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InFocus

Life science & healthcare legal e.bulletin



Introduction

This is the fourth issue of InFocus, Taylor Wessing's life science and healthcare e.bulletin. In this edition we look at some of the issues arising from enlargement of the EU and consider what their impact has been on LSH companies 6 months on. We review the scope of legal advice privilege post the recent House of Lords decision in *Three Rivers*. We also report on two recent cases. The first illustrates the importance of careful drafting of jurisdiction clauses in contracts and the second the importance of confidentiality agreements when negotiating possible technology sharing arrangements. We also include a summary of the government enquiry into relaxing pre-emption rights for technology companies and a short case study to illustrate some of the possible perils of not involving lawyers early on in a transaction.

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Key features

EU enlargement - 6 months on [Back to contents](#)

On 1 May 2004, 10 new Member States joined the European Union: Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Malta, Hungary, Poland, Slovenia and Slovakia. The Accession Treaty included a "Specific Mechanism" effecting parallel trade in certain pharmaceuticals from the accession countries (except Cyprus and Malta). At about the same time the overhaul of the European regulatory regime for pharmaceuticals, the so-called Pharma Review Package, was completed. In this briefing, we look at the impact of the Specific Mechanism on life science companies 6 months on and we discuss some of the issues which have arisen. We also consider the likely impact of the Bolar Provision included in the Pharma Review Package and some of the unresolved issues. The Bolar Provision is due to be implemented into national legislation by November 2005.

Parallel trade from accession countries: the specific mechanism

"With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at the time when such a protection could not be obtained in one of the above mentioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding the import that one month's prior notification has been given to the holder or beneficiary of such a protection".

(article 22 and annex IV.2 of the Accession Treaty)

Unlike previous derogations, for example when Spain and Portugal joined the Community, the transitional period is not fixed but is linked to the duration of the relevant patent and/or supplementary protection certificate and whether it was possible at the time to get equivalent protection in the Accession State. Accordingly, it will not apply to all pharmaceutical products being imported from accession countries but only those which satisfy the criteria set out in the specific mechanism. Since accession two issues appear to have given rise to most uncertainty: the requirements as to notification and the practical interpretation of the words "patent or supplementary protection certificate". These two are discussed below.

Notification

Linkage of the transitional period to specific products necessitates a notification procedure in order to allow the patentee to check whether the Specific Mechanism can be invoked. The EMEA "Notification of parallel distribution for centrally authorised medicinal product" requires that the parallel importer indicate whether the Specific Mechanism applies and where it does to confirm that one month's advance notice has been given to the patent holder.

No guidance has been given in the Treaty or by the Commission, EMEA or MHRA as to the information which should be provided in the advance notification to the patent holder. The Commission, EMEA and MHRA have indicated that no such guidance is being prepared. Neither the EMEA nor the MHRA intend to investigate or satisfy themselves as to the adequacy of the notice. It is their opinion that it is the National Courts that will have to consider failure to give notice or the adequacy of the notice.

In our opinion, given its purpose, the notification should allow the patent proprietor to assess whether or not the conditions of the Specific Mechanism are met. In order to do this the notice should contain details of the product, the country of export, the country of import and the commencement date.

There is also no guidance as to the course of action a patentee can take if a parallel importer fails to give sufficient details in its notice. At the very least, our advice is that companies should state that until the notice is adequate, the one month period is not satisfied.

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Under the current law there are no express sanctions for failing to notify. This can be compared to case law relating to repackaging of pharmaceutical products where failure to notify alone has been held to amount to trade mark infringement.

Germany's guidance on content of notice

Unlike the UK, in Germany guidelines issued by the BfArM (Bundesinstitut für Arzneimittel and Medizinprodukte) state that the notification (to the patent, SPC or marketing authorisation holder) must include the name, pharmaceutical form, active ingredients, marketing authorization number, name and address of parallel importer and marketing authorization holder. Furthermore, on application for its parallel import licence, the importer must evidence that the deadline of one month was met (for example with a copy of his notification), otherwise the "BfArM" will reject the application as incomplete.

"Patent protection or supplementary protection"

The fact that patents or supplementary protection certificates (SPC) can be the basis for preventing imports may lead to further uncertainties. Take the following example: A company files a patent covering a process in UK and in Poland. It then applies for an SPC covering the product obtained from the process in the UK at a time when SPCs were not available in Poland. The Specific Mechanism covers products directly obtained by means of a patented process. The patent was filed in UK at a time when patent protection could be obtained in Poland. However the SPC was filed at a time when SPCs could not be obtained in Poland.

What remedy would the patentee have if the parallel importer imports infringing products from Poland to the UK (i) before UK patent expiry (ii) following patent expiry and during the SPC term? One interpretation is that the Specific Mechanism does not apply in (i) but does in (ii) because patent protection was available in Poland at the time of the filing of the UK patent, however SPC protection was not. Alternatively the Specific Mechanism does not apply in (i) or (ii) because the words "such a protection" refer to patents or SPCs and patent protection was available in Poland at the UK patent's filing date. The third possibility is that the Specific Mechanism applies in (i) and (ii) because even during the patent term, the patentee can rely on the fact that an SPC was not available in Poland at a time it was in the UK.

