

October 2007

# InFocus

Life sciences & healthcare legal e.bulletin



## Introduction

This is the 17th issue of InFocus, Taylor Wessing's life science and healthcare e.bulletin.

Key issues discussed include:

- The importance of setting out the basis on which approval under a licence can be withheld
- A recent CFI case which reaffirms that communications between in-house counsel and internal clients are not privileged
- Consolidation often means redundancies - how to deal with them
- Recent ratification of the London Agreement by France – what now?
- The Penalties Regulation – does it mean double trouble?
- Apotex's recent award of a compulsory licence in Canada to export to Rwanda
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# Key features

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### Overview

In the case of *Lymington Marina Ltd v Macnamara and others* [2007] EXCA Civ 151, the Court of Appeal examined the scope of a clause in a licence allowing a licensor to refuse to approve a proposed sub-licensee. The licence in question granted the licensee a right to berth a yacht in the licensor's marina.

The Court of Appeal held that the grounds on which the licensor could withhold its approval were limited to those which relate to the proposed sub-licensee himself and which arise out of his proposed use of the marina. A term should be implied in the licence that the licensor must exercise its power to withhold approval in good faith and should not withhold it arbitrarily, capriciously or in bad faith.

In construing the licence to assess the scope of the licensor's power to refuse to approve a proposed sub-licensee, the Court of Appeal looked at the express wording of the licence. In contrast to the power to withhold consent to sub-license, which expressly required the third party sub-licensee to be approved by the licensor, the licence stated that the licensor could withhold consent to assign the licence in its "absolute discretion".

### Case Summary

A company called Lymington Marina Limited ("L") had granted a 98 year licence to berth a yacht in its marina. The licence was, at the time the dispute arose, in the name of Bingham Macnamara ("B"). B wished to grant sub-licences to use the berth to his two brothers on a rotational basis. L brought an action for a declaration as to the scope of its powers under the licence to refuse a request to sub-license.

The licence contained two provisions of relevance relating to assignment and sub-licensing:

*"The Licensee may:*

*3(k)(i) assign this Licence as a whole (but not any of the rights hereby granted separately) to an assignee approved by the Company which approval **may be granted or withheld at the Company's absolute discretion.**" [Emphasis added]*

*"3(k)(ii) authorise a third party to exercise all the rights hereby granted as a whole but not any of the rights hereby granted separately for a period of not less than one month and not more than twelve months PROVIDED ALWAYS that such third party shall first be **approved by the Company.**" [Emphasis added]*

### First instance decision

At first instance, the judge held that B's right to grant sub-licences of his mooring rights under the licence was subject to three restrictions: (i) the sub-licence should be of all B's rights for the period of the sub-licence, (ii) the term of any sub-licence should be between one and twelve months, and (iii) the sub-licensee should be approved by L.

In relation to clause 3(k)(ii), the judge held that L could not decline to approve a sub-licensee except on grounds concerned with the identity of the sub-licensee in relation to his proposed use of the marina. L was not entitled, under the terms of the licence, to decline to approve a sub-licensee simply to protect its own commercial interests. The power of approval had to be exercised in good faith on relevant grounds. The judge accepted both parties' submissions that there was no duty on L to give reasons for a rejection of a proposed sub-licensee, although he noted that the court could infer from a failure to give reasons that no such reasons existed.

### Court of Appeal decision

L appealed the decision of the High Court. One of the issues which arose on appeal concerned the scope of L's power to decline to approve a third party sub-licensee under clause 3(k)(ii) of the licence.

The Court of Appeal considered that there were two material questions to be answered on this issue:

1. Is L's power to refuse to approve a sub-licensee restricted to grounds related to the particular sub-licensee?
2. Is the power to refuse to sub-license subject to any restrictions, such as that it must be exercised in good faith, and for grounds related to the grant of the sub-licence?

In essence, the first question considers the scope of L's power, and the second question examines the manner in which the power can be exercised.

### Scope of the power to refuse to approve a proposed sub-licensee

On the first question, the Court of Appeal looked at the meaning of clause 3(k)(ii) in the context of the licence as a whole. In particular, Lady Justice Arden, who gave the leading judgment in the case, held that the express wording of clauses 3(k)(i) and (ii) made it impossible to find that there was no distinction between L's power to refuse under the two provisions. Clause 3(k)(i) clearly gave L a power to withhold its approval in its absolute discretion. Furthermore, clause 3(k)(ii) expressly states that it is the **proposed third party sub-licensee** for whom L's approval is required – it says nothing, for example, about the terms of the sub-licence. Although the Court of Appeal approved of the first instance judge's finding that L could not approve a sub-licensee on the basis that the grant of such a sub-licence would be contrary to L's commercial interest, it held that this should be subject to a caveat: L could refuse to approve a sub-licensee where L's commercial interests coincide with the reasons for refusal of a sub-licensee on grounds related to that particular sub-licensee.

For example, if a particular sub-licensee was known to have avoided paying mooring fees previously, this could suggest that they would avoid paying such fees under the sub-licence, and this would be an acceptable reason for L to refuse to approve that particular sub-licensee. Such a refusal would be based not only on grounds relating to the particular sub-licensee, but also on the basis that allowing the grant of such a sub-licence would be contrary to L's commercial interests.

### Manner in which the power can be exercised

In relation to the second question, the Court of Appeal asked whether a term should be implied into clause 3(k)(ii) so that, even if L exercised the power not to approve a proposed sub-licensee for reasons related to the identity of the proposed sub-licensee, the exercise of the power could be set aside if the grounds of refusal of approval were, for example, in bad faith or wholly unreasonable. Lady Justice Arden applied the "business efficacy" test in assessing whether such a term should be implied. The test states that a term is only to be implied if it is so obvious that reasonable parties would not have thought it necessary to include it or if the implication of the term is necessary to give the contract business efficacy.

The Court of Appeal held that there was an implied term in the licence that L must exercise its power to withhold approval in good faith and should not withhold it arbitrarily, capriciously or in bad faith. Any refusal of approval by L does not need to be objectively justifiable – such a term would be onerous on L and so would not have been implied by the business efficacy test. The Court of Appeal concluded that all L needed to do was to consider any application for approval made to it – there was no obligation on L to seek out other facts in relation to the approval request.

## Commentary

This case emphasises how important it is for parties to a licence to agree the basis on which approval under a licence, be it for sub-licensing, assignment or anything else, may be withheld by a licensor.

If a licensor wishes to have the power to refuse to allow sub-licensing, the licence should state expressly that the licensor has "absolute discretion" to withhold its approval. Where sub-licensing is to be subject to the licensor's "approval", the licence should set out clearly what aspect of the proposed sub-licensing requires the licensor's approval (for example, the identity of the proposed sub-licensee or the terms of the sub-licence). In the absence of an express term agreeing the manner in which the licensor can exercise its power to grant or refuse such approval, a court will imply a term into the licence that the licensor must exercise the power in good faith and must not withhold approval arbitrarily.

*Tim Worden*

# Legal professional privilege, in-house counsel and European Commission competition investigations

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## Summary

The practical issues facing in-house counsel in relation to claims of legal professional privilege during European Commission competition investigations resurfaced in the recent decision of the Court of First Instance in joined cases T-125/03 & T-253/03, Akzo Nobel Chemicals Ltd and Akcros Chemicals Ltd v Commission of the European Communities. Key points include:

- The procedure to be followed when privilege is claimed during an investigation.
- The scope of legal professional privilege in competition investigations.

