The AppleP[R]ip

Life Science & Pharmaceutical News

Bolar exemption update

Proposed amendment approved by UK Government and will come into force 1 October 2014

Find out more inside.

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Update on Bolar (Research) Exemptions

Amendment to UK Law Scheduled for 1st October 2014

In our previous edition of The Applepip, we ran an article about the delayed implementation of an amendment to the UK law to clarify that all clinical trials (including Phase III) would be exempt from patent infringement.

We are pleased to report that a proposed amendment was approved by the UK government on the 25th July 2014 and will now come into force on 1st October 2014.

Rather than making any substantive amendments to the UK Patents Act to provide new exemptions from infringement, the amendment adds to the scope of the exemptions for acts "done for experimental purposes relating to the subject matter of the invention".

The Amendments

The amendment now provides clarity that the UK jurisdiction will apply a broad interpretation of the 'Bolar exemptions' and specifically excludes clinical trials for generic and innovative medicines from infringement.

In particular, the amendments will include a new Section 60(6D) which will state that:

> "anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention"

New Section 60(6E) goes on to clarify that:

> "medical product assessment means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—
>
> (a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);
>
> (b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;
>
> (c) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—
>
> (i) providing health care on behalf of such a government or public authority, or
>
> (ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care, to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care."

The full amendments can be downloaded here: http://www.legislation.gov.uk/uksi/2014/1997/pdfs/uksi_20141997_en.pdf

Exemptions under the Unitary Patent Court (UPC)

Of course, there still remains an issue with the wording of the Court Agreement for the UPC which currently only provides for a narrower exemption of infringement for clinical trials which would not at present protect parties conducting clinical trials for innovative medicines.

No doubt there will be further updates on European 'Bolar exemptions' when the UPC nears reality and European states have to adapt their national laws in-line with Articles 25 and 27 of the Court Agreement.

Conclusions

The amendments to the UK Patent Act are likely to be welcomed by the industry and will make sure that the UK is once again a good place to undertake clinical trials for a range of medicine and not limited to testing purely generic medicines for confirming bioequivalence.

Simon Bradbury

Two Herceptin Patents Invalidated

Hospira UK Ltd v Genentech Inc

In a recent decision by Mr. Justice Birss in the High Court, two separate European patents EP(UK)1210115 and EP(UK)1308455 were declared invalid, effectively clearing the way for the production of a generic version of Herceptin® (the antibody trastuzumab used for the treatment of breast cancer) as the Supplementary Protection Certificate for the base patent expired in July of this year.

As Herceptin carries a fairly large price tag for a course of treatment, this decision will undoubtedly reduce the costs due to generics companies entering the market place.

Dosage Regime

In EP(UK)1210115, a dosage regime of 8mg/kg of Herceptin followed by 6mg/kg every three weeks was claimed. This dosage regime was ultimately held to be invalid over the known dosage regime of 4mg/kg followed by 2mg/kg every 1 week approved by the FDA in combination with the skilled clinicians' common general knowledge of the pharmacokinetics of the drug. Birss commented that even if the patent was considered to be valid, it was not sufficient because, "the skilled team would not conduct a clinical trial on the dosage regime from the information in the patent".

Purified Composition

In EP(UK)1308455, the purified antibody composition of drug having less than 25% deamidated acidic residues of aspartate was claimed. This composition was held to be invalid over a previous Genentech filing in which a composition having 18% of the deamidated residues was disclosed, and over a presentation made by an employee of Genentech at a conference.

Medical Use Claims

A further point of interest in the case include the parties' agreement that the meaning of 'for' in a second medical use claim should be understood to mean not only 'suitable for' but also 'intended for' the named medical use.

"Less Than" Claim Language

The parties agreed that in accordance with recent case law that the lower limit of the less than 25% amount should be considered as 24.5%. It is unclear whether Genentech had intended this interpretation or if "25% or less" was the actual intended range in the claim and if so this is the claims language which should have been used in the original patent application.