THE BOLAR PROVISION - Pre-patent expiry clinical trials within the EU

Background

A Bolar provision has been introduced into Directive 2001/83 (by Directive 2004/27) to allow certain pre-patent expiry testing work. Prior to this, the only relevant provisions were the experimental use exemptions under national law. These were interpreted differently by the different European jurisdictions and in many of the "old" Member States they either did not permit or substantially limited the work that could be carried out to obtain regulatory approval.

A narrow interpretation used to be the position in the US, *Roche Products v Bolar Pharmaceuticals* (1984) 733 F.2d 858. However, this case led to the Hatch-Waxman Act, which permits activities related to the development and submission of information to the FDA.

By contrast, many of the new Member States already have Bolar-type provisions in their national law. The following table summarises the current position in all 25 Member States.

Bolar exemption - the national law in EU member states

	Member State	Bolar exemption in national law?
1	Austria	No
2	Belgium	No
3	Denmark	No
4	Finland	No
5	France	No
6	Germany	No
7	Greece	No
8	Ireland	No
9	Italy	Yes

	Member State	Bolar exemption in national law?
10	Luxembourg	No
11	Netherlands	No
12	Portugal	No
13	Spain	No
14	Sweden	No
15	United Kingdom	No
16	Cyprus	No
17	Malta	Yes
18	Hungary	Yes
19	Poland	Yes
20	Slovakia	Yes
21	Estonia	No
22	Lithuania	No
23	Czech Republic	No
24	Slovenia	Yes
25	Latvia	No

The Bolar Provision

Article 10(6) of the new Directive seeks to harmonise the position throughout the Member States:

Conducting the necessary studies and trials with a view of the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

The issues

■ When will the Bolar provisions apply?

For it to take effect, the new Directive needs to be implemented into national legislation, which is due to happen by November 2005.

■ What types of product will be covered by the Bolar provision?

Clearly, work carried out to obtain regulatory approval for a "generic medicinal product" will be covered by the Bolar provision. What is not so clear is whether it will also cover clinical trials generally, for example for competing innovator products. One of the earlier drafts of the Directive made clear that the Bolar provision would apply only to an application for a generic medicinal product. However, the final version did not have this wording. This could be interpreted as meaning that it will apply to all types of medicinal products, since paragraph 3 of Article 10 (which paragraph 6 refers to) relates to clinical trials for medicinal products not falling within the definition of generic medicinal product. Alternatively if the "pre-clinical tests or clinical trials" referred to in paragraph 3 are merely intended as a reference to bridging data required for a generic product, the scope of the Bolar provision will be more limited.

■ When can the tests covered by the Bolar provision be carried out?

It seems that it will be possible to perform the tests and trials covered by the Bolar provision immediately following implementation of the Directive without there being patent infringement, provided of course the work relates to one of the activities covered by the Article. Thus, for an abridged generic application, it will only be possible to use these results under the new regime (8+2+1). The 8+2+1 regime will apply only where the innovator's application is submitted after implementation of the Directive so it follows that it will not be possible to use such results for an abridged application until October 2013. In the meanwhile the existing regime of 6 or 10 years data package exclusivity, with no Bolar provision, will apply to abridged applications for generics.

■ What is meant by "necessary studies and trials" and the "consequential practical requirements"?

In order to obtain a product licence, as well as showing bioequivalence etc. the applicant will need to validate its manufacturing facility (requiring, say, 3 manufacturing runs). It seems that these validation runs will also be covered by the Bolar provision. There is likely to be debate over what is the minimum production quantity that is required by the regulatory authority, compared to what is the maximum quantity possible that enables the generic to stockpile product pending patent expiry.

■ Can the data and/or product be used only for applications for EU product licences?

While it is clear that the Bolar provision will apply to obtaining regulatory approval in the EU, it is not clear from the Directive what the position will be if the test data and/or manufactured product is used abroad. Compare the Hatch-Waxman Act which applies to activities "solely for uses reasonably related to" submissions to the FDA. And the European Council explicitly rejected the European Parliament's proposal to include products for export.

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Background

The recent case of Stanelco Fibre Optics Limited v BioProgress Technology Limited centred on an entitlement dispute in relation to three families of patents owned by Stanelco in the field of radio frequency (RF) dielectric welding for making ingestible capsules. Issues of joint ownership, breach of confidence and estoppel were also relevant.

The three families shared a core inventive concept, which was the use of RF welding to seal water-soluble polymeric film materials into the shape of capsules. The first family (the First Family) claimed a process using two films of a water soluble polymeric material with the welding process being dielectric welding performed between two opposed electrodes. The second family (the Rotary Die Family) used dielectric welding at rotary dies, with the liquid to be held in the capsule already present in the recess. Finally, the third family (the Three Film Family) claimed the horizontal orientation of two of the three films when the recesses are filled with flowable materials.

BioProgress had been seeking to develop biodegradable capsules from materials (water-soluble, film forming polymers) other than gelatine and had approached potential partners for help in achieving a technique for sealing the capsules. Without knowing the precise details of the process, BioProgress's head of R&D, Mr Nowak, had already appreciated that RF dielectric welding might be a suitable sealing method and was referred to Stanelco. Stanelco's employee, Mr Draisey was able successfully to weld samples of film provided by BioProgress. More specifically, Mr Nowak had asked Stanelco to weld samples through oil. Stanelco did not initially know precisely what the films were for (Mr Nowak had been careful not to reveal too much information), and a certain amount of trial and error was necessary before a successful weld was achieved. Nevertheless, the judge decided that this work was nothing out of the ordinary.