## Background

In 2003 the European Commission carried out a dawn raid at the premises of Akzo Nobel Chemicals Limited ("Akzo") and its subsidiary, Akcros Chemicals Limited ("Akcros"). During the raid, a dispute arose as to whether certain documents were protected by legal professional privilege. The documents included a typewritten memorandum containing information gathered by the general manager in the course of internal discussions with other employees in connection with a competition law compliance programme, and also two e-mails between the general manager and the in-house lawyer at Akzo responsible for competition law. In due course, Akzo and Akcros brought actions against the Commission before the Court, whose decision shed some light on the question of procedure during an investigation, and also revisited the scope of legal professional privilege.

## Investigation Procedure

There are now clear guidelines for dealing with a claim of privilege during a competition investigation.

- If a company claims that a document is privileged, then it must provide Commission officials with relevant material demonstrating that the conditions for privilege are satisfied. The mere assertion of privilege will not be sufficient. However, this does not mean that the company must disclose the contents of that document.
- In some cases, a cursory look by Commission officials at the document will enable them to determine whether the document is protected by privilege. In other cases, however, even a cursory look may give the Commission access to privileged information.
- If a cursory look at the document is impossible without revealing privileged information (and if the company gives the Commission appropriate reasons for that view) then the company is entitled to refuse Commission officials even a cursory look at the document.
- If the Commission believes that the company's information or material does not prove that the document is privileged, then Commission officials may place the document in question in a sealed envelope and remove it with a view to a resolution of the dispute.
- In any event, where the Commission is not satisfied with a company's explanation as to why a document is covered by privilege, the Commission must not read the contents of the document before it has allowed the company to refer the matter to the Court.

## The Scope of Privilege

In relation to the scope of privilege, the Court essentially applied the reasoning from the decision in *AM & S v Commission* (Case 155/79). Documents will gain the protection of legal professional privilege where they are made for the purposes of the exercise of the client's right of defence, and they emanate from independent lawyers.

- Independent lawyers. In *AM & S*, independent lawyers were held to be those not bound to their clients by a relationship of employment: communications with in-house lawyers had been expressly excluded from the protection of privilege. The matter of independence was at stake in *Akzo* because the documents included communications with a member of the in-house legal department. *Akzo* and a number of interveners presented the Court with a range of arguments in favour of extending the scope of legal professional privilege to in-house lawyers beyond that which had been set out in *AM & S*. The Court, however, was not persuaded. In *AM & S*, communications with in-house lawyers had been expressly excluded from the scope of privilege, and they were excluded again in this case.
- Internal and preparatory documents. It should be noted that privilege will also extend to internal company documents reporting the text or content of communications with independent lawyers containing legal advice. Certain preparatory documents, if made exclusively for the purpose of seeking legal advice from an independent lawyer could also be protected by privilege. However, in order to enable the Commission to carry out its investigations effectively, the protection of preparatory documents by legal professional privilege will be construed restrictively by the Court.
- Compliance documents. Simply because a document has been drawn up under a compliance programme does not mean that it will automatically benefit from the protection of privilege. It would be necessary to demonstrate that the document had been prepared with the exclusive purpose of seeking legal advice in exercise of the rights of defence. Discussing a document with a lawyer would not be sufficient to ground the claim of privilege.

### Comment

Regarding communications with in-house counsel, the Court did little more than confirm the earlier *AM & S* decision and did not develop new law in *Akzo*. However, the decision is a useful reminder that internal communications between a company and its in-house legal department will not be protected by privilege, and in-house counsel (especially in jurisdictions where communications with in-house lawyers generally attract privilege) must develop procedures for dealing with competition law communications in order to minimise potential disputes during investigations.

The Court has now clarified the procedure to be followed during an investigation. Under some circumstances, companies may refuse the Commission even a cursory look at a document during an investigation. However, companies should resist any temptation to use this procedure as a delaying tactic. The Court noted that the Commission has the power to penalise a company for excessive tactical use of the privilege procedure, or take such behaviour into account as an aggravating circumstance when calculating the level of any fines to be imposed.

The decision has attracted a substantial degree of criticism from industry, bar councils and law associations. It is regarded as controversial, and is likely to be appealed. The scope of legal professional privilege in Commission competition investigations has not yet reached a final conclusion.

*Stephen Whitfield*

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## Mergers and Acquisitions and the Risk of Redundancies [Back to contents](#)

Increased competition has resulted in the creation of international pharmaceutical heavyweights over recent years following a number of mergers and acquisitions. This is a trend, which seems set to continue. Merging with a complementary pharmaceutical company can have major advantages in terms of business expansion and financial security. However, there will almost certainly be an element of overlap between the merging companies, which will inevitably lead to redundancies.

This article looks at the issues to be taken into consideration when dealing with such redundancies.

### Unfair dismissal

Employees with 51 weeks or more continuous service have the right not to be unfairly dismissed. For such employees, following a fair consultation procedure before dismissal is essential in defending an unfair dismissal claim and avoiding liability for compensation of up to £60,600 per employee. The following points should be addressed as part of a fair redundancy consultation procedure.

### Selection Criteria

Mergers often result in the need to reduce the number of employees within specific departments or locations as complementary companies invariably have common interests in the market in which they are active. Employees who carry out identical or similar roles in departments, which are overstaffed following a merger, form a "pool" from which those who are to be made redundant should be selected.

Objective selection criteria should be established in order to identify which employees are provisionally selected for redundancy. Selection criteria commonly adopted by employers include skill and experience, qualifications, performance and disciplinary records but ideally a combination of these factors should be used.

### Collective Consultation

A pharmaceutical company merger will often involve collective dismissals, that is the dismissal of 20 or more employees at the same establishment over a period of 90 days. For collective dismissals, the main provisions to bear in mind are as follows:

- A company should consult with appropriate trade union or employee representatives about the redundancy scenario;
- Consultation should take place in "good time", and at least 30 days in advance of the first dismissal taking effect (or 90 days if there are 100 or more redundancies). Following European case law in this area, the safest option would be for the company to consult at least 30 (or 90) days in advance of the first notice of dismissal being served;
- In the absence of a recognised independent trade union, consultation must take place with employee representatives of the employees at risk of redundancy (there are statutory guidelines regarding the election process for representatives);
- Failure to comply with the statutory duty to consult collectively may result in a protective award for any affected employee of 90 days' pay. This may be in addition to unfair dismissal compensation as referred to above.

### Individual Consultation

Together with the obligation to consult collectively, in order to avoid an unfair dismissal claim employers need to consult individually with employees (regardless of the fact that the statutory dismissal procedures do not apply where 20 or more employees are being dismissed).

Consultation should be meaningful and undertaken with a view to reaching agreement with consideration of ways of avoiding dismissal, which includes identifying whether there are any suitable alternative positions for the individual at the company.

### The Consultation Process

The main steps, which should be followed in a redundancy consultation process, are set out below. When dealing with a collective redundancy scenario, a company should consult employee representatives from step 3 onwards:

1. Identification of the departments where a reduction in the number of employees is proposed;
2. In a collective redundancy scenario where the work force is unionised or there are existing employee representatives, consult with the representatives about the proposed redundancies;
3. Make a general announcement to the affected departments that the company is considering making redundancies but reassuring employees that no one will be made redundant until a fair consultation process has been followed;

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4. In a collective consultation scenario where there are no existing employee representatives, organise elections for employee representatives;
5. Ask for volunteers for redundancy;
6. Establish objective selection criteria and attempt to agree the criteria with the employees or their representatives before they are applied. Consider whether it is appropriate to offer employees who have been identified as redundant the right to remain at home during the consultation process;
7. Consider whether any suitable alternatives exist for the employees who are selected for redundancy in other departments within the company or its wider group if applicable;
8. Consult individually with the employees about their thoughts on the redundancies and discuss their ideas on suitable alternatives;
9. Notify the DTI where 20 or more employees are to be dismissed at one establishment within a period of 90 days. Notice must be provided to the DTI 30 days before giving notice to terminate an employee's contract of employment if 20 to 99 employees are to be dismissed or at least 90 days before giving notice of dismissal where 100 or more employees are to be dismissed;
10. Issue dismissal notices to the employees.

