RSC | Advancing the Chemical Sciences

RSC Law Group Newsletter

Issue 6

April 2011

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Message from the Editor

Dear members,

As a result of our AGM in 2010, and our first teleconference of this year, I can announce that we have three new committee members. They are:

Joseph Lenthall
Leythem Wall
Jenny Harris

The law group would like to welcome these new members to the committee. I have detailed their profiles on pages 2-3.

Unfortunately, we have also lost two of our committee members: Michael Edenborough and Jeanette Mole. The law group would like to thank Michael and Jeannette for their valuable contributions and we hope to see them at our future meetings.

In addition, Don Lewis has become the group's immediate past chair. The group would also like to thank Don for his continued support and enthusiasm towards the law group. The positions within the group have been voted in as follows:

Chair: Stuart Jackson
Immediate past chair: Don Lewis
Secretary: Graham Burnett-Hall
Treasurer: Tony Chalk
Programme Chair: Alex Rogers.
Publicity Chair: Richard Toon.

I hope to see you all at our events in 2011.

Richard Toon.

Case Law Seminar—November 2010

Recent Chemistry Case Law-Patents

The RSC Law Committee held another seminar on updates in case law, at Burlington House. This has become an annual event, which will help all of us to keep up to date in this fluid field.

The seminar focused on recent, high profile case law developments in the UK, Europe and the US, relevant to the field of chemistry.

Speakers included:

Graham Burnett-Hall
Stuart Jackson
Alex Rogers
Jonathan Couchman
Howard Rosenberg
David Rose
Don Lewis.

The seminar had a high attendance and generated some interesting discussions

Another case law seminar may be held towards the end of 2011.

Richard Toon

Seminars for 2011

Indian Patent Enforcement in the Chemical Arts: 26th September 2011.

Don Lewis is organizing an event, which will discuss the aspects of patent enforcement in India.

Case Law Seminar. 29 November, 2011. Burlington House, London

After the popularity of this event in the past two years, the Law Group will be holding another seminar on recent patent case law relevant to the chemical and pharma fields. It will look at developments over the past year in the UK, Europe and the US. Speakers will include: Joseph Lenthall, Graham Burnett-Hall, Stuart Jackson, Jennifer Harris, Leythem Wall and Don Lewis, all members of the Law Group Committee - see back pages for details. This seminar is being organised by Alex Rogers.

AGM, 29th November 2011, Burlington House, London

Another date for your diaries - the Law group's AGM will be held immediately before the Case Law Seminar. If you want to have your say about how we have been doing and our future direction, please come along. More details will follow in due course.

Richard Toon

Law Group on LinkedIn!

Just a reminder to our readers that the Law Group has set up a group on LinkedIn, simply titled the "Royal Society of Chemistry Law Group".

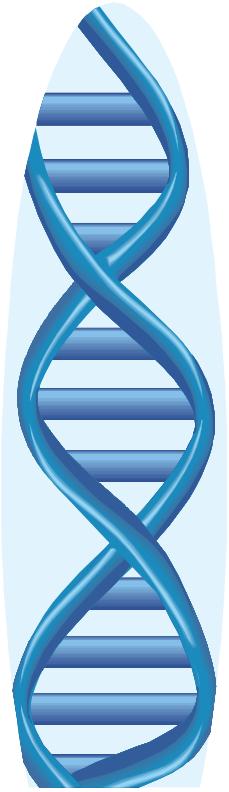
Membership of the LinkedIn group is entirely optional and all newsletters and other Law Group communications to members will continue to be sent by email. Nevertheless, if you wish to discuss a topic or ask general questions on legal matters, this LinkedIn Group will be an ideal forum.

Profile of new members, 2011

Jennifer Harris

Jennifer gained a Double Honours degree in Chemistry and Biochemistry from the University of Southampton, and during the course of her degree spent time gaining practical experience in the areas of medicinal and combinatorial chemistry at BioFocus. Since 2001 she has been working in the patent profession, qualifying as both a UK and European Patent Attorney in 2005 and working with Kilburn & Strode LLP since 2006. Jennifer's practice focuses on the drafting and prosecution of patent applications before the EPO, UKIPO and worldwide, representing clients in hearings at the EPO and providing infringement and validity opinions. She works with companies ranging from start-ups and university technology transfer offices to multinational companies. Her work has a particular emphasis on pharmaceuticals, but she also works in many diverse areas of chemistry, including glass, ceramic and composite material technology and process chemistry.