The two parties subsequently entered into a non-disclosure agreement and began more detailed discussions, but these soon broke down. By this stage, Stanelco (with BioProgress's knowledge) had already applied for the first family of patents. The other two families of patents were obtained later.

BioProgress claimed to be entitled to ownership of each family of patents, and claimed there had been a breach of confidence. Stanelco denied this and asserted that since BioProgress had acquiesced to their filing patent applications it should be estopped from asserting any rights of its own.

The law

The judge briefly set out the law in each relevant area:

Entitlement

Under s7(3) Patents Act 1977 the inventor of a patent is the 'actual deviser of the invention' - i.e. the invention as described in the claims. In particular, the judge held that an antecedent worker who came up with an idea consisting of all the elements of the claim should normally be found to be an inventor. The actual reduction into practice of a working invention was (unlike in the US) not necessary.

Joint ownership

The judge reviewed the authorities and concluded that it was wrong to follow a mechanistic, element-by-element analysis of the claims to determine who was responsible for each element. The approach to take was to decide whether the second individual made such a contribution as to be jointly responsible with the first for devising the

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inventive concept. In this context, whether the invention was 'inventive' with respect to the prior art was not an issue: what was relevant was the invention as described in the claim. A causal link between the antecedent work and the invention was necessary.

Breach of confidence

The judge set out the law, which is well known. The information must have the necessary quality of confidence, must be imparted in circumstances giving rise to an obligation of confidence and there must be an unauthorised use of the information to the detriment of the person who communicated it.

Estoppel

The judge quoted from *Taylor's Fashions v Liverpool Victoria Friendly Society* where it was held that in order to determine if there should be an estoppel the question is whether it would be unconscionable for a party to be permitted to deny that which, knowingly or unknowingly he had encouraged another to assume to his detriment.

The judge's findings

Entitlement

The First Family

The judge held that it was Mr Nowak who came up with the idea of a process for making capsules by RF welding and was therefore entitled to be considered an actual deviser. He also found that Mr Draisey could not be said to have played any part in the actual devising of the invention since he did nothing more than exercise his common general knowledge to demonstrate that the invention worked - he did not contribute a non-routine means of achieving the inventive concept.

The judge went on to look at the subsidiary claims as well. In the case of those that contained a different inventive concept (adding a heater and forming films into bags before filling and welding them), he held that Messrs Nowak and Draisey were joint inventors; Mr Draisey having come up with the additional features himself.

The Rotary Die Family

In the case of the second family, the judge held that Mr Nowak contributed no more than the core inventive concept. At a meeting between the parties, the topic of rotary machines had been raised (by another BioProgress employee, put forward at trial as an inventor in relation to this family), but dismissed as unworkable in the context of RF welding. The judge held that the raising of this issue at the meeting had not contributed to the inventive concept, which had finally been arrived at by Stanelco much later, after their initial dismissal. To consider Mr Nowak (or anyone else from BioProgress) to be a joint inventor would be to fall into the trap of carrying out an element-by-element analysis of the claim.

None of the additional features in the subsidiary claims could enable Mr Nowak to be treated as an inventor either, even though one claim was deduced by Mr Draisey from what he had been told by BioProgress.

The Three Film Family

The judge took a similar view on this family. BioProgress's contribution extended no further than the core inventive concept and the invention of the family was a genuine combination of that with a further inventive concept, not just a refinement.

Estoppel

Stanelco's arguments on estoppel were based on the contents of a letter from BioProgress to Stanelco. The letter failed to assert that Stanelco was not entitled to file a patent application, but did assert that such an application would be invalid because of prior use. The judge found that the letter was far from an encouragement to Stanelco to file an application, and on that basis, held that there was no estoppel.

Breach of confidence

The judge held here that it ought to have been obvious to Stanelco that BioProgress was not making a routine request, but that it was a specific approach in relation to a novel application of a technique in relation to particular films. In that case it was an approach such that the necessary obligation of confidence arose.

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Although the individual elements of the idea were in the public domain, the concept as a whole was not and thus had the necessary quality of confidence. The judge also found that the use of the core inventive concept as the basis for patent applications was a misuse of the information to the detriment of BioProgress.

Conclusions

The case is a reminder that parties considering pooling their resources (and particularly from the point of view of the party offering the bulk of any information) ought to enter into a confidentiality agreement at as early a stage as possible. It is advisable for such an agreement to contain a clause prohibiting the receiving party filing applications for patents (or other appropriate rights) based on the information disclosed to it. Even in the absence of a written confidentiality agreement, the disclosing party ought to make it clear that the information is confidential in character and should be kept confidential.

Keeping a careful record of all new materials and ideas developed, when and by whom is also a wise precaution, as is taking a careful note of all matters discussed at any meetings between the parties.

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In brief

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The recent decision of the English Court of Appeal in *Celltech v MedImmune* provides a reminder of the importance of getting the drafting of jurisdiction clauses right. The case is also interesting as it illustrates how the context in which agreements are made could be important in establishing the scope of a clause.