## Payments

On termination of employment, all redundant employees will be entitled to the following:

- Salary to the date of termination together with any accrued but untaken holiday pay;
- If the company does not require the employee to work out their notice period, payment representing salary in lieu of the contractual notice period; and
- Those employees with more than two years' continuous employment at the date of termination will be entitled to a statutory redundancy payment calculated in accordance with their age, length of service and gross weekly pay up to the statutory maximum of £310 per week. The maximum possible payment is £9,300 per employee, based on 20 years' service.

Employees may also be entitled to an enhanced redundancy payment under a company's redundancy policy.

The guidance given above is of a general nature only – specific legal advice should be sought in each redundancy scenario. The main point to remember is that no employee should be informed that they are redundant until a fair consultation period has been carried out. It is possible that they are provisionally selected for redundancy before then, but confirmation of redundancy should be seen as a last resort and only made once all alternatives have been assessed.

*Nicola Goodey*

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# In brief

## London Agreement is now a reality [Back to contents](#)

A significant development in reducing the cost of prosecuting European patents to grant has been achieved through France's ratification of the London Agreement. The London Agreement represents something of a triumph for the European patent community, it only having been conceived in 1999, agreed in 2000 and yet it has already acquired sufficient numbers of ratifications by participating states for it to enter into force sometime next year<sup>1</sup>.

The advantage of the potential multi-jurisdictional coverage of a patent filed under the European Patent convention (EPC) carries with it an associated financial burden. Patents granted by the EPO are approximately three times more expensive than in Japan and up to five times the cost of those in the US. For a European patent translation, costs account for about one third of its total cost. This is, in the main, due to the requirement under Article 65 EPC, to translate a European patent into the official language of an EPC contracting state within a short time of grant in order for the patent to enter into force in that contracting state. In contrast, patents in Japan and in the US do not require any translations. Although only a minority of EPC contracting states have to date agreed to enter into the London Agreement, the anticipated cost savings are expected to be significant with savings on translation costs for "typical" European patents<sup>2</sup> being 45%. Obviously, the greater the number of EPC contracting states that participate in the London Agreement, the greater will be the cost saving associated with obtaining a patent grant across those EPC contracting states. There is also the hope that as more countries contract into the London Agreement, patentees will be encouraged to take patents to grant in more EPC contracting states, increasing the coverage of the patent right.

The London Agreement was entered into at an intergovernmental conference in London in October 2000<sup>3</sup>. This agreement focuses on amending Article 65 EPC which gives contracting states the right to impose a requirement that a translation of a European patent into the official language of that state be filed within a specified period after grant. If this is not done, then the patent is deemed void ab initio in that contracting state. Virtually all contracting states have transposed this requirement into national law, for example, in the UK this is achieved via section 77(6) Patents Act 1977. The London Agreement now gives contracting states the "option" of choosing to forego the translation of granted European patent under EPC into their official language if (a) one of their official languages is English, French or German or (b) if they have "designated" one of these languages as their official language.

Article 1(1) London Agreement provides that any contracting state having an official language in common with one of the official languages of the EPO (English, French or German) can dispense with the translation requirements according to Article 65 EPC. However, under Article 14 EPC, the requirement to translate the claims into all three EPO official languages remains. This means, for example, that for patents prosecuted and granted in German or French, if countries with English as their official language do not require translation into English (through the London Agreement), then it is only the claims that will be available in English.

Article 1(2) London Agreement further provides that those contracting EPC states that are party to the London Agreement and have no EPO official language as their official language may designate one of these official languages. Then, if the European patent is not granted in this designated official language, these states can require this to be done. Further, under Article 1(3) such states may still require a translation of the claims into that country's official language under Article 65(1) of the EPC<sup>4</sup>. Practically, this means that, for example, in Denmark, translations of granted European patents would be required in English, with claims also filed in Danish.

The Agreement has been entered into by 11 EPC states<sup>5</sup>, but before it could come into force it had to be ratified by eight of the signatories, and these had to include the UK, France and Germany. This has now been done<sup>6</sup> and it is

<sup>1</sup> The status of the agreement can be monitored at <http://www.epo.org/patents/law/legislative-initiatives/london-agreement/status.html>

<sup>2</sup> The EPO's own literature considers such patents to be those granted in seven contracting states and requiring translation into five different languages.

<sup>3</sup> The agreement can be found at [http://documents.epo.org/projects/babylon/eponet.nsf/0/595FE5E1FC71DD4FC12572BC0058E29D/\\$File/Agreement\\_17102000.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/595FE5E1FC71DD4FC12572BC0058E29D/$File/Agreement_17102000.pdf)

<sup>4</sup> Such regimes are set to come into force in both Denmark and Sweden

<sup>5</sup> Denmark, France, Germany, Iceland, Latvia, Liechtenstein, Luxembourg, Monaco, the Netherlands, Sweden, Slovenia, Switzerland and the UK

<sup>6</sup> At the time of writing, the instrument of ratification had been adopted by the French National Assembly and the French Senate was expected to confirm this on 9 October 2007.

expected that the agreement will come into force in these countries through the first half of 2008. There are also reports that Latvia and Belgium are considering ratifying the agreement. Obviously, the greater the number of EPC contracting states that participate in the London Agreement, the greater will be the cost savings involved for patentees seeking patent protection through those states<sup>7</sup>.

One point of detail that could lead to some confusion lies in the voluntary nature of most of the provisions of the London Agreement. In creating a relatively benign, non-prescriptive document, that was probably gauged to cause the least political angst to EPC contracting states' governments, a regime has been introduced that includes several measures to which parties entering into the agreement can opt in or out. For example, the requirement to file claims in the official language of the contracting state is optional, as is the requirement to file a translation of the patent upon commencement of litigation on the patent in a particular contracting state<sup>8</sup>. Whilst giving contracting states freedom to choose the elements of the agreement that they wish to contract into, these options may result in a patchwork of measures through London Agreement participating states such that patentees need to be alive to the particular legislative regimes in each state (in particular the Article 2 translation requirement prior to litigation may catch some patentees out). Whether this will be a real issue is debateable as it is envisaged that most, if not all, participating states will require both a translation of the claims on grant and the litigation translation when enacting laws to implement the agreement.

In summary, it is anticipated that the London Agreement will lead to typically broader patent coverage and cheaper patents within Europe. Given the near interminable problems being experienced by the Community Patent project, the entering into force of the London Agreement is to be welcomed as one of the most significant developments in the prosecution of European patents since the EPC itself in 1973.

*Dr Gareth Morgan*

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## Compulsory Licences and access to Medicines – the Rwanda experience [Back to contents](#)

Rwanda has recently become the first country to make use of the new compulsory licensing provision, 31bis of TRIPS. Canadian company Apotex Inc. has been awarded a compulsory export licence under the provisions to supply a combination AIDS drug to satisfy Rwanda's health needs. Previously, countries have awarded compulsory licences internally and relied upon either a domestic manufacturer or manufacturers from countries where no patent protection exists. So, will this case lead to more countries using these provisions to obtain cheap supplies of its required drugs or have the delays experienced by Rwanda and Apotex demonstrated the problems that exist with the provisions as they stand?