Appeal

Genentech sought leave to appeal the decision on the dosage regime patent EP(UK)1210115 on the basis that claimed dosage regime of a 8 mg/kg loading dose followed by a 6 mg/kg three weekly maintenance dose was inventive despite the fact that a skilled person would have arrived at a similar dosage from the prior art FDA label. However in a decision at the end of May, Mr. Justice Birss refused the request on the basis that this was a new line of argument. Genentech will now have to ask for permission from the Court of Appeal directly, which is expected to happen given the significance of the drug to Genentech.

Costs

Hospira had argued that they should be entitled to costs on an indemnity basis because Genentech did not reveal the question of construction of the claim around the feature of percentage ranges claimed. Furthermore Genentech argued only in the pre-trial that the methods Hospira used to determine their percentage of acidic variants in the composition were incorrect. Hospira argue that these two points in particular led to deliberate delays by Genentech. In the end, Hospira's lack of clarity on how much their true costs were, and the unnecessary requests for costs on an indemnity basis led Birss to award a cautious 50% of the actual costs billed. This still amounted to around a £1.3 million interim payment, but this may have been significantly more had Hospira been more definitive about their costs throughout.

Ellie Purnell

Stem Cell Update

Patentability of Parthenotes

Last year, we reported the revocation of the Brüstle patent (EP1040185) and the fact that the Comptroller of the UK Intellectual Property Office (UKIPO) had forwarded the question of whether parthenotes were patentable (or excluded from patentability) under the European Biotechnology Directive to the Court of Justice of the European Union (CJEU).

The Advocate General has come back with an opinion which is broadly 'yes' – provided that the parthenote cannot, or is not manipulated to, develop further embryonically.

Background

In Brüstle, it had been decided that "any human ovum must, as soon as fertilised, be regarded as a 'human embryo'…since that fertilisation is such as to commence the process of development of a human being" and that this, "must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis".

The interpretation of what constitutes a 'human embryo' within the meaning of the EU Biotechnology Directive is important as inventions involving embryos are excluded from patentability in Europe.

Parthenotes are activated unfertilised oocytes which are arguably not capable of developing into a human being as the paternal DNA is missing.

In a UK case concerning International Stem Cell Corporation, it had been argued that the CJEU seemed to believe that parthenotes are capable of commencing the process which leads to the human being and that this was wrong because parthenotes are not totipotent and therefore inventions concerning parthenotes should be patentable and not fall within the exclusions. Furthermore, evidence had been presented that showed that the parthenotes could only develop to the blastocyst stage.

Advocate General's Opinion

The opinion of the Advocate General was that parthenotes should be patentable, provided that they are "not capable of developing into a human being and have not been genetically manipulated to acquire such capacity".

Conclusions

It should be noted that at this stage, the Advocate General's opinion is only in a preliminary form. However, it is envisaged that the CJEU's decision will follow a similar sensible approach to the patentability of parthenotes and provide some legal certainty to patentability of inventions within this expanding area of research.

Simon Bradbury

European Medical Use Claims

Swiss-Style & EPC 2000 Medical Use Claims Can Coexist

In a decision of the examination Board of Appeal in T1780/12, the EPO decided that a patent containing a Swiss-style medical use claim and a related divisional patent containing an EPC 2000 medical use claim directed towards the same medical use did not constitute double patenting.

Examples of the two types of claims are:

i. Swiss-style claim: "Use of composition X, in the manufacture of a medicament for the treatment of disease Y"

ii. EPC 2000 claim: "Composition X for use in the treatment of disease Y"

The Board decided that the format of the Swiss style claims was essentially a process claim and that the format of the EPC 2000 style claims is essentially a product claim. Therefore the two claims are in different claim categories and as such, are allowed to coexist without any double patenting issues because they protect different scopes of the invention.

The Board referred to the preparatory document of the EPO from the EPC 2000 legislators and the decision T250/05, both of which discuss the different extent of protection offered by the two types of claim. This decision seems somewhat contradictory to the EPO position of converting between the two claim types which it does not see as adding matter to an application, and to the view on validity where both claim types do not seem to be distinguished in relation to novelty. Although this situation in reality seems to apply to relatively few patent applications captured in the transitional provisions on second medical use claims, it could be used by applicants to ring-fence drugs with dual protection on second medical uses.