Background

The claimant, Celltech R&D Limited (C), and the defendant, MedImmune Inc (M), entered into a patent licence agreement. The terms of the agreement stated that M had to pay royalties in respect of products that, were it not for the licence, would infringe C's patents.

M declined to pay certain royalties, and started an action in the US seeking to revoke one of the patents and seeking a declaration that the patent was not infringed. C applied to the US court to decline jurisdiction and brought proceedings against M in England for non payment of royalties. M then applied for a stay of the English proceedings.

Clause 13 of the licence agreement provided that the validity, construction and performance of the agreement should be governed by English law and that any disputes, claims or proceedings between the parties relating to this should be subject to English law.

First Instance and Court of Appeal decisions

At first instance, the licence agreement was held to confer jurisdiction on the English courts and therefore the judge declined to stay the English proceedings pending the outcome of the US decision.

In the Court of Appeal case, the question was whether the English courts had jurisdiction and if they did whether the first instance judge correctly exercised his discretion in refusing a stay of the English proceedings. It was decided that the jurisdiction clause did confer jurisdiction on the English courts and the judge correctly exercised his discretion.

The reasoning behind the decision

■ First question - the scope of the jurisdiction clause

The Court agreed with the view of the first instance judge that the issue of infringement of a patent should only be determined by one court to increase the chance of consistency of decisions. This is because there are many countries in which C's licensed patent rights subsist. The crux of the argument, as explained in the first instance decision is that

"...although it is not strictly necessary to do so, one can see that it makes good commercial sense for the parties to have agreed rather than have the issue of infringement determined in up to 24 different countries where M may sell its products, all the issues of infringement should be determined in one court which could effectively become a specialist in determining that issue."

The first instance decision stated that it was reasonable to assume that parties chose not to leave issued of validity and infringement to be decided together on a country by country basis. It seems that the intention of the parties was to have the question of the liability for payment of royalties to be determined by the English courts.

Therefore, the first instance court decided that the parties should be kept to their agreement that issues of infringement should be determined by the English courts.

The Court of Appeal considered the significance of various provisions of the licence agreement and the commercial background against which clause 13 should be considered. Clause 13.1 and 13.2 provided that the validity, construction and performance of the agreement should be governed by English law and that any disputes, claims or proceedings between the parties relating to this should be subject to English law. It was put to the court that the word 'performance' in clause 13 should have a restricted meaning and not cover question of the scope of the licensed patents. The judges rejected this and decided that the obligation to pay royalties should be included in the term 'performance'.

Therefore, this was a dispute about the performance of the agreement coming within clause 13 and to be governed by English law.

It made sense for the parties to select a jurisdiction with a specialist, experienced court to decide matters, and the Court thought this was what they had done.

■ Second question - whether the court should in its discretion decline jurisdiction

This second question related to the risk of inconsistent decisions by different courts.

The Court of Appeal stated that there must be "strong reasons" for granting a stay of proceedings where the contract in question does give jurisdiction to the court. It is for the court to decide.

The judge at first instance did not exercise discretion wrongly in refusing a stay of proceedings for a number of reasons. The parties bargained to give jurisdiction to the English court concerning the scope of the licensed patents. There was only a remote possibility of different interpretations of the validity of the patents in both the UK and US and it was thought to be highly improbable that a US court would depart from an English decision on validity. As a result there was little risk of inconsistent decisions.

Why is this case of interest?

The courts considered the jurisdiction clause against the commercial background of the agreement. They considered what was taken into account when the agreement was drafted and considered it against the backdrop of the patent world where uncertain patent law can result in different results in different countries.

The courts tried to determine what the parties intended. This is interesting for parties to bear in mind when drafting agreements. The context in which agreements are made could be very important in establishing the scope of a clause.

The case further illustrates the importance of careful drafting of jurisdiction clauses particularly where you are dealing with a cross border transaction involving intellectual property rights. Each and every clause including every boilerplate clause needs to be considered in the context of the deal and not simply considered as standard wording.

Government enquiry into relaxing pre-emption rights by technology companies

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Since the 1980's company law has required that if a company wishes to issue new shares it must, in the first instance, offer those shares to its existing shareholders on a pro rata basis. The legislation provides that a company, if so authorised by its shareholders, can disapply these "pre-emption rights".

The Association of British Insurers ("ABI") which represents the interests of many institutional investors, issued the Pre-emption Guidelines in the wake of this legislation which stated that in any 12 month period any public company whose shares are quoted on a public market in London can issue new shares for cash other than on a pre-emptive basis, provided those shares do not constitute more than 5% of the existing share capital. Accordingly, if such a company wishes to issue shares representing more than 5% of the existing share capital in any one year (or more than 7.5% over a 3 year period) then the ABI recommend that shareholders should not waive their pre-emptive rights.

In 2001 the UK Company Law review considered the existing pre-emption rights regime and recommended that the present statutory pre-emption requirement should be retained. In Europe, pre-emption rights were one of the issues considered by the High Level Group of Company Law Experts which was tasked with considering ways in which European company law can be harmonised and improved upon. The Group published its report in November 2002 and suggested some relaxation of the current pre-emption rules, to cut down on the formal processes that need to be followed to get approval from shareholders for a waiver of pre-emption rights.