### Background

Article 31 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out provisions that apply to the use of the subject matter of a patent without the authorisation of the patent holder. In particular, article 31(f) provides that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use". Whilst least developed countries (listed by the UN) are not obliged to implement Section 5 of Part II of TRIPS, which includes article 31, until 1 January 2016, under the WTO Decision of 27 June 2002, if they are unable to manufacture themselves, a country could not import the drug as a result of this article. Article 31(f), therefore, effectively prevents the supply of patented medicines to countries that do not have the capability to manufacture them.

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<sup>7</sup> There are now over 30 EPC contracting states with Norway set to join soon, see <http://www.epo.org/about-us/epo/member-states.html>

<sup>8</sup> Article 2 London Agreement

Paragraph 6 of the Doha agreement, which was adopted on 14 November 2001, recognises that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." The WTO Council were instructed to find an expeditious solution which it did by its decisions of 30 August 2003 and 6 December 2005, which allowed compulsory export licences to be granted in certain circumstances. Applicants must have made efforts to obtain authorisation directly from the rights holder and the export licences granted must, inter alia: be non-assignable; specify the amount of product to be manufactured and the duration of the licence; limit export to only the countries specified; and provide for remuneration to the patentee. The Decision of 6 December 2005 permanently added article 31bis to the text of the TRIPS agreement.

The provisions have now been implemented in a number of countries. In the EU, Regulation 816/2006 was adopted on 17 May 2006 so the provisions apply in the UK. In Canada, the provisions have been implemented by Canada's Access to Medicines Regime (CAMR).

### Rwanda's Notification and Apotex's Compulsory Licence

On 19 July 2007, Rwanda notified the WTO that based on its public health needs, Rwanda expected to import 260,000 packs of TriAvir (a combination of Zidovudine, Lamivudine and Nevirapine used to treat HIV/AIDS) over two years. The manufacturer was named in the notification as the Canadian company, Apotex Inc.

Apotex was unable to agree a licence with the patentees: GlaxoSmithKline, Shire and Boehringer Ingelheim. It therefore made an application under CAMR for an export licence. On 20 September 2007, The Federal Commissioner of Patents granted a compulsory licence to Apotex to supply TriAvir to Rwanda.

Apotex was critical of the "unnecessarily complex" system and claimed that it did not "adequately represent the interests of those who require treatment". GSK and Shire did not oppose the application but did not grant a voluntary licence, forcing Apotex to make an application. Despite ApoTriAvir being approved by Health Canada in August 2006, there was significant delay in the granting of the compulsory licence

### Why did Rwanda need to notify?

Rwanda is listed on the UN's list of least developed countries. So, according to at least one commentator, it doesn't technically need to notify the WTO of its desire to be an eligible importing member under paragraph 1(b) of the Annex to the TRIPS agreement because least developed countries are included as of right. The reason behind the notification, however, is more likely to be from the point of view of Apotex, the exporter. Article 31bis of TRIPS states that article 31 will not apply if the export is to an eligible importing member in accordance with the terms of paragraph 2 of the annex. Paragraph 2(a) requires the eligible importing member (including a least developed member) to have made a notification to the Council. So, whilst a least developed member does not need to comply with article 31 or 31bis itself, if it wants to be supplied by an exporting member, it appears that it is necessary to notify the Council so Rwanda's actions were necessary.

### Other recently granted compulsory licences

On 29 November 2006, Thailand issued a compulsory licence, also for an HIV/AIDS drug. The government issued the compulsory licence to import Merck's drug efavirenz from India to supply 200,000 people a year for five years (until 2011). Merck will receive 0.5% of the total sale value and the generic product. There has been criticism of Thailand for not negotiating with the patentee prior to granting the compulsory licence. The government stressed however that it is seeking to address a public health emergency and the material imported will be used for a non-commercial public treatment program. In these circumstances, there is no obligation to negotiate with the patentee under article 31(b). The obligation is to inform the patent holder of the licence as soon as is practicable. Moreover, Thailand referred to paragraph 6 of the Doha declaration which recognises the difficulties facing WTO members with insufficient or no manufacturing capacities.

Similarly, Brazil awarded a compulsory licence to import efavirenz from India on 4 May 2007. Brazil only took this step after two years' negotiations with the patentee, Merck.

In neither case was there a need to use the provisions under article 31bis because there is no patent protection for efavirenz in India so no exporting licence was necessary.

Zambia granted a compulsory licence to a Zambian national company on 21 September 2004 for a triple combination

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AIDS therapy containing lamivudine, stavudine and nevirapine. The compulsory licence was to last until the state of emergency, which was declared on 3 September 2004, was over. The patentees receive a 2.5% royalty.

Indonesia granted a compulsory licence to its government on 5 October 2004 in respect of nevirapine and lamivudine. The royalty to be paid to the patentees was 0.5%.

## Future

There have been at least five compulsory licences granted under TRIPS in the past three years. Does this represent a new precedent for the approach to compulsory licences by less developed countries? The majority of compulsory licences have been granted for domestic manufacture and use only and so rely on a supply from homegrown manufacturers or from non-patented countries. The threat to patentees is real, though, and an increased willingness to grant compulsory licences might provoke the patentees into greater discounts. Only time will tell whether this will be the case.

Only one of these compulsory licences has been granted under the article 31bis provisions and, following the criticisms of the procedure from Apotex, it seems unlikely that the provisions will be used regularly. The burden on the foreign manufacturers, who are already agreeing to supply the drug for little or no profit, is great so they must be committed to want to make the application. There is little likelihood that the provisions will be simplified, not least because there would clearly be great opposition from the innovator patentees. Unless generic companies begin to act more altruistically, like Apotex, news of this compulsory licence is unlikely to open the floodgates for use of the Article 31bis procedures.

*Matthew Royle*

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## Recent US legislative developments [Back to contents](#)

### Biosimilars

#### The legislation

The passage of US legislation governing biosimilars seems likely to take longer than it otherwise might have done after the Biologics Price Competition and Innovation bill ("BPCI") was not included in the final version of the Prescription Drug User Fee Act reauthorisation bill ("PDUFA") that was approved by Congress on 20 September and signed into law on 27 September.

The passage of PDUFA as part of more wide ranging legislation concerning the FDA had to be achieved as a matter of urgency in September because of the strain on FDA funding and the apparently imminent threat of redundancies that brought.

#### Consequences

This leaves the BPCI to continue through Congress as a stand-alone bill. It seeks to strike a compromise between the interests of innovator companies and the pro-biosimilar lobby and consequently has attracted criticism from both those groups, for instance as to the appropriate length of the data exclusivity period allowed to the innovator biological product. This lack of consensus means that passage of the legislation may take longer than lawmakers first hoped.

In the meantime the FDA will continue to lag behind Europe in tackling the mechanism of approval specifically for biosimilars. Applications for approval of so-called "follow-on biologics" (e.g. Sandoz's Omnitrope) have been successful in the US within the framework of the Food Drug and Cosmetic Act, but that legislation dates from 1984 when small molecule pharmaceuticals were being considered, not large biologically derived materials. That is not to say it will be easier to obtain approval for a biosimilar product in Europe than the US, but the legislative framework may be more predictable from the applicant's perspective.