Ellie Purnell

Appleyard Lees Growth Fund

We Extend Our £50,000 Growth Fund to Bioscience SMEs

We have now extended our annual £50,000 fund to help life science, pharmaceutical and chemical start-up companies protect their innovation.

Grants from the Appleyard Lees Growth Fund will be awarded on a case by case basis to bioscience companies with winning ideas, a track record for innovation and a sound strategic approach.

Each application will be assessed by partners at the firm and funds will be granted to projects which meet the criteria. We do not take any equity stake in the companies or IP protected.

For more information on the Appleyard Lees Growth Fund, please contact us for a leaflet and discuss taking part in this exciting initiative.

Simon Bradbury

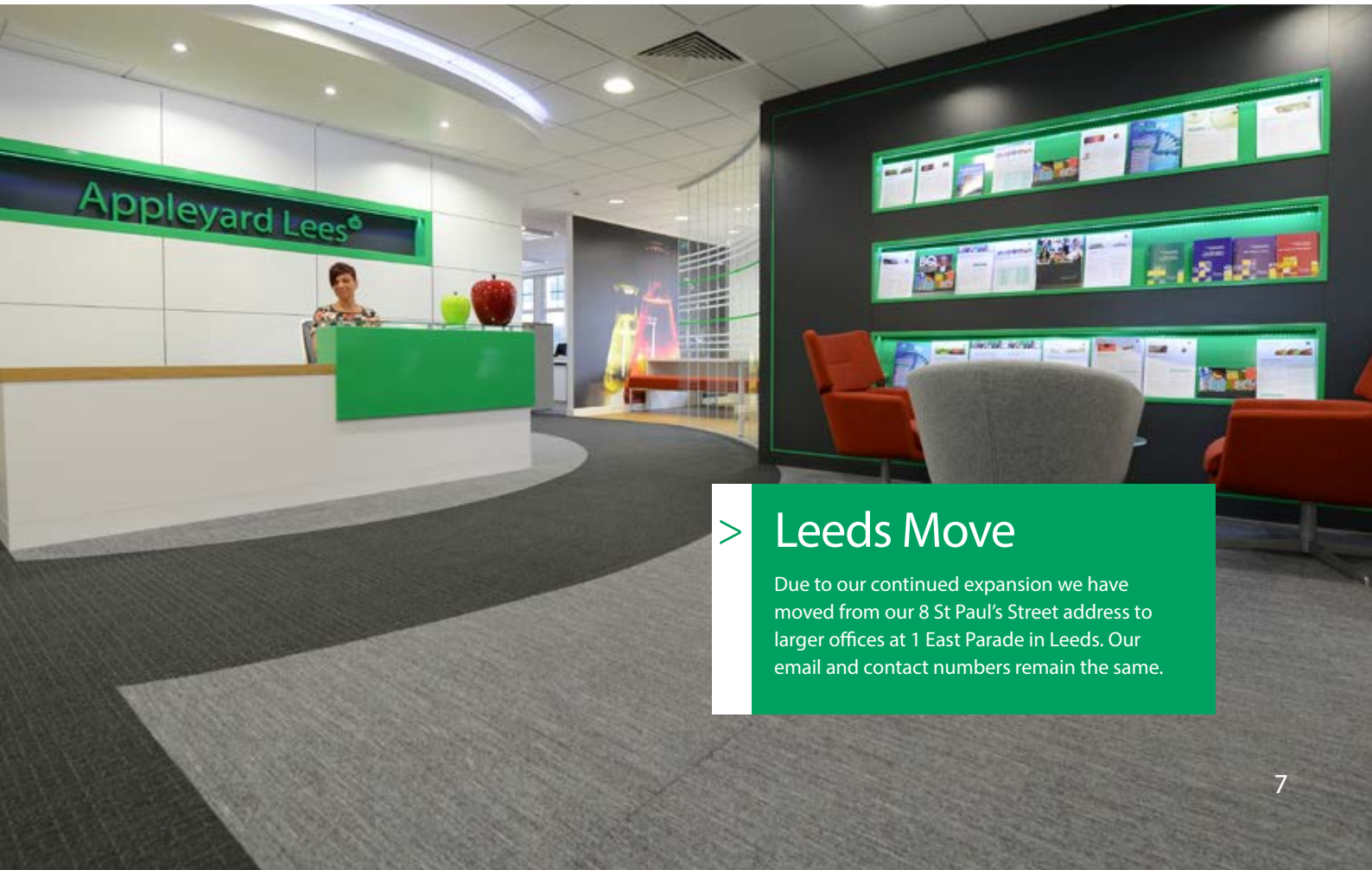
Opening of New Alderley Park Office

We are pleased to announce the opening of a new office at the BioHub at Alderley Park, Cheshire, UK.

With state of the art research facilities and high-end office space, the BioHub plans to provide a bioscience business cluster of international importance. This new office is an important step in our on-going commitment to the pharmaceutical and life sciences sector in the North West of England.

Our office is based in the prestigious Alderley Park Conference Centre and our attorneys are there 5-days a week to provide on-site support to our existing clients and also to new start-up companies and entrepreneurs in the bioscience sector.

We would also be pleased to welcome our international clients and associates at our new office as it is conveniently located just 10 minutes away from Manchester International Airport.



Leeds Move

Due to our continued expansion we have moved from our 8 St Paul's Street address to larger offices at 1 East Parade in Leeds. Our email and contact numbers remain the same.

Confidentiality at the Heart of the Matter for Clinical Trials

AGA Medical Corp v Occlutech (UK) Ltd

The High Court has held that AGA's patent, EP(UK)957773, relating to medical devices for occluding defects in the atrial septum of the heart ('hole in the heart') is invalid on the grounds of lack of inventive step and anticipation by first clinical trial.

The medical devices for occluding defects in the atrial septum of the heart are marketed by AGA under the name 'Amplatzer'. AGA initially claimed that Occlutech's devices infringed the patent, however, Occlutech counterclaimed for revocation of the patent. The decision is the second judgement in UK patent proceedings between the two parties. The Court of Appeal held in July 2009 that the previous generation of devices made by Occlutech did not infringe AGA's earlier patent, EP(UK)0808138.