In January 2003 the Bioscience Innovation & Growth Team ("BIGT") was set up by the Government with the mandate to formulate a strategic approach to the future of the bioscience industry. In its report (Bioscience 2015) the BIGT suggested that the Pre-emption Guidelines constrain the growth of companies that seek to finance the transition from research and development to product launch. They recommended that bioscience companies should be able to issue up to 20% of new shares in any 3 year period without the pre-emption rights applying and called on the Government to press for a review of the Guidelines and, in the longer term, to support changes to the Second Directive which had initiated the original proposals back in the 1980's. In its response, the Government noted that securing the support of shareholders for any changes to the Pre-emption Guidelines would require more evidence of the benefits to shareholders of allowing greater financial flexibility. It also noted that the Pre-emption Guidelines were a matter for companies and their shareholders, but undertook to see if it could facilitate ways forward between the two parties.

This facilitation took the form of an announcement by the Government in September 2004 of the formation of an advisory group to review whether or not the current application of pre-emption rights upon the issue of new shares hinders companies from raising finance to innovate and grow their businesses.

The ABI and other institutional groupings argue that the current pre-emption regime provides an important financial and governance safeguard for shareholders, ensuring they cannot be diluted against their will by the sale of equity to third parties. They argue that a loosening of these guidelines would go against the exaltation to investors to be long termist. On the other hand the biotechnology industry complains that it is losing out to rivals in the US, where the pre-emption rights are either limited or non-existent and companies have far more freedom to issue shares to new investors. The biotechnology industry argues that its shares tend to be more volatile than other sectors and that the length of a rights offer, up to 42 days, can prejudice the success of an offering which may have to be carried out very quickly to take advantage of a sudden window of opportunity. They point to rivals in the US who have this flexibility and as a result appear to be far more successful in raising fresh funds in the public market. Not only is the current regime seen to assist US based companies, it is argued that US investors in particular have been put off investing in the UK because they often find that pre-emption rights are a complication with which they do not wish to deal.

The Myner's Committee has now published a discussion paper seeking views on specific issues, including:-

- The flexibility of the Pre-emption Guidelines such as:
 - Whether the criteria for determining whether or not to disapply pre-emption rights should be set out in the Guidelines and if so what those criteria should be.
 - Whether the "comply or explain" approach which has been adopted by the corporate governance regimes put in place over the last decade should be applied to the application of pre-emption rights.
- Directors' duties to shareholders, including:
 - Whether there is any evidence of shareholder value and abuse through non-pre-emptive issues in the US.
 - Whether the UK should move to a US style "liability approach", relying on litigation through class action to obtain compensation, rather than relying on the current "property approach" which confers an absolute right on minorities to avoid dilution.
 - If not, whether the current property approach could be more flexible and allow a company to choose from various pre-emption right options (regimes that allow 5%, 10%, 20% or other limits to other non-rights issues, where the market would price the shares accordingly).
- The feasibility of other capital raising models, such as whether they offer a practical way around the pre-emption problem, in terms of size of issues and speed and relative costs. For example, although reference is made above to the fact that it can take up to 42 days for a rights offer, it can take 21 days for a placing. On the other hand the mandatory convertible loan stock, more colourfully known as a "trombone rights issue", allows funds to be drawn down on specific events such as an acquisition or the passing of a crucial stage in drug development. Once the hurdles are passed, the loan stock converts into equity. It may well be that structures like this are better suited to biotechnology companies.
- Capital raising in the US, including where the balance of advantage lies between the constraining effects of pre-emption rights and their safeguarding of shareholder value and owner's rights; and why the lack of pre-emption rights and other jurisdictions apparently does not deter UK investors and what price is placed on the additional risks.

The consultation paper notes that the purpose of capital issues is to raise additional cash, not to introduce investors to the share register, but this seems to miss the point that before significant new investors can be introduced to the share register it is necessary to go through the pre-emptive process if a company is seeking to issue shares which constitute more than 5% of its issued share capital in a 12 month period. Given the need for regular funding rounds for many biotechnology companies this percentage figure is almost always likely to be exceeded and therefore the need to comply with the Pre-emption Guidelines is likely to be a hindrance to such fund raising efforts.

The reaction to the discussion paper from those in the City has been favourable which suggests that the changes sought by the biotechnology companies might not be forthcoming. However, comments in the paper that more flexibility might need to be introduced to the guidelines and an acknowledgement that the comply or explain regime may well be the way to ensure that there is not an abuse of such flexibility give some hope to biotechnology companies that changes may well be forthcoming.

Responses to the discussion paper must be received by 15 December and a final version is intended to be delivered by early next year. The discussion paper is available on the DTI web site http://www.dti.gov.uk/cld/pdfs/11_02_discussion_paper.pdf

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After nearly six months of e-mails, conference calls and flying visits, the Term Sheet is finally signed. Thank goodness. There hasn't been an announcement for some time, and now there is some positive newsflow. The arrangement with the US licensee looks good and will help the stock price.

Does this sound familiar?

The Business Development and R&D teams have worked hard and long. The final deal was shown to the CEO and CFO and both said it looked fine. It was not discussed with external lawyers, for various reasons. They can be long winded, do not really understand the business need and anyway at this stage, as it's only a Term Sheet, legal help is not really needed.

