the polymorphic form more amenable to large scale processing.

However, the Board decided that screening for polymorphic forms of a drug substance was commonplace at the time of filing the application. The Board also recognised that crystalline forms were generally easier to handle and process. Accordingly, the Board found that the mere provision of a crystalline form, without overcoming any technical prejudice or providing any unexpected property, was not inventive.

The case has similarities to some recent UK court decisions on enantiomers (discussed at the RSC case-law seminar in November 2011). In particular, a claim to an enantiomer was held to be obvious over a disclosure of the racemate, because the resolution of the racemate was considered standard in Generics (UK) Ltd. v Novartis AG [2011]. However, a claim to an enantiomer was held to be inventive over the disclosure of a racemate in Generics v Lundbeck [2007]. In this case, the resolution of the enantiomer was only possible by an unusual route, and so the method of resolution provided an inventive step for the enantiomeric product.

Joseph Lenthall

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 2012.

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 RSC.

IP Snippets

Bayh-Dole Act (US)

The Supreme Court, in the case of the *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc*., (No. 09-1159) held that the University and Small Business Patent Procedures Act of 1980 (the "Bayh-Dole" Act) does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions.

Source: www.mondaq.com

Personalised Medicine (US)

The court in the Federal Circuit's decision in *Assoc. for Mol. Pathology v. USPTO* (2010-1406) (the Myriad Decision) confirmed that isolated DNA molecules are patent-eligible subject matter, as they, "have a distinctive chemical identity and nature-from molecules that exist in nature.

Source: www.mondaq.com

Inequitable conduct (US)

The Court of Appeals for the Federal Circuit issued a ruling in *Therasense* and revised the materiality prong of the inequitable conduct defence. Where an applicant has failed to disclose prior art to the USPTO, the trial court will be required to determine whether the undisclosed art meets a, "but for" materiality test.' This requires that the USPTO would not have allowed a patent claim if it had been aware of the undisclosed prior art.

Source: www.mondaq.com

Richard Toon

The Law Group's current committee has the following members:

Chair — Stuart Jackson, solicitor at Kempner Robinson (jackson@kempnerandpartners.com)

Immediate Past Chair — Dr. Don Lewis, US patent attorney at the Californian firm, Lewis Kohn & Fitzwilliam (dlewis@lewiskohn.com)

Secretary — Graham Burnett-Hall, solicitor at Marks & Clerk Solicitors (gburnett-hall@marks-clerk.com)

Treasurer — Dr. Tony Chalk, patent attorney at Harrison Goddard Foote (tchalk@hgfip.com)

Programme Chair — Alex Rogers, patent attorney at Haseltine Lake (arogers@haseltinelake.com)

Publicity Chair, Dr. Richard Toon, University Enterprise Business Manager (rctoon@hotmail.com)

General members:

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