Anticipation by Clinical Trial

Occlutech claimed that the patent was anticipated by non-confidential clinical trials carried out at the Bratislava Children's Hospital in Slovakia in 1995. The case principally rested on:

> i. Were the devices which were subject to the clinical trials the same shape as the device claimed in the patent, and
>
> ii. Was there an implied obligation of confidence such that there was no relevant novelty-destroying disclosure to the public?

The Judge decided that at least some of the devices used in the clinical trials were the same shape as those claimed in the patent. Therefore, the key issue was whether the clinical trials were conducted under conditions of confidentiality. In making the decision on this point, the Judge applied the principles of English law which, in contrast to the EPO, does not have a prima facie presumption of confidence for clinical trials. Instead, Mr Justice Roth stated that "everything depended on the facts of the case".

On the facts of the case, the Judge did not consider that the doctors involved in the clinical trial ought to have known that it was "fairly and reasonably to be regarded as confidential" for at least the following reasons. Firstly, the inventor, Dr Amplatz, had visited Bratislava in his capacity as Professor of Radiology rather than as a businessman. Secondly, the trials were not a commercial venture between the doctors and AGA or Dr Amplatz. Thirdly, it was considered that this was a major event for the doctors involved and they would, naturally, wish to speak about it to their medical colleagues (which did indeed happen).

As there was no indication to the contrary from either AGA or Dr Amplatz, the Judge did not find it surprising that the doctors did not regard the devices as confidential. Finally, the doctors could reasonably assume that appropriate steps had been taken to obtain the patent protection that was available for a newly developed and innovative device.

Inventive Step

Despite the patent being held invalid on the basis of lack of novelty, the Judge further considered other grounds for invalidity. With regard to inventive step, Occlutech relied upon a presentation made to a medical conference in 1996 where an earlier prototype of the patented device was described. The device disclosed at the conference comprised two flat discs whereas the device of the patent had at least one cupped disc. However, the Judge held that this would have been an obvious and non-complex change in order to address the small but significant risk of a blood clot occluding in the atrial septum of the heart.