# Patent law reform

## The legislation

Greater progress has been made by the Patent Reform Act (the "Act"), which will amend US Patent Law, and was passed by the House of Representatives on 7 September. The Act still needs to be approved by the Senate and signed into law by the President, but if it progresses in its present form, the key reforms will include:

- Subject to the significant caveat explained below, adoption of a "first to file" system in place of the present "first to invent" system with:
  - Consequential changes to the assessment of novelty and obviousness;
  - The disappearance of interference proceedings;
  - A limit on the applicability of the "grace period".
- Changes to the provisions for calculating damages based on a reasonable royalty such that the court must consider the "economic value" of a patent.
- Treble damages to be payable solely in the case of wilful infringement, where what is "wilful" is quite narrowly defined in the Act.
- Removal of the carve-out to the 18-month publication rule for applications not filed in other "publishing" jurisdictions.
- Provision for the USPTO to require search reports and other information relevant to patentability to be submitted by an applicant for a patent.
- Provision for any person to petition the USPTO within twelve months of grant for cancellation of a patent through a post-grant review proceeding. This would be in addition to the existing provisions for re-examination.

## Consequences

Even if the Act is ultimately passed into law, there is a significant hurdle to overcome before the "first to file" and related provisions will apply. The Act presently provides that those provisions will only take effect when the major patenting authorities (which includes the patenting authorities in Europe) have adopted a grace period having substantially the same effect as the one contained in the amended provisions. There are no current plans to adopt a US-style grace period in Europe, so the first to file provisions may in reality be some way off at present.

Having said that, if the provisions of the Act are an attempt at encouraging a degree of two-way harmonisation with European and other patent authorities, perhaps at some point we can expect a change to the European provisions on disclosures by the inventor in the twelve months before filing. If it does come about, harmonisation should facilitate the co-ordination of multi-jurisdictional patent litigation that includes the US, since validity issues will be more focused on similar prior art and issues of timing of invention would be less relevant.

Although there has always been the potential for reasonable royalty calculations to lead to a degree of economic debate, this will now be compulsory in the absence of a damages settlement. It may be difficult for patentees to show that the patent's contribution is the "predominant basis" for market demand for infringing products (a new requirement before the court will consider the whole value of the infringing product in the damages calculation). This, together with the restriction on circumstances where treble damages may be awarded, may lead to a reduction, on average, of the level of damages awarded in US patent litigation. Whether this leads to any change of focus in global litigation strategy, due to damages awarded in jurisdictions outside the US accounting for a larger proportion of a patentee's potential recovery, remains to be seen.

Until now, it has been possible for an applicant for a US patent to certify that the invention has not and will not be the subject of an application in another country that requires publication after 18 months. Under such circumstances, the US application is not automatically published after 18 months, but otherwise it is. The Act changes the position.

Some of the other reforms, including the search report requirements and wider possibilities for post-grant challenge, do seem to be somewhat burdensome for patentees generally, with the intention appearing to be to discourage applications and patents for bad inventions. This has been a particular concern for companies in the IT and telecoms

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industries where the activities of so-called "patent trolls" have led to increasing amounts of litigation. In the life sciences and healthcare sectors, on the other hand, the very high cost of research and development means that positive rewards for innovation are more important than deterring applications for bad patents, at least from the innovator perspective. While life science companies will not think twice about obtaining patent protection in the US, increased costs of obtaining and maintaining patents will have to come from somewhere.

## Changes to patent examination practice

### The rules

In advance of any changes to US patent legislation, new rules concerning examination practices in the USPTO come into force at the beginning of November.

The changes will limit the number of claims that the USPTO will generally consider in a single application – five independent claims and 25 claims in total (the "5/25 rule"). There are options open to applicants to circumvent these limits but these will involve the expensive preparation of an analysis of the filed claims and the prior art by the applicant (an Examination Support Document, or ESD), or will require the filing of divisional applications.

The rule changes will also require applicants to identify "related" patents and applications to determine the degree of similarity or overlap between them. The 5/25 rule will be applied to related applications as a group, so that applicants may have no choice but to prepare an ESD in order to maintain all the claims.

Finally there will be a restriction on the number of continuation applications (by which improvements may be added to the claimed invention) that may be filed.

### Consequences

According to the USPTO, the changes to the rules are intended to make the patenting process more efficient and effective. That may be the case, but innovator companies are concerned that they may also represent a significant reduction in the flexibility they have been able to rely on in prosecuting US applications.

This is particularly the case in the pharmaceutical industry where it has been common to file broad applications at an early stage, which are then refined through continuation applications in order better to specify the invention(s) as the development of a commercial drug unfolds. Indeed, GlaxoSmithKline has recently filed a complaint against the Director of the USPTO seeking an injunction against the implementation of the new rules and a declaration that they are vague and outside the scope of the USPTO's powers. In spite of that, it appears that the office has already begun identifying those applications which exceed the 5/25 rule.

*Edward Vickers*

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## ECJ holds that EU Member State courts can apply TRIPS [Back to contents](#)

In a preliminary ruling on a referral from the Portuguese Supremo Tribunal de Justiça, the European Court of Justice recently held<sup>9</sup> that a national Member State court can apply TRIPS. This is an important decision because it serves as a reminder that a number of European Member States may have non-TRIPS compliant regimes for the protection of intellectual property (even following the establishment of the European Patent Organisation and enactment of the European Patent Convention). The decision both gives further ammunition to patentees to argue for TRIPS effectiveness where regimes appear deficient and also is a warning to potential infringers that they should review national laws in the light of TRIPS.

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<sup>9</sup> Case C-431/05, Merck Genéricos - Produtos Farmacêuticos Ld<sup>a</sup> v Merck & Co. Inc. and Merck Sharp & Dohme Ld<sup>a</sup>

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The TRIPS Agreement can be found at Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994<sup>10</sup>. The agreement is the most significant multi-lateral agreement dealing with intellectual property and sets down minimum standards which WTO member states should comply with. It does not prescribe maximum levels of intellectual property protection and so WTO members are free to enact provisions that provide for additional protection.

The relevant provision of the TRIPS Agreement that was in issue was Article 33. This provides that:

"The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date"

This should be contrasted with the relevant law in Portugal which stated that that patent life extended for only a period of 15 years from patent issuance (Article 7 of the 1940 Industrial Property Code (the law then applicable in Portugal)). This said the patentee meant that the law applicable to the patent in suit was not compliant with TRIPS and that the Portuguese Court should both hold that this was the case and then find that TRIPS should be applied to extend the life of the patent, i.e. that TRIPS was directly effective.

The patentee had lost at first instance, succeeded in the Court of Appeal (although this court appears to have decided the correct patent term was 20 years from issuance). The case was then heard by the Supremo Tribunal de Justiça. This court was of the opinion that no domestic Portuguese law could be interpreted to assist the patentee but that if Article 33 of TRIPS applied, this would alter the outcome of the case. The court further considered that under Portuguese law international agreements such as TRIPS could be relied upon as between individuals as having direct effect. The questions referred to the ECJ by the Portuguese court were:

1. Does the Court of Justice have jurisdiction to interpret Article 33 of the TRIPS Agreement?
2. If the first question is answered in the affirmative, must national courts apply that article, on their own initiative or at the request of one of the parties, in proceedings pending before them?

The ECJ heard submissions from the parties involved but also from the Commission and three member state governments, such was the interest in this issue. The ECJ decided that:

1. Yes, given the WTO Agreement was concluded by the Community and all its member states, and where the ECJ was hearing a case brought before it under provisions of the EC treaty, the ECJ was competent to interpret Article 33 of the TRIPS Agreement.
2. However, as patent law was an area where member states remained "principally competent", it was a decision for the individual member state to make, as to whether or not to give direct effect to the provisions in this article.