Profile of new members, 2011 (continued)



Dr Joseph Lenthall MRSC

Joseph gained a Chemistry degree from Durham University. During and after his degree, Joseph gained experience of IP law by working for the technology transfer offices of Oxford University and the Medical Research Council. Joseph returned to Durham University to complete a Ph.D. working on selective recovery of platinum group metal catalysts from mixed metal solutions (sponsored by BP Chemicals). Joseph is now a UK patent attorney at the firm Mewburn Ellis LLP. Joseph works on the drafting and prosecution of UK and European patent applications, with an emphasis on pharmaceuticals and polymers.

Leythem Wall

Leythem read Chemistry at The Queen's College, Oxford University, which involved a final year working for Professor Peter Edwards FRS, investigating the dielectric catastrophe in high temperature superconducting systems. His interest in the Law and Chemistry first arose during his gap year, before entering University, when working in Eli Lilly's research and analytical laboratories, the patent on prozac expired. Following University, he entered the patent profession training in the Biotechnology and Chemical departments of a private practice of Patent and Trademark attorneys in central London. During this time, he gained his Postgraduate Diploma in Intellectual Property Law from Queen Mary's University of London. Leythem is a UK and European patent attorney, a European trademark attorney and works for ExxonMobil Chemical Europe as in-house Intellectual Property counsel based in Brussels, Belgium.

Patenting Medical Inventions at the EPO – A Review of 2010

Rather than bringing breaking news at the start of a new year, this is an opportunity to sum up two key EPO Enlarged Board of Appeal decisions relating to the patenting of medical inventions and their potential impact on pharmaceutical patenting in Europe.

The European patent system seeks to prevent patents hindering the legitimate activities of medical practitioners, by excluding methods of treatment of the human or animal body by therapy or surgery from patentability. Medical use claims enable innovators to seek patent protection for medical inventions without falling foul of this exclusion.

For many years, 'Swiss-style' medical use claims have been used to protect the medical use of a substance. The claims take the following format: 'Use of product X in the manufacture of a medicament for the treatment of disease Y'. The implementation of current European law (EPC 2000) initiated a shift away from this type of claim by providing statutory basis for a simpler format of medical use claim, i.e. 'Product X for use in treating disease Y'. Article 54(5) EPC 2000 provides that a substance for any specific use in a method of treatment by surgery or therapy may be patented, if the medical use is not known.

The first key decision, G2/08, concerns the issue of patentability of dosage regimes, but is more broadly applicable. G2/08 concerned a drug already known to treat a certain disease, with the only distinction from the prior art being a new dosage regime. Before G2/08 there had been conflicting EPO case law as to whether a new dosage regime can give rise to a patentable invention. In a ruling that is likely to provide opportunities for extending patent protection in respect of pharmaceuticals, G2/08 clarified that the 'any specific use' of Article 54(5) EPC 2000 should not be limited only to new diseases. Accordingly, a dosage regime can be a specific use capable of giving rise to a patentable invention. Of course, it should be remembered that all other patentability requirements of the EPC must be met and the EPO has emphasised that new medical uses must give rise to a genuinely new and inventive technical teaching.

The logic of G2/08 applies not only to dosage regimes, but also to other specific uses such as treatment of patient sub-populations and drug administration routes. Thus, G2/08 may leave open many avenues for extending patent protection for pharmaceuticals.

G2/08 also looked at medical use claims more generally, ruling that Swiss-style claims will no longer be allowable under the EPC. The decision has no retroactive effect, but European patent applications with a filing or earliest priority date of 29 January 2011 or later will not be granted if they contain Swiss-style claims. Swiss-style claims are, however, still a recognised and accepted claim format in many other countries, so should still be included in patent applications intended for multiple jurisdictions.