Added Matter

With regard to added matter, the Judge rejected an attack on this ground. However, it is interesting that, in contrast, the Opposition Division of the European Patent Office have held the patent to be invalid for added matter (this decision is currently under appeal).

Summary

This case highlights the importance of ensuring that obligations of confidentiality are explicitly stated and imposed by those arranging or conducting clinical trials. This applies to both the doctors conducting the trials and the patients taking part.

Sarah Dobson

Problems with the Morning After Pill

Generics UK Ltd v Richter Gedeon Vegyeszeti Gyar RT

In this decision Generics sought the revocation of EP(UK)1448207 directed towards a dosage regime for the contraceptive drug levonorgestrel. The main claims essentially defined a single dose of the drug at 1.5 ± 0.2mg for use as emergency contraception.

Generics relied on prior art of an article published by the WHO reporting the use of a single dose of levonorgestrel instead of the current standard of two such doses. However, the article contained an unfortunate mistake in the amount of the drug, stating it to be 1.5 grams instead of milligrams.

Despite this, the claims were judged to be obvious over this document in combination with the skilled persons' capacity for reasonable trial and error. Justice Sales added that, in any case, the experimental evidence for efficacy of Richter's regime was not convincing of any technical effect over and above that contained in the WHO paper, regardless of the statement at the end of the prior art paper that further work in the area was required. Accordingly, the UK part of Richter's European patent was revoked by the High Court for a lack of inventive step. Interestingly, no parallel infringement action was brought, allowing the case to be held in an unusually short amount of time and presumably clearing the way for Generics to produce a similar emergency contraceptive product.

Ellie Purnell

New Patent Laws in New Zealand

On 13 September 2014, a new Patents Act commenced in New Zealand. The new Act represents the first major change to New Zealand's patent legislation in over 60 years, by replacing the 1953 Act. The new Act also brings New Zealand patent legislation into line with most other countries around the world. So, how does the new Act do this?

Patentability

In terms of patentability, applications under the new Act will be examined for inventive step (or obviousness) as well as novelty. When novelty is assessed, the new Act introduced a change from local novelty (known or used in New Zealand) to absolute novelty (known or used anywhere in the world). Therefore, the novelty and inventive step of an invention will now be assessed against matter made available to the public anywhere in the world, rather than just what was known or used in New Zealand. Also, secret use of an invention in New Zealand before the earliest priority date will destroy novelty. However, there will be exceptions for use which is a reasonable trial or experiment and which is authorised by the applicant/patentee.

Exclusions

The new Act also introduces certain subject matter exclusions. It is expected that computer software protection may be more limited under the new Act. Additionally, the new Act states that inventions considered to be contrary to public order or morality are not be patentable, and provides examples of some inventions that will not be patentable.

18-Month Publication & Access to File History

The new Act brings some help to third parties in assessing pending applications in New Zealand. Previously, patent applications in New Zealand were not published until they had been examined and accepted by the Patent Office, such that only limited information on file was open to public inspection. Under the new Act, specifications of pending patent applications will be published 18 months after the applications earliest priority date. It seems that correspondence between the patent applicant and Examiner is likely to be made available online after this date too.

If third party patent property is identified that causes concern, the new Act provides a number of new options for challenging a patent application or granted patent. Third parties can now bring relevant documents to the attention of the Examiner prior to patent applications being examined, similar to filing third party observations before the European Patent Office. It is also now possible, under the new Act, for any interested party to request re-examination of a patent application or granted patent. It remains possible to oppose a granted patent in New Zealand and revocation is now available throughout the life of the patent.

Procedure & Fees

Finally, the new Act has brought some changes to procedures and fees in New Zealand. Under the old law examination of patent applications was automatic, but under the new Act examination must be requested. Annual maintenance fees are now payable from 4 years from the filing date, with renewal fees being payable annually after grant.