The Portuguese court is now at liberty to give direct effect to the provisions of the TRIPS agreement in the instant case.

This ruling is notable for clarifying that TRIPS is part of the legislative framework of the European Union and as such is directly effective in areas where the Community has not assumed responsibility for legislating, for example, patent law. This does create interesting scenarios whereby patentees may choose to rely on TRIPS if national laws appear defective in any way. TRIPS is far more wide ranging than prescribing patent term as in this case, it includes provisions dealing with patentability and exclusions therefrom; the rights of patentees to deal with their rights; restrictions on the types of compulsory licensing regimes that can be imposed and also a requirement not to discriminate between fields of technology. If patentees were not aware of this possibility beforehand, TRIPS should now form part of their legislative review in the event that a member state patent system can be argued to be non-TRIPS compliant in any way that might assist their case.

**Dr Gareth Morgan**

<sup>10</sup> See [http://www.wto.org/english/docs\\_e/legal\\_e/marrakesh\\_decl\\_e.htm](http://www.wto.org/english/docs_e/legal_e/marrakesh_decl_e.htm)

## European Nanotechnology developments [Back to contents](#)

It has been a busy summer for those involved in the regulation of nanotechnology at the Commission.

In July the Commission announced a public consultation on a code of conduct for responsible nanoscience and nanotechnological research<sup>11</sup> which closed on 21 September. The consultation will be used to filter into a voluntary code of conduct for establishments conducting nanotechnology research and development. The aim of this code of conduct is to "promote safe and responsible nanotechnology research and pave the way to its safe and responsible application and use".

It is intended that the Code of Conduct will take the form of a European Commission Recommendation. The Commission itself would abide by this code when implementing its own research policies.

The stated advantage of the Code of Conduct would offer those following it recognition that theirs is a responsible approach towards research. The hope within the Commission is therefore that governance of nanotechnology can be achieved through this type of voluntary regime.

The Commission intends to adopt this code by the end of 2007. Also, the Commission is keen to promote a coherent international approach to research in nanoscience. To that end, the Commission is looking to stimulate an extended dialogue with other organisations<sup>12</sup>.

Also, in early September the Commission released a communication concerning the first implementation report of the Nanoscience and Nanotechnologies Action Plan for Europe 2005-2009<sup>13</sup>. The report summarises the progress that has been made towards implementing this action plan. The report highlighted that although public funding for nanoscience related research has increased and is now at the highest level worldwide, poor response from private industry has meant that Europe is not hitting its target of 3% GDP investment in research and development overall. Additionally, the report raises concerns that the multi-disciplinary nature of nanoscience related research could lead to inefficiencies across Europe due to a lack of a proper infrastructure within which the research is performed and also possible duplication of effort due to the fragmented nature of funding structures at present. The report also made reference to the development of a common ethical framework within which to operate nanoscience research, the above Code of Conduct being an obvious example of one such initiative. The report also contains a summary of the efforts made by the Commission at an international level to arrive at a wider consensus on an ethical and safety framework within which to conduct this research.

The report further makes reference to the ongoing monitoring that the Commission is undertaking in order to identify any need for new legislation or regulatory gaps that are apparent from scientific developments in this area, but it stresses the desire of the Commission to apply existing regulatory systems as far as is possible.

In summary, the areas identified for special attention in the remaining two years of the Action Plan were:

- The development of interdisciplinary infrastructures;
- Appropriate conditions for the safe and effective use of nanotechnology; and
- A shared understanding of the responsibility of researchers within an ethical framework.

The next report on the 2005-2009 action plan is set for the end of the plan period in two years' time.

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<sup>11</sup> See [http://ec.europa.eu/research/consultations/pdf/nano-consultation\\_en.pdf](http://ec.europa.eu/research/consultations/pdf/nano-consultation_en.pdf)

<sup>12</sup> For example UNESCO, OECD, the STS Forum, ISO, etc. and in particular the International Dialogue on Responsible Nanotechnology <http://cordis.europa.eu/nanotechnology/src/intldialogue.htm>

<sup>13</sup> See COM(2007) 505

## Interim Injunctions pending appeal [Back to contents](#)

The recent case of *Les Laboratoires Servier v Apotex* [2007] EWHC 1538 (Pat) raised interesting issues relating to interim injunctions pending appeal which could allow a patentee to extend its monopoly beyond an unsuccessful decision at first instance.

The dispute related to perindopril, an ACE inhibitor (blood pressure controller) marketed by Servier and, in particular a patent covering a particular crystal form of the drug (EP (UK) 1 296 947). Apotex launched its generic perindopril product in the UK at the end of July 2006 and enjoyed a few days on the market before being sued by Servier and enjoined by Mann J on 8 August applying the familiar principles governing interim injunctions as set out in *American Cyanamid*<sup>14</sup>.

Apotex were not the only generic interested in perindopril. Krka were also sued by Servier and Lupin brought an action for the revocation of the patent. However, both settled with Servier before trial, which was heard by Pumfrey J in March 2007. After consideration, Pumfrey J held that the patent was invalid and should be revoked as it was anticipated and obvious in light of a prior art patent, EP 0 308 341, which was also owned by Servier.

At the hearing following judgment, Servier were given leave to appeal. Not, as is normal, because the appeal had any real prospects of success, but following recent guidance from the Court of Appeal in *Pozzoli v BDMO*<sup>15</sup>. The guidance suggested that if it would take the appeal judge more than an hour or so to get to grips with the case and decide whether an appeal had merit then generally leave to appeal should be given by the trial judge.

At the same hearing, Servier applied for a continuation of the injunction that had been in place since 8 August 2006 pending appeal. The court was not aware of, and was not directed to, another case where an injunction had been applied for (let alone granted) when a patent had been held to be invalid at first instance. This is presumably because everyone assumed that it was not possible to assert an invalid patent. Pumfrey J did not, however, refuse the application on this basis. Instead, he used the (slightly modified) criteria from *American Cyanamid*. In order to get an interim injunction pending appeal, a patentee must show (1) that there was an arguable appeal (2) that damages were not an adequate remedy and (3) that the balance of convenience favoured it. Servier failed at the first hurdle as Pumfrey J had already decided that their appeal had no real prospects of success so, ultimately no injunction was granted pending appeal.

Servier appealed this decision but the Court of Appeal agreed with Pumfrey J that Servier's appeal had no real prospects of success and so an injunction pending appeal should not be granted following *American Cyanamid*. The Court of Appeal applied the *American Cyanamid* criteria but did not consider whether this was the right test to apply.

The decision opens the way for patentees to retain their monopoly even if they lose at first instance. In this case, Servier's appeal had no real prospect of success and so no injunction was granted pending appeal. In a lot of cases, however, there will be an arguable appeal so the balance of convenience will have to be considered and it is difficult to see how it will have changed between the first interim injunction hearing and trial because other generic companies are unlikely to have launched without being enjoined. The question really is whether an invalid patent can prevent any generic launches pending appeal. If this is to be possible, the High Court must reach the conclusion that its own decision to invalidate the patent following a full trial has not altered the question of whether the patentee has an arguable case. This would appear to put the High Court in a difficult position and highlights a possible flaw in Pumfrey J's reasoning.

Only time will tell whether Pumfrey J was right to apply *American Cyanamid* but until further guidance is given, patentees may well decide to apply for injunctions pending appeal whatever the result in the High Court.