The Term Sheet had the following terms:

1. The Licensee had rights to certain patents, to be finalised.
2. The term of the licence was for the life of the patents that were to be licensed.
3. The licence was to be exclusive
4. It was a worldwide licence.
5. An upfront payment of \$5m was to be made, and thereafter payments would be due on the achievement of certain milestones. Following development, royalties would be paid on sales of the products.
6. Disputes would be settled by mediation: in the US if the English licensor wished to bring a claim and in the UK if the US Licensee wished to bring a claim
7. The law of the contract is England and Wales.

Reading though these terms, it all looks fairly clear and straightforward: A worldwide exclusive licence to certain patents, with an upfront payment together with milestones and royalties based on sales. The parties expected the negotiation of the full licence agreement to take several weeks. However, having given the term sheet to their lawyer, in order to start drafting the final agreement, the Company realised that things were not so straight forward. After reading through the Term Sheet, there was a list of preliminary questions

- Was the licence for patents and patent applications or just granted patents? ("The IP")
- Which IP was actually to be licensed?
- Presumably the licence was to all IP in the respective field of use.
- What for? What is the field of use?
- What could the IP be used for? Development, manufacture, use and/or sale?
- Did the licence include any improvements made to the IP during the term of the licence? Did it to include divisionals and/or Continuations in Part? If not, could the Licensor develop a similar product under that non-licensed IP which could compete with the licensed product?
- Did the licence include the right to grant sub-licences? If so, were the sub licensors, bound by the same terms as the head licence or did the licensee have some freedom in terms of the contract obligations?
- What were the milestones? When would they be payable? Who decides the triggering events for payment? Are milestones refundable against royalties or not? How much were the future royalties? What were the royalties to be paid against? Are " sales", end-user sales or sales to the wholesaler? Are the sales figures the net sales value or gross?

It was soon apparent that depending on the answers to some of these question, the deal which looked so good, could either just about break even, or in the worst case could actually operate at a loss.

Lawyers who know your industry, understand your timetable and are brought in earlier enough can really help to make your business grow.

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Reviewed

The scope of legal advice privilege is restored - but who is the client? [Back to contents](#)

The House of Lords decision in *Three Rivers District Council and others v The Governor and Company of the Bank of England* given on 11 November 2004, has provided a welcome return to a wider test for legal advice privilege.

Communications that are subject to legal professional privilege are protected from production not just in legal proceedings, but also in investigative actions by regulators and in other non-adversarial contexts. Privilege is intended to ensure that a client can consult freely with his legal advisers without fear that others can use his admissions or discussions against him.

There are two branches of legal professional privilege in England: litigation privilege and legal advice privilege. Litigation privilege applies when litigation exists or is in prospect. It protects confidential communications passing between a client and his lawyer (or either of them and a third party) that were created for the dominant purpose of obtaining or giving legal advice in relation to that litigation or for the collection of evidence. Legal advice privilege protects confidential communications passing between a client and his lawyer where the dominant purpose is to obtain or give legal advice. It applies whether or not litigation is anticipated.

The Court of Appeal ruling in the *Three Rivers* case as to the ambit of legal advice privilege caused particular concern and attracted much legal comment. In the course of proceedings, the liquidators of BCCI sought disclosure of documents passing between the Bank of England and its lawyers relating to an enquiry that was held to investigate the collapse of BCCI. The Bank conceded that litigation privilege did not apply, as there were no proceedings, simply a non-adversarial inquiry. It resisted disclosure of various categories of communications with its lawyers, however, on the basis of legal advice privilege. The Bank had set up a unit comprised of three senior officials (known as the Bingham Inquiry Unit ('BIU')) to co-ordinate its response to the Bingham Inquiry and seek legal advice from the Bank's lawyers in this regard. In a previous application ('*Three Rivers* (No. 5)'), the Court of Appeal had determined that for the purpose of legal advice privilege, the 'client' was not actually the Bank of England and any of its employees, but was limited to the BIU. It therefore granted the liquidators disclosure of communications that were created by employees of the Bank other than the BIU. It concluded that as such communications were made by those who were not the 'client', they constituted no more than raw materials on which the BIU would seek advice, or were communications with third parties and were not privileged. Consequently, only those particular employees designated to request or receive legal advice could be said to be "the client" in this context. Alternatively, they held that the dominant purpose of the majority of documents was to seek and obtain presentational rather than legal advice, namely advice as to how the Bank could best comply with its duty of putting all relevant factual material before the enquiry.

As a result of this alternative finding that many of the documents related to presentational matters and were not privileged, the liquidators then sought disclosure of materials that it had previously assumed were privileged, namely communications between the BIU itself and the external solicitors. On this application, the Court of Appeal found in the liquidator's favour, concluding that broad protection would only be given to confidential communications where the solicitor-client relationship was formed for the dominant purpose of obtaining advice or assistance in relation to legal rights or liabilities. Since the dominant role of the Bank's solicitors was simply to advise on the preparation and presentation on evidence to the enquiry so as to portray the Bank in the best possible light, the majority of documents were not on the face of it privileged. Prior to this judgment, it was considered that such documents would have been privileged. The Court of Appeal appeared to be restricting the ambit of the privilege on the basis that the role of solicitors had expanded and that therefore it was no longer justifiable to attach privilege to all communications between a solicitor and a client relating to the solicitor-client relationship.