The old Act will continue to apply to pending applications that were filed in New Zealand before the date on which the new Act came into force, as will pending PCT applications if they were entered into the national phase in New Zealand before the new Act came into force.

Conclusions

It seems clear that the new Act will make it harder than before to obtain patent protection in New Zealand, with examination being more stringent, but patents which are granted should be more robust. This should provide greater legal certainty for patentees and third parties alike.

Kate Hickinson

Unusual Twist in Pfizer's Norvasc Jamaican Patent Invalidity

Pfizer Ltd v Medimpex Jamaica Ltd

The Judicial Committee of the Privy Council (JCPC) has dismissed Pfizer's appeal from the decision of the Jamaican Court of Appeal that Pfizer's Jamaican patent for an antihypertensive drug was invalid.

The case related to Pfizer's drug amlopidine besylate, sold under the brand Norvasc®, for the treatment of high blood pressure. Patents directed to the drug were filed in a number of countries in 1986. However, under the local novelty provisions in Jamaica, a patent was not filed in this country until 1992. Furthermore, the patent was applied for in the name of an attorney in Jamaica, Mr Robinson, upon instructions from Pfizer. Mr Robinson assigned the patent to Pfizer once it had granted (patent no. 3247) in 2002 for a nominal sum. Pfizer then brought infringement proceedings against Medipex Jamaica Ltd and Lasco Distributors Ltd (Medipex) who had been importing and selling a generic version of amlopidine besylate in Jamaica since 2001. In response, Medipex counterclaimed for invalidity.

During proceedings, a couple of issues were considered; i) whether Mr Robinson acted on his own behalf or on Pfizer's behalf by filing the application in his own name and ii) whether the expiration of a patent in another country before grant, in this case the corresponding Egyptian patent (where the patent term at the time was only ten years), rendered the Jamaican patent invalid under Section 29 of the Jamaican patent act or if the applicant had to be the same in both countries for this provision to take effect. Section 29 reads:

"No applicant shall be deprived of his right to a patent in this Island…for his invention by reason of his having previously taken out Letters Patent therefor in any other country:

Provided, that such invention shall not have been introduced into public and common use in this Island prior to the application for a patent therein [i.e. local novelty]; and that the patent granted in this Island shall not continue in force after the expiration of the patent granted elsewhere; and that where more than one such patent or like privilege is obtained abroad, then immediately upon the expiration or determination of the term which shall first expire or be determined of such several patents or like privileges, the patent granted in this Island shall cease to be in force

With regard to the latter issue, the Privy Council held that earlier decisions from the Court of first instance and the Jamaican Court of Appeal were erroneous in their findings that the expiry of the Egyptian patent rendered the Jamaican patent invalid regardless of the respective applicants. Therefore, the case turned on the former issue.

Pfizer argued that the Mr Robinson was the applicant and not the attorney on the basis that a power of attorney was not filed, that Pfizer was not "an absentee" that required representation and that Mr Robinson was named as the applicant and, therefore, relationship between himself and Pfizer was "neither here nor there". It must be noted that Section 29 of the Jamaican patent act would only apply if Mr Robinson was Pfizer's attorney meaning that the applicant would be the same for the patents in both Jamaica and Egypt. The Privy Council decided that Mr Robinson applied for the patent as Pfizer's attorney, stating:

"The attorney has neither identified a new and useful invention abroad nor decided to import that invention into Jamaica. He is still acting throughout on the instructions of the principal and consequently holds the application to the principal's order"

Accordingly, the Privy Council held that Pfizer's Jamaican patent had the same applicant as the Egyptian equivalent and that is was therefore invalid by virtue of Section 29. Pfizer's appeal was therefore unanimously dismissed.

The case is clearly an unusual one bringing together issues of invention by importation, local novelty and ten-year patent terms. These issues are infrequently encountered by European and UK patent attorneys. Indeed, Sir David Kitchen, sitting on the Privy Council, noted that local novelty which allows invention by importation "may seem somewhat surprising to those familiar only with the provisions of the European Patent Convention" (although it was a feature of UK law until 1978).

Sarah Dobson

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