*Simon Cohen and Matthew Royle*

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<sup>14</sup> [1975] RPC 513  
<sup>15</sup> [2007] EWCA Civ 588

# Regulatory review

## New drug approvals and the Financial Penalties Regulation [Back to contents](#)

On 15 July 2007 the European Commission's Financial Penalties Regulation<sup>16</sup> (the "Regulation") came into force. Under the Regulation, the Commission can impose financial penalties on a company which infringes any of a number of obligations connected with its centralised marketing authorisation for a new drug. The obligations listed include:

- Completeness and accuracy of its application for marketing authorisation or other documents/data submitted to the EMEA
- Conditions or restrictions of the marketing authorisation or in connection with the product's supply or use
- Making variations to its authorisation to meet scientific progress
- Supplying information which may entail a variation
- Marketing a product in accordance with the product's SmPC and package leaflet
- Notification of dates of actual marketing and withdrawal of product
- Correct reporting of adverse effects
- Communication of pharmacovigilance concerns to the public.

Under Article 84(1) of Regulation 726/2004 (governing centralised marketing authorisations), individual Member States have power to impose financial penalties for breaches of that Regulation. So as to in some way limit a Market Authorisation (MA) Holders exposure to double fines the Financial Penalties Regulation imposes the following further requirements which have to be satisfied before penalties can be imposed at a Community level, namely that the infringement:

- Has significant public health implications in the Community or
- Has a Community dimension by taking place or having its effect in more than one Member State or
- Where the interests of the Community are involved.

To mitigate further against double exposure to infringement proceedings, the Regulation requires that the EMEA and Commission take into account national infringement procedures taken against the same MA holder based on the same legal grounds and the same facts.

## Infringement Procedure

The infringement procedure is divided into two stages: the inquiry stage and the decision making stage.

### Inquiry stage

The EMEA can initiate infringement proceedings on its own initiative or following a request from the Commission or a Member State. Before initiating the procedure the EMEA can request information from the MA holder giving the holder at least a four-week time limit to comply. On initiation of the procedure, the EMEA must send a written notification (the "Notification") to the MA holder, the Member States and the Commission. The Notification must specify the provisions allegedly infringed and the evidence on which the allegations are founded and give notice that fines or periodic penalties may be imposed.

Following the Notification, the EMEA may ask for the MA holder to give written or oral explanations or documents. At the end of the enquiry the EMEA will prepare a Report to the Commission, Member States and the MA holder

<sup>16</sup> Commission Regulation No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation No 726/2004.

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summarising its findings and where the report finds an infringement, asking for a financial penalty to be imposed. The EMEA, before adopting its report, must give the MA holder the opportunity to submit its written observations. The EMEA must prepare its report within 18 months after Notification.

### Decision making stage

If, upon receipt of the EMEA's report, the Commission decides to continue with the infringement procedure it will send to the MA holder a Statement of Objections. The Commission must provide an explanation if the Statement is not sent within 18 months of the EMEA's Report. The Commission shall set a time limit of at least four weeks for the MA holder to make its written observations on the Statement and if requested, give the MA holder the opportunity for an oral hearing.

### Financial Penalties

Where the Commission finds that the MA holder has intentionally or negligently committed an infringement it may impose a fine of up to 5% of the MA holder's Community turnover in the preceding business year. Where the infringement has not been terminated, the Commission may impose periodic penalty payments per day of up to 2.5% of the holder's average daily Community turnover in the preceding year. Periodic payments can run from the date of Notification until the infringement has been brought to an end. Furthermore, periodic penalty payments and fines of up to 0.5% may also be imposed for non-compliance with the infringement procedure.

In determining the appropriate financial penalty, the Regulation requires the Commission to be guided by 'the principles of effectiveness, proportionality and dissuasiveness'. The Regulation lists the circumstances that must be taken into account and includes:

- The seriousness and effects of the infringement in particular on patient rights, safety or well-being or whether it poses a risk to public or animal health or the environment;
- Whether the MA holder has acted in good faith or shown wilful deceit
- Whether the MA holder has cooperated in the procedure and applied corrective action or has been obstructive or non-compliant
- The turnover of the medicinal product concerned
- The repetition, frequency or duration of the infringement by the MA holder
- Prior sanctions imposed on the same MA holder
- Any penalties imposed on the MA holder at a national level on the same legal grounds and facts.

*Marjan Noor*

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# Environmental Highlights

## New Department for Business, Enterprise and Regulatory Reform ("BERR") [Back to contents](#)

*The former DTI (Department for Trade and Industry) was reorganised and rebranded the Department for "BERR" following Gordon Brown's appointment as Prime Minister earlier this year. It brings together former functions of the DTI, including productivity, business relations, energy and competition together with the "Better Regulation Executive" previously enshrined in the cabinet office. The new BERR Department, headed by the Rt. Hon. John Hutton, is to work closely with the new Department for Innovation, Universities and Skills ("DIUS") whose brief encompasses the Government's long-term plans for science, research and innovation.*

### 2007 Pre-Budget Report

The 2007 Report delivered to Parliament on 9 October by the Chancellor, Alistair Darling, makes a number of environmental announcements:

- **Climate Change** – It has now been forecast that a climate change bill will be put before Parliament during the course of November 2007, following on from the previous consultation drafts (see July In Focus);
- **Emissions Trading** – The Government intend to encourage the EU to introduce stricter caps on national allocations for Member States under the EU ETS (European Union Emissions Trading Scheme) to ensure a scarcity of supply for Phase II of the Scheme (2008-2012). The UK Government has also announced that it intends to auction off surplus allowances rather than awarding them to companies for free. In terms of aviation, the Pre-Budget Report makes it clear that the Government supports its inclusion in the EU ETS.

The European Commission's proposals on the future of the EU ETS post 2012 are now anticipated for publication in December 2007.

*NOTE: This is not an exhaustive list of environmental announcements made.*

### Energy White Paper

Published by the Government on 23 May 2007, the Policy paper sets out a proposed short-term and long-term preferred strategy for energy, its aim; to meet the energy challenges facing the UK, focusing primarily on climate change and security of energy supply. Key proposals include:

- **Improving energy efficiency** – the Government's intention to consult on the detail of the CRC (Carbon Reduction Commitment) previously known as the "Energy Performance Commitment" was announced in the White Paper. The CRC is a new legally binding Emissions Trading Scheme for large non-energy intensive businesses in both private and public sectors (e.g. hotels, supermarkets).
- **Encouraging greater use of renewable energy and bio-fuels** – The Government's aim is to achieve a target of 10% for UK electricity generated from renewable energy sources by 2010, increasing this threshold to 20% by 2020.
- **Providing new opportunity for investment in nuclear energy** – the most controversial aspect of the Government's proposals, particularly in light of the recent "Greenpeace Challenge" (see In Focus July 2007). The Government have subsequently indicated their intention to forge ahead with proposals for new nuclear sites and in line with this objective; they launched a new consultation, "The Future of Nuclear Power" on 23 May 2007.
- **Encouraging the development of clean fuel technologies** (e.g. carbon capture and storage) – the Government's aim is to encourage the EU in its efforts aimed at strengthening the current EU Emissions Trading Scheme (EU ETS).

### **Carbon Reduction Commitment (CRC)**

The Government launched a consultation on the detail of the new CRC regime; a mandatory auction based Emissions Trading Scheme for non-energy intensive businesses, on 26 June 2007, following the announcement made in the Energy White Paper. The CRC is expected to come into force in 2010, and as a consequence, the prime focus of this consultation is the operation of the Scheme on a "cap and trade" basis, examining thresholds, the proposed definition of a CRC organisation, specific activities and emissions, design of the CRC auction and league tables, monitoring, reporting and penalties.

