

RSC LAW GROUP NEWSLETTER

May 2013

Message from the editor

Dear all,

This is the first newsletter of the year and provides an update on the activities over the last twelve months. The group organised three events last year. A seminar entitled, Basic IP for Researchers, was held on the 22nd May, 2012 and a seminar on Licensing: A practical guide, was held on the 21st June 2012. The final seminar, and an annual event for the law group, was an update in IP case law, held on the 29th November 2012, at Burlington House.

Other events throughout last year included representation at a special interest group meeting, held by the RSC's Industry and Technology Council. Graham Burnett-Hall represented the group and discussed issues to do with increasing interactions with the council and other interest groups. This is an important area for the group, to ensure that we are the first point of contact for professional legal development within the RSC.

Stuart Jackson, conducted a webinar on behalf of the law group entitled, "Making the most of your IP". Again, this is an important activity for the law group and adds a different and exciting dimension to our outreach activities. You can register and watch the seminar at http://chemistryworld.gav.co.uk/webcasts/event-detail/19/making-the-most-of-your-ip.html?utm_source=house-list&utm_medium=email&utm_campaign=mkt-ind-08-cw-webinar-13nov-fu

I aim to invite a guest article, for each newsletter, from individuals or companies, who may not be directly involved with our group, but share common interests. On behalf of the law group, I would like to thank Michael Pears and Mike Snodin for their contribution to this issue.

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

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Chemical Sciences

We would welcome any suggestions from our members.

Richard Toon

Forthcoming seminars

28th October 2013: "IP Enforcement around the World in the Chemical Arts"

Synopsis

In 2006, the RSC Law Group was launched with a symposium on IP Enforcement around the World. The late Sir Hugh Laddie served as keynote speaker at that symposium. The present symposium is a reprise of our inaugural symposium. The purpose of the symposium is to examine key differences in IP enforcement in the chemical arts in major jurisdictions around the world. Speakers at our 2013 symposium include pre-eminent IP litigators specializing in the chemical arts within major jurisdictions round the world, including China, Japan, India, North America, Australia, the UK, and continental Europe. Our keynote speaker, The Rt. Hon. Lord Justice Floyd, formerly Judge in charge of the Patents Court, has been requested to provide comments on his perspective of IP enforcement from a comparative law point of view. The symposium will be held at the RSC's offices at Burlington House and is being organised by Don Lewis, a California IP lawyer.

28th November 2013: "Recent Chemistry Case Law"

Synopsis

Our annual and highly popular seminar will focus on recent high profile patent law developments in the UK, Europe and the US in the field of chemistry and pharmaceuticals. The seminar will be held at the RSC's offices at Burlington House and will be chaired by Alex Rogers, Patent Attorney, Haseltine Lake LLP.

Guest Article

Even more protection for new uses of “old” actives

The Court of Justice of the European Union (CJEU) has delivered its hotly anticipated judgement in the *Neurim Pharmaceuticals* case (C-130/11) relating to Supplementary Protection Certificates (SPCs). The case considered the possibility of obtaining an SPC based on a marketing authorisation (MA) where there has been an earlier MA for the same product but for a different medical use.

The ruling significantly liberalises SPC practice by relaxing the bar somewhat on SPCs for previously authorised products. Just how low the bar has come, however, remains to be seen.

SPCs

SPCs are national rights in Europe that extend patent protection for medicinal, veterinary or plant protection products. Their aim is to compensate patentees for the years of patent term lost during lengthy regulatory approval processes that are necessary to get such products to market. The protection provided by SPCs is especially valuable since it can effectively block generic competition for up to five (or even five and a half) years beyond patent expiry.

Background to the case

Neurim had a European patent for using the natural hormone melatonin to treat insomnia (in humans). After applying for the patent in 1992, it took Neurim over 15 years to obtain an MA in 2007, when they marketed the product as Circadin®. With a patent and MA in hand, Neurim applied for an SPC for melatonin at the UK Intellectual Property Office (UKIPO).