The second key decision, G1/07, addresses the exclusion from patentability of methods of treatment by surgery and considers the extent to which methods which involve an invasive intervention on the body are excluded from patentability. Rather than providing clear cut boundaries, G1/07 sets out guidance on how the surgical methods exclusion is to be applied on a case-by-case basis by the EPO.

G1/07 involved an MRI method including a step of injecting a contrast agent directly into the heart. The question posed, in essence, was whether an intervention step on the body caused a method to be excluded even if the step itself was not aimed at maintaining life and health. Previous EPO case law conflicted on whether it is the nature or the purpose of the intervention step that determines if a method is excluded.

G1/07 rules that it is the nature of a physical intervention that determines if a method is excluded from patentability. Thus, if an intervention step is 'surgical' the method comprising the step will be excluded from patentability, irrespective of the purpose of the intervention step. G1/07 does, however, recognise that methods involving only a minor intervention with no substantial health risks may not be excluded.

Patenting Medical Inventions at the EPO – A Review of 2010 (cont.)

Room has been left open for interpretation on a case-by-case basis as to what constitutes a 'surgical' intervention and more case law on this issue is likely to arise.

Overall, G2/08 and G1/07 represent welcome clarification on exclusions from patentability for medical inventions and G2/08, in particular, is welcome news for applicants seeking to maximise patent protection for pharmaceutical products.

Jennifer Harris.

Generics & Paragraph IV Certifications.

The Food and Drug Administration (FDA) controls the drug approval process in the USA. Manufacturers provide the data in a New Drug Application (NDA) which includes all of the scientific and clinical data.

If approved, the drug will have two forms of market protection. Data Exclusivity which precludes the FDA from approving a generic drug application for that product until the exclusivity period expires and also Patent Protection. The NDA holder can apply to the FDA to list relevant patents against its product in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book.

When a generic company wants to sell its generic version of a branded product, it usually does so through an Abbreviated New Drug Application (ANDA). When it files an ANDA, it must show that it meets certain bioequivalence standards and must certify against any listed patents.
In 1984, Congress passed The Drug Price Competition and Patent Term Restoration Act that came to be known as the "Hatch-Waxman Act." The Hatch-Waxman rules created processes and incentives for both branded and generic companies but involved challenges to patents.

For a generic company to file an Abbreviated New Drug Application (ANDA) it must also certify against all the patents listed in the Orange Book for that particular product. The certification must state that either (a) FDA should approve of its generic version after the date the last patent expires (a "Paragraph III" filing) or (b) that its generic product does not infringe on the listed patents or that those patents are not enforceable (called a Paragraph IV filing).

If the generic company files an ANDA with a Paragraph IV certification, then the branded company is notified. After the notice, the branded company has 45 days to file a patent infringement action against the generic company. After the suit has been filed, the FDA cannot approve of the application until the generic company successfully defends the suit or until 30 months, whichever comes first.

If a generic company is the first to file its Abbreviated New Drug Application (ANDA) with a Paragraph IV certification and prevails in the subsequent lawsuit, that generic company is granted a period of market exclusivity of 180 days.

The 180-day exclusivity incentive can be significant for a generic company as it could be the only generic version on the market. (see http://www.paragraphfour.com/explained.html)

Over the years, litigation highlighted many aspects of the system that were unclear or unfair… such as multiple 30 month stays; the first to filer not launching their drug, thus blocking the market; litigation/arguments with FDA as to who was in fact the first to file; and legal attempts by later filers to upset the first to filer's 180 day exclusivity etc.

Generics & Paragraph IV Certifications (continued)

The FDA makes it very clear that it does not get involved with patent issues and leaves that to the courts.

As an attempt to solve these problems another act was introduced, the MMA act, to update the Hatch-Waxman Act. It introduced, for example, a Forfeiture clause to stop a first to filer blocking subsequent filers from getting their generic products onto the market.

Forfeiture Events

(I)Failure to Market
(II)Withdrawal of Application
(III)Amendment of Certification
(IV)Failure to Obtain Tentative Approval Within 30 Months.
(V)Agreement With Another Applicant, the Listed Drug Application Holder, or a Patent Owner
(VI)Expiration of All Patents

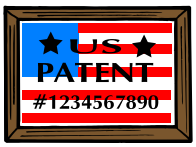
Of these the first clause is rather complex in format but of key importance in paragraph IV planning and litigation.

