RSC | Advancing the Chemical Sciences

RSC Law Group Newsletter

Issue 7

October 2011

Message from the Editor

Dear members,

This is the second newsletter of the year. I would like to take this opportunity to promote the final event which we have planned for this year, an update on case law on November 29th, at Burlington House. This has become an annual fixture in the group's diary and provides an excellent update. The group also recently held a seminar on Indian patent enforcement.

We have a number of exciting seminars lined up for next year and more will be reported in due course.

Our new members on the committee have already been proactively involved in areas such as speaking and authoring articles for the newsletter.

May I also take this opportunity to remind our readership that articles and comments are most welcome.

I hope to see many of you at our update in case law seminar in November. *Richard Toon.*

Indian Patent Seminar—September 2011

The RSC Law Committee held a symposium on "Indian Patent Enforcement in the Chemical Arts", on September the 26th, at the Law Society Common Room in London. This was chaired by Don Lewis and focused on the evolving patent landscape in India. It featured an impressive list of speakers, including three Indian IP practitioners (Elizabeth Varkey, author and advocate, Kerala High Court, Bhaskar Bhattacharya, head, IP Due Diligence and Litigation Practice, Corporate Law Group, New Delhi, and Manoj Pillai, Partner, Lex Orbis IP Practice, New Delhi), two IP practitioners from the pharmaceutical arena (Balaram Gupta, VP DRL Patent Estate, Dr. Reddy's Laboratories Inc, and Gurmeet Kaur Sidhu, Senior Patent Litigation Council, Sandoz International), and one UK academic (Matt Fisher, Senior Lecturer, UCL Laws). Slide decks from speakers who have consented are posted on our website.

In summary, the speakers unanimously agreed that the policy changes encompassed by India's Patents (Amendment) Act 2005 had been radical. There was also a consensus that Indian IP policy will have a significant global impact on the future development of chemistry. However, the speakers provided diverse views as to how best to conform with the legislation, particularly in view of its evolving judicial interpretation. The session culminated with a lively and extended panel discussion.

Don Lewis.

Inside this issue:

Seminars for 2011

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

Owing to the popularity of this event over the past two years, the Law Group will be holding another seminar on recent patent case law relevant to the chemical and pharmaceutical 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 are members of the Law Group Committee - see back pages for details. This seminar is being chaired by Alex Rogers.

For further details, please e-mail Maggi Churchouse (maggi@maggichurchouseevents.co.uk) or see www.rsc.org/law.

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 are performing, and our future direction, please come along. More details will follow in due course.

A review of the Government's Response to the Hargreaves Review of Intellectual Property and Growth.

The Government's response to the Hargreaves Review can be summarised as follows:

- The major challenge of today has been identified as digital copying.

- The Government believes that a Digital Copyright Exchange (DCE) has the potential to offer a more efficient market-place for owners and purchasers of rights. The Government is considering how to facilitate its creation.

- The Government has welcomed the European Commission's initiative in proposing a cross-border licensing framework and will help develop such proposals.

- Proposals for an orphan works scheme, that allows both commercial and cultural uses of orphan works, which protects both owners and rights holders

- The Government will bring forward proposals for extended collective licensing.

- Design Rights may be included in the DCE.

- Proposals will be put forward for a substantial opening of the UK's copyright exceptions regime.

- The Government will resist extensions of patents into sectors which are currently excluded, unless there is clear evidence of a benefit to innovation and growth.

- Publication of a cross-government IP Crime Strategy .

- Establishing the value for money case; the introduction of a small claims track in the Patents County Court for cases worth £5000 or less as issue.

- Consideration will be given in renaming the Patents County Court as the Intellectual Property County Court.

The Government will consider the next steps, over the following months, and will set out plans, in a White Paper, in Spring 2012.

Richard Toon

EPO Rules on Disclaimers in G2/10

The EPO's Enlarged Board of Appeal has given its decision on whether or not amending a claim to disclaim (i.e. to exclude subject-matter by a negative limitation) an embodiment of the invention given in the original application adds subject-matter according to Article 123(2) EPC.

The EPO examining division refused a patent application claiming a general class of enzymatic molecules for cleaving nucleotide sequences. A number of enzymatic molecules are described in the application, including a prototype motif that was specific for a particular nucleotide sequence substrate.

However, the prototype motif was made public before the filing date of the application, and so the applicant introduced a disclaimer into the claims (a negative limitation) to exclude the prototype from the scope of the claims and gain novelty over the earlier disclosure.

The examining division followed an EPO Board of Appeal decision (T1050/99), which considered that an embodiment in the application "is present as part of the invention, not as an area to be excluded". Accordingly, such a disclaimer is a so-called "undisclosed disclaimer" and the criteria set out in the EPO's Enlarged Board of Appeal decisions G1/03 and G2/03 apply.

According to G1/03 and G2/03, where a disclaimer is not disclosed in the application as originally filed, the disclaimer could nevertheless comply with Article 123(2) EPC if the disclaimer:

- restores novelty over subject-matter that was in an earlier filed European patent application published after the filing date of the present application;
- restores novelty over subject-matter that is an "accidental anticipation"; or
- disclaims subject-matter which is excluded from patentability for non-technical reasons, such as methods of medical treatment.