The stumbling block for Neurim was the requirement in the SPC legislation that the MA for the product must be the ‘**first authorisation**’ to place that product on the market. This provision had previously been thought to mean that SPCs for second or further medical uses of known active ingredients were not allowed (or even if they were, they would have no positive term).

The UK Intellectual Property Office refused Neurim’s SPC on this ground, in view of an earlier MA for the use of melatonin in regulating reproduction in sheep. On appeal, the UK High Court agreed.

Neurim, however, argued that the ‘first authorisation’ should be a relevant MA that is covered by the patent, and that the earlier MA for use in sheep was therefore irrelevant as it was not covered by the patent.

Neurim’s position held more weight at the UK Court of Appeal who took the view that if Neurim could not secure an SPC for melatonin, the SPC system would “*not be fit for purpose*”. Accordingly, the CJEU was asked to clarify whether the existence of an earlier (veterinary authorisation) for the active ingredient melatonin precluded the grant (or determined the duration of) an SPC based on Neurim’s MA for the first human medicinal product containing melatonin.

The Decision

The CJEU ruled that the existence of earlier (veterinary) marketing authorisations should not prevent the grant of an SPC to Neurim. The Court concluded that a patent and new authorisation for a “different application” of an “old” active ingredient should lead to the grant of a new SPC.

The CJEU also decided that the term of Neurim’s SPC should be set by “*the marketing authorisation of a product that comes within the limits of protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate*”.

Commentary

The judgement appears good news for the innovative pharmaceutical industry as, for the first time, companies that provide valuable new treatments by finding new uses for “old” active ingredients may be entitled to an extended monopoly period for those treatments.

Although the decision clearly has a liberalising effect on the granting of SPCs, some issues do remain. The judgement is open to several different interpretations and the next months and years are likely to see the various national patent offices and courts working out which ones are correct.

For example, the CJEU answered the first question only in the context of there being an earlier authorisation for a **veterinary** medicinal product. It is not completely clear how the ruling should be applied in situations where there is an earlier authorisation for a human medicinal product. The CJEU's reasoning behind the decision, however, would suggest that the result should be no different.

Further, it is not certain what is meant by "different application". Plainly, a different application encompasses a new therapeutic indication (as in Neurim). Thus, where the patent protects a second medical use of a product, the 'first authorisation' is the first one for that therapeutic indication; earlier authorisations for different indications can be disregarded. However, a broader construction of the term would read onto any new application of a known active ingredient, for example in a new formulation.

Also, when addressing what the 'first authorisation' is for the purposes of calculating SPC term, the CJEU refers to an MA for the "product" that falls within the limits of protection of the patent, not the **application** of the product. This makes a difference because if the 'first authorisation' is just for the product *per se*, SPCs to new applications of a product will generally have little or no term. Arguably, the CJEU's intention was to determine SPC term based on the first MA for the new application, but this is not what the Court said.

Conclusion

Despite the uncertainty discussed above, a bar has been relaxed to open up the SPC system to those companies that obtain both patents and marketing authorisations for new therapeutic indications of at least some previously authorised active ingredients. Further, it is possible that the judgement could be applied in future to other medicinal products containing "old" active ingredients, such as reformulations.

Michael Pears (Associate) and Mike Snodin (Partner) of Potter Clarkson LLP, Nottingham.

European Unified Patent Court given the go-ahead

February 19th, 2013 marked a major milestone for the European patent, as almost all of the European Union member states signed an international agreement for the creation of the Unified Patent Court ("UPC"). It is no exaggeration to say that the UPC will be the greatest and most significant development of the European patent system for 40 years. This agreement, in conjunction with two EU regulations that were passed last December, will enable the European Patent Office to grant "unitary patents", that is, a single patent that covers every country that has signed up to the agreement, rather than, as is the current practice, granting a European patent that takes effect as a bundle of national patents, one for each jurisdiction. Assuming all the current signatories ratify the agreement, this means the unitary patent will span the whole of the European Union, save for Poland and Spain.