(I) Failure to Market

The first applicant fails to market the drug by later of
(aa) the earlier of
(AA) 75 days after final approval; or
(BB) 30 months after ANDA submission;
Or
(bb) The date that is 75 days after the date as of which, as to each of the patents that qualified the first filer for exclusivity, at least one of the following has occurred:
(AA) Final decision of invalidity or noninfringement.
(BB) Settlement order entering final judgment.
(CC) NDA holder delists patent from Orange Book.

The FDA also attempted to resolve some problems that it had which has resulted in the word 'exclusivity' being redefined! Originally a successful first to filer obtained 180 days marketing exclusivity over its rival generics. However, the FDA changed its rule for working out who was first to file from being the first to physically register their file with the FDA based on a time stamp, to everybody who correctly filed any time on the earliest legally acceptable day. As a consequence for many drugs there are multiple first filers all of whom are potentially able to garner 180 days marketing 'exclusivity'. So if several generic companies file on the same day and all get approved, without forfeiture, they all have the same 180 day 'exclusivity'!

Howard Rosenberg



IP Snippets

(US) Are contact lists trade secrets?

A recent recommendation that a head-hunter's lists were not a protectable trade secret has been approved by a District Judge. The reasoning was around the readily available nature of the list on social networking sites. *Sasqua Group, Inc. et al. v. Lori Courtney et al., 2010 U.S. Dist. LEXIS 93442 (Aug. 2, 2010).*

Source: www.mondaq.com

(UK) Cookie Consent

There has been an amendment to the E-Privacy Directive (2002/58/EC) on the use of cookies and consent. The revised Directive now requires an opt-in system, where the user concerned has given consent.
Source: www.mondaq.com

(UK) Battle of the Budweisers (acquiescence)

An opinion has been made in the trademark Case 482/09 on a reference from the English court of Appeal. The 5 year acquiescence period was deemed to run from the later of the dates when the later mark became registered.
Source: www.mondaq.com

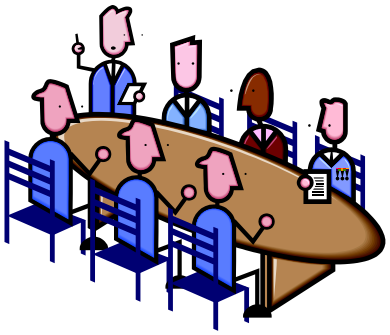
Any minor bits of information, which members would like to share, would be welcome.

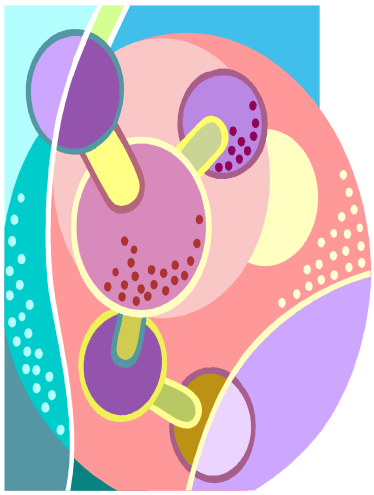
Richard Toon

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 (see above for contact details). We aim to send the next issue out in summer 2011.

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.

Attendance at the Midlands Regional Meeting

Richard Toon attended the above meeting at the Crowne Plaza Hotel, Birmingham, on the 3rd February, on behalf of the law group. This was a good networking meeting for the local subgroups and I am pleased to say that there was some interest in the role of the law group. I hope to consolidate this interest during future meetings. We had a presentation on the direction of the RSC and a general debate on numerous issues raised by the attendees.

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:

Dr. Howard Rosenberg, Scientific Advisor, Frommer, Lawrence and Haug, LLP (hrosenberg@flhlaw.com)

Jennifer Harris, patent attorney at Kilburn & Strode LLP, jharris@kstrode.co.uk

Dr. Joseph Lenthall, patent attorney at Mewburn Ellis LLP, Joseph.Lenthall@mewburn.com

Leythem Wall, patent attorney, leythem.wall@hotmail.co.uk