As the present disclaimer did not fall under any of the situations described in G1/03 and G2/03, the claim was refused. On appeal, the Board of Appeal was in general agreement with the examining division. However, the Board referred the following question to the Enlarged Board of Appeal:

"Does a disclaimer infringe Article 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed?"

In its decision, the Enlarged Board considered that the criteria of G1/03 only apply to disclaimers where both the negative limitation (i.e. the disclaimer) and the excluded subject-matter were not disclosed in the application as filed. Accordingly, the criteria do not apply to the disclaimers of this referral.

The Board considered that the disclaimers that excluded subject-matter disclosed as part of the invention in the original application do not necessarily add subject-matter. The Board stated that the allowability of such disclaimers should be assessed using the established added subject-matter criteria, for example as set out in the Board's decisions G3/89 and G11/91.

So, such disclaimers may be allowed at the EPO, and their allowability assessed on whether or not the skilled person would, using common general knowledge, *regard the remaining claimed subject-matter* as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed [emphasis added].

Joseph will be talking about the decision and its implications at the RSC Law Group's annual IP case-law seminar on 29 November 2011.

Joseph Lenthall

Great Danes! CJEU Rules on Referral on Repackaging of Pharmaceutical Parallel Imports

The Court of Justice of the European Union (CJEU) has handed down a preliminary ruling from a referral from the Danish Supreme Court regarding the repackaging of pharmaceutical parallel imports in joined cases C-400/09 and C-207/10.

In C-400/09, Merck made medicinal products under a trade mark name, which were imported in parallel on to the Danish market by the Orifarm group, Orifarm and another company, Handelsselskabet. These companies held the authorisations to market and sell those medicinal products. Two additional companies in the Orifarm group, Orifarm Supply and Ompakningsselskabet, carried out the repackaging and held authorisations to do so.

The packaging of the products indicated that they had been repackaged by either Orifarm or Handelsselskabet (as appropriate). In other words, the packaging had Merck's original trade mark and indicated that the repackaging was performed by the importer and not the actual repackager.

Parallel importation within in the EU of goods carrying a trade mark is allowed under the principle of "exhaustion of rights". The principle sets out that the proprietor of a trade mark cannot stop use of the trade mark on goods once those goods are placed on the market in the EC by the proprietor (or with their consent).

However, Article 7(2) of Directive 89/104 states that exhaustion of rights "shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market"

Under settled case-law, the proprietor of a trade mark may not legitimately oppose the further marketing of a pharmaceutical product bearing his trade mark which has been repackaged by an importer who has reaffixed the mark if (amongst other conditions):

> the new packaging clearly indicates the *repackager* of the product and the name of the manufacturer [emphasis added].

Merck sued Orifarm, Handelsselskabet and Ompakningsselskabet, on the ground that the name of the actual repackager did not appear on the packaging of the products. The Danish Supreme court referred a number of questions to the CJEU after the court of first instance decided that the defendants had infringed Merck's trade mark rights by failing to indicate on the packaging the name of the undertaking which had actually performed the repackaging. The circumstances in case C-207/10 were essentially the same, and the Danish Supreme court referred further questions to the CJEU for a preliminary ruling.

The CJEU replied rather more succinctly by ruling that the proprietor may not oppose the further marketing of a pharmaceutical product in repackaged form on the sole ground that "the new packaging indicates as the repackager not the undertaking which, on instructions, actually repackaged the product and holds an authorisation to do so, but the undertaking which holds the marketing authorisation for the product, on whose instructions the repackaging was carried out, and which assumes liability for the repackaging."

Joseph Lenthall

Baby Steps Towards a Unitary European Patent, but Italy and Spain Still Throwing their Toys out of the Pram.

A single unitary European patent, along with a European Patent Court, has been an objective for the European Union for many years. Such a system would significantly reduce the costs of obtaining patent protection across Europe, because the costs associated with "validating" a European patent application in each country are greatly reduced. European patent applications would still be examined and granted by the European Patent Office.

The biggest hurdle to the formation of such a unified patent system is language, and some countries have stalled the process significantly. In order to progress proceedings, several EU countries have entered into an "enhanced cooperation procedure". The enhanced cooperation procedure allows new legislation to be created despite opposition from some countries. As a result, all EU states, except Spain and Italy, will participate in the enhanced cooperation procedure in order to progress plans for the European patent.

Recently, the EU Competitiveness Council (made up of ministers from each State) was in general agreement about the creation of a unitary patent system under the enhanced cooperation procedure. This marks another important, albeit small, step along the road to achieving a unitary patent system. However, there are still many hurdles to overcome before a unitary patent is a reality. For example, the proposals will go before MEPs in the European parliament and the CJEU will consider the legality of a Unified Patent Court.

Meanwhile, Italy and Spain have each launched legal proceedings with the CJEU, claiming that the enhanced cooperation procedure is discriminatory under EU law. The grounds put forward by each country differ in some aspects, and so the cases will probably not be considered together, resulting in a slow-down of the enhanced cooperation procedure.