Eventually, the UPC will have exclusive jurisdiction over unitary patents, existing and future European patents that are in force in a participating member state (but which are not unitary) and supplementary protection certificates issued for a product protected by such patents. A decision from the UPC on infringement or validity – and associated injunctions – will then have effect Europe-wide, rather than just in a single country.

This will have a profound effect on disputes in the EU. Up to now, such disputes often involve multi-jurisdictional proceedings. Victory – or defeat – in one country in no way means the end of the war. Even though the alleged infringements and the patents concerned may be identical in every respect, there is the prospect of different courts in different jurisdictions coming to different conclusions. But a decision from the UPC will be binding across all participating jurisdictions – it will no longer be possible to start new proceedings in the courts of another country in the hope of getting a different result.

The UPC has a somewhat complicated structure, a consequence of the negotiations that preceded the political agreement. At first instance there will be a number of local and regional divisions, which will have primary responsibility for infringement proceedings. Importantly, there is also a central division, whose jurisdiction will include revocation proceedings, though revocation counterclaims

may be handled by the local/regional division seised with the related infringement proceedings. The central division will in fact be split between three locations: Paris, London and Munich. Allocation of cases will be by patent classification. For the lifesciences industry, London will be the key location, as the London section of the central division will be allocated all cases concerning chemistry (which encompasses pharma and biotech), metallurgy and "human necessities". Patents concerning mechanical engineering and weapons will go to Munich. Almost all others, e.g. telecoms patents, will go to Paris. A further important feature of proceedings in the central division is that, regardless of location, the default language of the proceedings is the language of the patent. For the vast majority of patents, this means English.

Ultimately the unitary patent and UPC should indeed bring greater certainty for litigants and the possibility of resolving disputes through one set of proceedings, rather than many, should reduce litigation costs. In the short term there may in fact be greater uncertainty, as the new court gets up to speed and litigants explore and learn the approaches taken by the various local, regional and central divisions to the exercise of their new powers. Transitional provisions mean that the existing system of national enforcement of European patents will continue alongside the UPC for at least seven years. In addition, holders of (non-unitary) European patents will be able to opt out of the jurisdiction of the UPC during this period.

A great deal of work needs to be done. The divisions of the UPC have to be established, judges appointed and trained, a secretariat staffed, IT systems installed and rules of procedure finalised. The earliest date on which the European Patent Office can grant unitary patents is 1 January 2014 but it is likely that it will take longer than this for ratification of the agreement to be completed and for the necessary administrative machinery to be in place. Nevertheless, all European patent holders need to start preparing for the new legal landscape, in particular by deciding whether to "opt-out" of the UPC system under the transitional regime and whether to seek European (unitary or non-unitary) or national patent protection for future inventions.

Graham Burnett-Hall, Partner

Marks & Clerk Solicitors LLP

Organic dyes: Germany's greatest industrial achievement?

One of the first industrial areas, involving chemical patents, was organic dyes, believed to be at least since the latter part of the nineteenth century (1). Serious research in this area began with the German Patent Law of 1877 (3). This prevented companies from simply copying new chemical processes and allowed German companies to rapidly overtake Britain as the leading producer of organic dyestuffs (2). It provided a common patent regime for all German states and stimulated German companies to invent around patents (2). It also had a strong impact on the chemical sector by supporting the industrialisation of inventions and establishing commercial interactions with academia (4).

Kekulé's discovery of the ring structure of benzene in 1865 opened up the science-based era of the chemical industry (1). Those producers skilled in organic chemistry were able to imitate new dyes and could be guided by chemical theory (1). The first large German chemical companies were established in the years after 1860. They invested heavily in their research and development capabilities, often copying French and British manufacturers, (1) but stimulated by the passing of the German Patent Law in 1877 (5). Once Germany had taken the lead, German companies then used patents systematically to exclude competitors and preserve their market position (6).