In its judgment, the House of Lords, had the opportunity to address the two important issues raised by the Court of Appeal in relation to legal advice privilege:

- (i) is the "client" restricted to a narrow group of an organisation's employees, such as the BIU, or may a much wider group of employees claim that their correspondence with their organisation's lawyer is privileged?
- (ii) should the privilege apply where the advice and assistance sought did not relate to the client's 'legal rights or obligations'?

Who is the client?

With regard to the first issue, submissions by the Law Society, the Attorney-General and the Bar Council as interveners in the case demonstrated concern that the Court of Appeal had gone too far in giving such a narrow interpretation to the term "client" in determining that only the BIU was the client. In their judgments, their Lordships recognised that this issue is of particular importance for corporate clients, who can only communicate through employees or officers, but, disappointingly, they declined to deal with it. Although the views of the House of Lords on this point would not, have constituted binding precedent on lower courts because it was not strictly the subject of the appeal before it, they may well have provided welcome clarity on this important issue. At present, it is important to bear in mind that for legal advice privilege, the "client" is unlikely to be the whole company, comprised of all of its employees, or even all senior officers, but a rather a more select group, based on those chosen to communicate with lawyers on a particular issue or identified as doing so on a regular basis. Care needs to be taken, therefore, not to unwittingly limit the number in respect of whom legal advice privilege can be claimed.

The scope of legal advice privilege

On the second point, however, the House of Lords unanimously rejected the Court of Appeal's narrow interpretation that legal advice privilege only applied to communications seeking or giving advice about a client's legal rights and obligations and did not include advice, for example, as to how best to present a case before an inquiry. They concluded that communications between the Bank's external solicitors and the BIU regarding the Bank's preparation and presentation of evidence to the Bingham Inquiry were privileged.

The House of Lords returned to the test laid down in 1998 that:

"...legal advice is not confined to telling the client the law; it must include advice as to what should prudently and sensibly be done in the relevant legal context".

If, therefore, lawyers are being asked to carry out a function which necessarily involves the use of "their legal skills", communications requesting or relaying this advice are likely to be privileged. This is a much wider test. Under it, legal advice privilege can apply to advice as to presentation and public law rights. It may also apply to those whose reputation may be at risk in an inquiry even if their rights and liabilities are not in question. Advice as to presentational issues before a coroner's inquest, a statutory inquiry or an ad hoc inquiry such as the Bingham Inquiry, therefore, may well be privileged. Lord Carswell remarked:

"The work of advising a client on the most suitable approach to adopt, assembling material for presentation of his case and taking statements which set out the relevant material in an orderly fashion and omit the irrelevant is to my mind the classic exercise of one of the lawyer's skills. I can see no valid reason why that should cease to be so because the forum is an inquiry or other tribunal which is not a court of law, provided that the advice is given in a legal context".

The House of Lords acknowledged that this might mean that an inquiry would be deprived of potentially useful evidence, but that the public interest in evidence being available was outweighed by the public interest in people being properly advised on the law.

Following this judgment, privilege will doubtless apply whenever there are questions of legal rights, liabilities, obligations or remedies of the client under either private or public law. Business advice, for example, advice as to investment or financial policy, may, however, lack a relevant legal context. It was accepted that there would always be marginal cases in which it is difficult to decide whether or not there is a "legal" context, but as Baroness Hale stated

"...much will depend upon whether it is one in which it is reasonable for the client to consult the special professional knowledge and skills of a lawyer, so that the lawyer will be able to give the client sound advice as to what he should do, and just as importantly what he should not do, and how to do it."

In the current case, therefore, the "relevant legal context" was the Bingham Inquiry and whether the Bank had properly discharged its public law duties under the Banking Acts. It was accepted that advice to the Bank as to whether a public law remedy (such as judicial review) might be available to quash any critical conclusions drawn by the Bingham Inquiry would be privileged. Lord Scott considered that it made no sense to "withhold the protection of that privilege from presentational advice given by the lawyers for the purpose of preventing that criticism from being made in the first place".

In their judgment the Court of Appeal had questioned the application of legal advice privilege generally. The House of Lords, however, has reaffirmed its importance and its scope.

Practical considerations following recent decisions relating to legal professional privilege

Legal Advice Privilege

Most work undertaken in the course of a relationship between a lawyer (in-house or external) and his client is likely to be protected by privilege e.g. drafting of agreements, advising on potential liabilities to third parties, legal rights and obligations under contracts etc.

Where there is no actual or pending litigation, however, the following issues should be considered:

- **Is one of the parties a lawyer?**
 - Communications with the following can be protected by privilege if the other conditions relating to privilege are met: UK in-house counsel (currently other than in EU competition investigations), solicitors, barristers, their trainees, and foreign lawyers. Advice provided by others such as accountants, unless they are legally qualified, will not be protected by privilege.
- **Who is the client?**
 - Identify the client in the widest terms in engagement letters.
 - Be wary of using one person or a nominated group within an organisation to correspond with lawyers. Doing so may mean that only that person or group is treated as the client for the purpose of legal advice privilege. In large organisations, information is often obtained from a wide circle of employees with only a small number communicating directly with lawyers. If that group collects information from other personnel within the company for the purpose of enabling legal advice to be given, that information may not be privileged, even if obtained at the request of the lawyer.
 - Consider whether preliminary investigatory work (e.g. interviewing personnel, collecting evidence, taking witness or expert statements) should be conducted by lawyers.
 - External accountants, tax advisers etc. will **not** fall within the definition of client and, so, any communications with such parties or information obtained from them in order to obtain legal advice is unlikely to be privileged if there is no litigation in prospect.
 - Routing everything through an in-house lawyer may not suffice if he/she is not giving legal advice, but is simply acting as a post-box to enable material to be gathered for use by external lawyers. In-house counsel should consider clarifying that requests for information are made in order that both he/she **and** external lawyers can provide the legal advice in question, although this may not always be enough.
- **Is the dominant purpose of each communication to seek or give legal advice?**
 - This includes advice as to what should prudently and sensibly be done in the relevant legal context.
 - Where the communications involve both legal and other (e.g. business) advice, privilege will only be afforded where the dominant purpose of each communication at the time of its creation was to give or obtain legal advice. Avoid mixing advice and requests for advice with issues concerning business strategy or presentational issues.
 - The emphasis on the face of the document or in the substance of advice should generally be on the legal issues involved, not just the practical/ factual issues, if privilege is to apply. In-house counsel, for example, should consider incorporating their legal opinions into statements of fact.
 - Label documents "privileged and confidential", but be wary of using this term indiscriminately. It will not give a non-privileged document privileged status.
- **Only documents which remain confidential can be privileged**
 - Once confidentiality in a document is lost, privilege is lost.
 - Be wary of wide dissemination of privileged material within an organisation. Once advice is received, privilege should attach to documents evidencing such communications that are disseminated internally provided that confidentiality is maintained. This will be a question of fact. Dissemination to those who do not need to know is likely to result in waiver of privilege.
 - Avoid revealing even parts of privileged documents to parties who do not need to see it: this may result in loss of confidentiality and waiver of privilege in the whole document.
- **Copies**
 - Copies of privileged documents will only be privileged if they too are made for a privileged purpose. Copies of non-privileged documents may be privileged if they are made for a privileged purpose and if you do not have the original in your possession.

Litigation privilege

- This privilege may only be asserted where litigation is 'reasonably in prospect'.

In the recent case of *USA v (1) Philip Morris Inc & Ors (2) British American Tobacco (Investments) Ltd*¹, the US Government wished to ask one of BAT's UK external lawyers questions regarding BAT's document management policy in the context of the Government's action against several tobacco companies in the US. BAT sought to assert litigation privilege over communications between itself and its external lawyers. Although at the time of these communications there were no actual threatened claim in England, there was substantial and increasing tobacco litigation in other jurisdictions, including approximately 200 actions in the USA. BAT contended that it expected to be sued in the USA and in other jurisdictions at the time of the lawyer's retainer. The Court of Appeal, however, held that a "mere possibility" of litigation was not enough to establish litigation privilege. They upheld the view of the judge at first instance that a "distinct possibility that sooner or later someone might make a claim" was insufficient. No claim had been "made or even threatened" and the fact that BAT considered it was desirable to put its house in order because of a "general apprehension of future litigation" did not satisfy the test.

- Consider making clear notes of any threatened claims so that litigation privilege can be invoked at the earliest stage.
- The communications in question must be made for the preparation or conduct of litigation involving the solicitor's own client for litigation privilege to apply. Adversarial proceedings "destined...for a contested hearing in a court or court like body" are required. In *USA v Philip Morris and BAT*, the Court of Appeal ruled that litigation privilege could not be claimed by the non-party (the lawyer of a BAT subsidiary not party to the action) who was ordered to produce relevant documents by way of letter of request for the purpose of an action in which he was not involved.

¹ [2004] EWCA (Civ) 330

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Life science and healthcare events

News from the LSH Group

On Wednesday 20 October 2004 three members of Taylor Wessing's Life Sciences and Healthcare Group (Mark Hodgson, Marjan Noor and Nigel Stoate) held a breakfast briefing at the Whitehall offices of the Association of the British Pharmaceutical Industry (ABPI) for an audience of approximately 50 people comprising representatives from leading pharmaceutical companies as well as service providers to the pharmaceutical industry. It was an inter-active presentation on the theme of 'EU Enlargement 6 months on'. Among the topics reviewed were the 'specific mechanism' in the Accession Treaty, Roche/Bolar, Community Trade Marks and Data Package Exclusivity.

A team of Taylor Wessing lawyers lead by LSH Group partner Simon Walker recently advised the shareholders of DNA Research Innovations Limited on the sale of their company to NASDAQ-listed Invitrogen Corporation.

Mark your calenders

On Tuesday the 30 November 2004 Taylor Wessing in association with the Jewish association for business ethics are holding a Patents and Ethics seminar " Whose idea is it anyway?" - the ethical issues of Intellectual Property. Speakers include The Hon. Sir Hugh Laddie, UK high Court judge and Dr Howard Rosenberg, head of pharmaceutical patents, Merck generics. LSH group partner Simon Cohen chairs the seminar. If you would like to attend this seminar please contact JABE on tel. 020 8200 8007 fax 020 8200 8061 E-mail info@jabe.org or Simon Cohen at s.cohen@taylorwessing.com

Dr Malcolm Bates is speaking about IP due diligence at Euro legal's BioPharm Licensing conference in London on Tuesday 30 November.

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