Joseph Lenthall.

SPCs – The Definite Article?

In a recent opinion of the EU Advocate General, the UK Courts' interpretation of part of the Supplementary Protection Certificate (SPC) Regulation has been questioned. If the opinion is followed by the ECJ, and the UK Courts' interpretation is overruled, it could lead to a greater likelihood of protecting combination products with SPCs, where only one of the active ingredients is covered by a patent. (Medeva BV v Comptroller General of Patents, C-322/10 and Georgetown University and others v Comptroller General of Patents, C-422/10, 13 July 2011.)

EU SPC law stands at the interface between pharmaceutical regulatory law and patent law.

The SPC Regulations were drafted as carefully as possible to try to take into account the different terminologies used in both spheres. However, occasionally, ambiguities arise for certain terms in the SPC regulations, which then must be interpreted by the national courts. Where the national courts consider a particular point of EU law to be unclear, they can ask the European Court of Justice for clarification. Before the ECJ rules, the EU's Advocate General will generally issue a non-binding opinion on the matter. This is indeed what has happened in the present case, and it is a sign of how the ECJ may ultimately rule. Here, the Advocate General looked carefully at the difference between the literal and teleological (i.e. purposive) interpretation of

SPCs – The Definite Article (cont.)?

certain terms in the SPC regulation and their consequences. The Advocate General came to the conclusion that the literal interpretation of these terms resulted in harsh consequences, and did not fit within the overall objectives of the Regulation.

Her view was that a teleological interpretation was far more appropriate and should be used to allow SPCs to be granted for a combination product, where only one of the active ingredients is covered by a patent. The Advocate General's opinion is not binding on the European Court of Justice, which will now consider the case and issue its judgment in due course, but such opinions have persuasive effect and are often followed. A little more explanation on the detail is given below.

SPCs provide an extension of a patent term for medicinal products that have been granted regulatory approval in the EU. There are a number of requirements to obtain an SPC. Two of these are that "the product is protected by a basic patent in force" and "a valid authorization to place the product on the market as a medicinal product has been granted". The SPC regulation recites that "a "product" means **the** active ingredient or combination of active ingredients of a medicinal product". The importance of this definite article is explained below.

Medeva is proprietor for a patent for a method of making whooping-cough vaccine. The patent was filed in 1990 but only granted in 2009. Regulatory approval had recently been granted and Medeva was trying to extend its protection beyond the normal 20-year term by applying for an SPC.

The actual product for which Medeva obtained regulatory approval was for a combination of vaccines for a variety of childhood diseases, but only one of these vaccines was the subject of the patent. Medeva had applied for an SPC, but this had been refused by the UK Intellectual Property Office, since it was deemed that the combination of vaccines, i.e. the "product", was not "protected by a basic patent in force". This follows earlier UK judgments that a patent directed to just one active ingredient could not be considered to be a "basic patent" for a combination of active ingredients. This in turn derives from the literal interpretation of "the active ingredient or combination of active ingredients" in the legislation. The Advocate General agreed that this interpretation was a correct literal one, but she realised that this limits significantly the protection that can be obtained for combination products, and questioned whether this fits within the aim of the regulation, i.e. to compensate patent owners with extra term of protection where regulatory approval has taken a long time. She considered whether a teleological interpretation should be applied so that "product" should cover not only 'the' active ingredient or 'the' combination of active ingredients, but also 'an' active ingredient or 'a' combination of active ingredients of a medicinal product. This would have the result that a basic patent for a single active ingredient could be considered the "basic patent" under the SPC regulation for a combination of this active ingredient with others.

The Advocate General's view was that a teleological interpretation of "product" was the correct one, and more consistent with the overall aim of the Regulation. We shall now have to wait to see if the ECJ follows this opinion. If so, it will open up more SPC protection in Europe for combination products.

The full Advocate General's opinion can be found here.

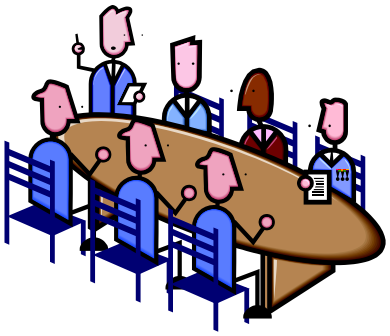
Alex Rogers

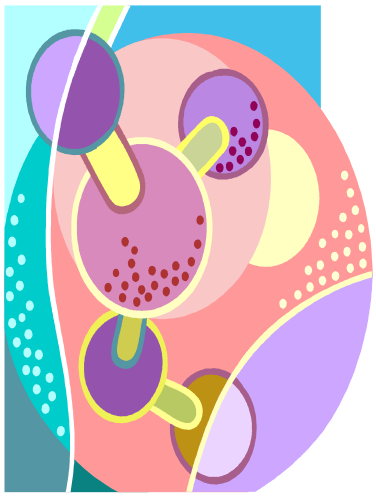
For more on the latest developments in SPCs, you are encouraged to attend the case law seminar in November (see page 2). Jennifer Harris, a partner at Kilburn and Strode, will give a talk about recent cases in this field.

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 early in 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

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)

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

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