Thus, small-scale laboratory experiments were transformed into large industrial-scale processes. This then spurred the integration of the engineering sciences into the chemical sector (7). Then, the support of the chemical, electrical and mechanical engineering transformed the technology of the processes (8).

German companies used a combination of know-how, patenting and secrecy to avoid full disclosure (2). For example, the precise composition of a dyestuff was kept secret, but the individual compounds were protected by patents (2). Another example included patenting entire groups of compounds with only a fraction having properties similar to the dye of interest (2). A competitor would have to undertake a substantial amount of work in order to discover the dyestuff taken to market. German firms also issued misleading 'evasion'

patents, which made it very difficult to link the patents with the market products (2). These sold for 40-50 % more than standard colours, where the composition was known (2).

The largest German dyestuff producers were established between 1863 and 1872 (1). By 1877, half the world production of dyestuffs had a German origin (9). Their success lay in the ability to study and modify structures (1). This led to a substantial innovative performance in the last quarter of the nineteenth century. One estimate put German imports into the United States at 90% of the dyestuff consumption before the War, with Germany owning a corresponding percentage of American dyestuff patents (10). The Swiss supplied the rest. It has been described as, "Imperial Germany's greatest industrial achievement (11)."

At the beginning of World War I, nearly all of the larger chemical companies in Germany produced inorganic chemicals, which were used in agricultural chemicals (1). The Haber-Bosch process (a high pressure process) influenced the production of fertilisers and explosives. The latter has blighted Haber's name ever since (12). The Haber-Bosch process has been credited with keeping Germany supplied with munitions during World War I (12).

However, during World War I, the British blockade prevented German dyestuffs from reaching the US (2). This encouraged Du Pont, an extremely important link in the history of dyes, to enter the dyestuffs business (2). In 1919, Du Pont managed to gain access to all German patents, from the Chemical Foundation in the US. The Foundation offered non-exclusive licenses on German patents, due to World War I (2). The Chemical Foundation was, at that time, a newly-established entity, which was incorporated with the objective of licensing and managing intellectual property assets for the benefit of the chemical industry in the United States (11). In 1918, the United States confiscated virtually all German-owned intellectual property assets within its jurisdiction (11).

There remains some controversy surrounding the role of the Chemical Foundation. The office of Alien Property Custodian was created under the US's Trading with the Enemy Act of October 6, 1917. Industrial and political confrontations then followed (11). German chemical company agents worked with American bankers and government officials to get the patents back. However, the banks and

their allies could not overcome protectionist opposition (11). The Attorney General at the time was indicted for taking a bribe to help the return of the German assets (11). J. Edgar Hoover was appointed to purge the FBI of suspected German Agents and the Government lost the suit it brought to force the Chemical Foundation to return the patents (11).

The actual procedure used by the Chemical Foundation involved identifying German property, sequestering it, valuing it and then holding it in a separate trust (11). As of December 5, 1918, over 32,000 separate reports of enemy property had been received and 29,000 trusts were administered, which amounted to a value of over \$500 million (11). There was actually no provision in the Trading with the Enemy Act which authorised this action (11). However, the Act authorised the Federal Trade Commission to grant licences at a flat rate of 5%. The royalties were held on trust for the owner until after the war (11).

High pressure methods very much supported the development of the sector in Germany (1). The Haber-Bosch process, for the production of ammonia, was protected by over 200 patents (2). Details of the catalyst, which was crucial to the successful process, were kept secret (13). In 1910, Bergius developed coal hydrogenation, which allowed the synthetic production of gasoline out of coal. The Fischer-Tropsch process was developed between 1913-1925. This enabled the production of gasoline, from coal, using low-pressure mechanisms (1). Between 1927 and 1944, large quantities of synthetic gasoline were produced in Germany (14). This, along with inorganic chemicals, made between 35-50% of the patent volume in chemicals in the 1910s and 1920s (1).

The development of plastics then followed. In 1920, Hermann Staudinger started theoretical research activities on the molecular structure of polymers. Important discoveries included the syntheses of styrene (1929) and caprolactam, the latter being used in the production of perlon (1). Large companies, such as Hoechst, owned 530 patents in the plastics sector, accounting for 13% of the total patents in plastics in Germany (1). German and American companies shared the lead in the plastics' patent field, until World War II (8).

By the twentieth century, this had spread to other sectors, such as the production of nylon, polyester fibres, plastics, pharmaceuticals and artificial sweeteners (1). The production of

dyes required large amounts of sulphuric acid and this prompted the production processes for this and other required materials, such as soda (1).

Patenting in the chemical industries has its origins based in Germany, around organic dyestuffs. Germany dominated such areas, due to a strong German patent law and skilful patenting, which prevented the entry of competitors into the organic dyestuffs markets. However, the end of World War I allowed large companies in the US to obtain a foothold into such markets. The skilful use of patents, established by Germany, has now spread into many areas of the chemical industry.

Richard Toon

References

1. I. Dominguez Lacasa, H. Grupp, U. Schmoch, "Tracing technological change over long periods in Germany in chemicals using patent statistics," *Scientometrics*, 2003, **57**, 175-195.
2. A. Arora, "Patents, licensing and market structure in the chemical industry," *Research Policy*, 1997, **26**, 391-403.
3. U. Marsh, "Strategies for success: Research organisations in German chemical companies and IG Farben until 1936," *History and Technology*, 1994, **12** (1).
4. G. Mayer-Thurow, "The industrialisation of invention: A case study from the German chemical industry," 1982, *ISIS*, **73**, 363-381.
5. A. Arora, R. Landau, N. Rosenberg (Eds), "Chemicals and long-term economic growth-insights from the chemical industry," 1998, New York, John Wiley and Sons.
6. J. Liebenau, "The Management of high technology: The use of information in the German Chemical Industry, 1890-1930," 1992, In A. Kudo, T. Hara (Eds) *International Cartels in Business History*, University of Tokyo Press, Tokyo.
7. E. Schmauderer, "Die Stellung des Wissenschaftlers zwischen chemischer Forschung und chemischer Industrie," 1976, In: W. Treue, K. Manuel (Eds) *Naturwissenschaft, Technik und Wirtschaft im 19. Jh.*, Bd 1 and 2, Goettingen, Vandenoek & Ruprecht, 614-653.
8. C. Freeman, L. Soete, "The economics of Industrial Innovation," 1997 London, Pinter.
9. P.A. Zimmerman, "Chemie-Politik-Fortschritt: Notizen zur Entwicklung eines Industriezweiges im Europa des 19. Jahrhunderts," *Technikgeschichte*, 1974, **41**, 53-67.
10. F.W. Vaughan, "Suppression and non-working of patents, with special reference to the dye and chemical industries," *American Economic Review*, 1919, **9**, 693.
11. C. Wadlow, "The great pharmaceutical patent robbery and the curious case of the Chemical Foundation, Pre-publication draft for Intellectual Property Quarterly, 2010, *Intellectual Property Quarterly*, 256-292. http://works.bepress.com/cgi/viewcontent.cgi?filename=0&article=1029&context=christopher_wadlow&type=additional
12. <http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/early-chemistry-and-gases/haber.aspx>
13. W. H. Haynes, American Chemical Industry, 1954, **1-6**, Van Nostrand, New York.
14. T. P. Hughes, "Das "technologisches Momentum" in der Geschichte zur Entwicklung des Hydrierfahrens in Deutschland 1893-1933," 1975, In: K. Hausen, R. Ruerup, (Eds) *Moderne Technikgeschichte*, Kiepenheuer & Witsch, 358-383.

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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 Spring 2013. 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.

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