### **Carbon Offsets**

The primary goal of "carbon offsetting" is to cancel all or part of the total amount of carbon dioxide emitted by way of prevention or reduction of carbon dioxide emitted to the atmosphere elsewhere. Carbon "credits or offsets" can be purchased from participating companies or "carbon offset providers" that invest and deal in carbon reduction projects. A final voluntary Code of Best Practice on carbon offsets, which is to apply to carbon offset providers, is now anticipated for 2007, following a consultation exercise that took place in April 2007.

### **Air Quality Strategy 2007**

The latest Strategy was published for England, Scotland, Wales and Northern Ireland on 17 July 2007 (Cmd Paper No.7169), setting a way forward for work and planning on air quality issues, providing details of the objectives and standards that are to be achieved, together with a new policy framework for dealing with fine particles, similar to the draft strategy being proposed for a new EC air quality directive. In addition, the Strategy identifies new measures to achieve targets. By way of background, the Environment Act 1995 requires the UK Government to produce a National Air Quality Strategy comprising standards, objectives and measures for improving ambient air quality and to keep policies under review. The first Air Quality Strategy was previously published in 1997.

### **REACH Update**

On 7 August 2007 the Government published a summary of responses received on proposals (March-June consultation) for the enforcement of a new EU Regulation on REACH – (R)egistration, (E)valuation, (A)uthorisation and (R)estriction of all (CH)emicals used by persons and business in quantities greater than 1 tonne per year (see In Focus July 2007). DEFRA has now indicated that it intends to consult further on a new draft statutory instrument to implement the regime in early 2008, the deadline for implementing the REACH enforcement measures in Member States being set for 1 December 2008.

In addition to the new draft implementing measures, the European Chemicals Bureau (ECB) has prepared two sets of guidance notes to help users of chemicals (i.e. manufacturers and suppliers) prepare for the new REACH regime. These are anticipated for publication in December 2007.

### **New ROHS Regulations**

The new Department for Business Enterprise and Regulatory Reform is consulting on new draft "Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment" (ROHS) Regulations. Once implemented, the Regulations will replace the former 2006 ROHS Regulations (SI 2006/1463) and are anticipated to enter into force on 1 February 2008. The new 2008 ROHS regulations will not change the substance of the 2006 Regulations, but rather expand on them to ensure that they automatically apply in the UK to new exemptions authorised by the EU and make it easier for the ROHS Regulator (i.e. the National Weights and Measures Laboratory) to enforce the requirements of the new regime. The deadline for responses on the draft regulations is the 29 November 2007.

### **Environmental Liability Directive (2004/35/EC) Update**

As previously noted in the July 2007 edition of In Focus, the Government is consulting on the precise mechanisms to implement the Directive, which imposes a strict liability regime on those who cause damage to biodiversity/water or land contamination with a significant risk of harm to human health. The first consultation closed on 28 February 2007, and a second consultation that is to comprise proposed draft UK implementing legislation is now anticipated for Autumn 2007.

### **Draft Revised Policy for Storage of Hazardous Liquids at COMAH Sites**

The Control of Major Accident Hazards (COMAH) Regulations 1999 (as amended) came into force in 1999 and implement the Seveso II Directive, repealing the Control of Industrial Major Accident Hazard Regulations 1984. In the main, they apply to the chemical industry and storage activities, explosives and nuclear sites, imposing a duty on operators to take all measures necessary to prevent major accident hazards and limit consequences.

In June 2007, the Environment Agency published draft revised policy on the bulk storage of hazardous liquids for consultation in response to the recommendations made by the Buncefield Major Incident Board for sites subject to the COMAH Regulations. It is intended that once finalised, revised policy will apply immediately to any new COMAH site. However, the Environment Agency estimates that it will take up to 10/20 years for existing sites to upgrade.

**Brian Greenwood** - Partner and Head of Taylor Wessing's Environmental and Planning Group.

**Sherryl L'oken** - Professional Research Lawyer

*If you have any queries on the issues raised in this environmental briefing, or if you would like a fuller explanation of the topics, please contact a member of the Taylor Wessing Environment and Planning Group.*

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# Companies Act 2006 – Headline Changes

## October 2007

<b>Directors</b>	
■ Codification of directors' duties (except conflicts of interest – see October 2008 overleaf)	ss170 - 174
■ Loans can be made to directors with shareholder approval	ss197 - 214
■ Directors' service contracts for guaranteed term of more than two years require approval	s188
■ New procedure for shareholder approval of directors' loans, long term service contracts and payments for loss of office – terms of transaction on display for 15 days up to and at meeting	Chapter 4, part 10
■ Votes of director and "connected persons" disregarded on resolution to ratify director's negligence, default, breach of duty or breach of trust to company	s239
■ "Connected persons" widened to include a co-habitee, children over 18, parents and children under 18 of co-habitee living with director	ss252 - 254
<b>Shareholders</b>	
■ New statutory derivative action for members against director and/or third party	ss260 - 264
■ Companies may provide in their articles for members to nominate another person to exercise their rights as member (except right to transfer shares)	s145
■ Registered members of listed companies can nominate beneficial holder of shares to enjoy all "information rights" (rights to receive all company documents and information)	s146
■ Restrictions on right to inspect register of members – must supply name, address, purpose for which information will be used (and same for person to whom information will be disclosed)	ss116 - 119
<b>Meetings and resolutions and accounts</b>	
■ Private company not required to hold AGMs (unless articles require them)	
■ Private company can pass written ordinary or special resolutions by simple majority or 75% majority (respectively) of those eligible to vote	s282(2) & s283(2)
■ Notice period for all general meetings (except AGMs of a public company – will be 21 days) will be 14 days, regardless of the type of resolution proposed (unless articles require longer)	s307(1) - (3)
■ Consent to short notice can be given by majority in number holding 90% of shares (if private company – subject to articles) or 95% (if public company)	s307(4) - (6)
■ Articles cannot require proxies to be lodged more than 48 hours before time of meeting – weekends and bank holidays will be excluded from counting for this 48 hour period	s327
■ Listed companies must disclose on website results of any poll taken at general meeting	s341
■ Listed companies (does not include AIM companies) must include in Business Review: <ol style="list-style-type: none"> <li>1. main trends and factors likely to affect business,</li> <li>2. environmental matters, employees and social and community issues, and</li> <li>3. information on supply chain</li> </ol>	s417

## April 2008

<b>Company secretaries</b>	
■ Private companies need not have a company secretary, although they may retain one if they wish. Public companies must still have a secretary	ss270 - 271
<b>Distributions in kind, accounts and offer of shares to public</b>	
■ Company with distributable profits (of £1 or more) can lawfully transfer asset intra-group at book value even if less than market value – value of distribution is zero	s845(2)(a)
■ Company with distributable profits can transfer asset intra-group at less than book value if it has distributable reserves to cover shortfall between consideration and book value	s845(2)(b)
■ Company without distributable profits cannot lawfully make an intra-group asset transfer at an undervalue	s845
■ Period for filing accounts reduced from 10 months to nine months for private companies and from seven months to six months for public companies	s442
■ Private company will no longer commit offence if it offers securities to public – instead, it may be compelled to re-register as public company or be wound up or suffer "remedial order"	ss755 - 759

## October 2008

<b>Directors</b>	
■ Codification of directors' duties relating to conflicts of interest – new ability for independent directors to approve a director's conflict of interest	s175
■ Companies must have at least one director who is a natural person	s155
■ Minimum age of 16 years for directors of all companies (age limit of 70 for directors of public companies repealed on 6 April 2007)	s157
■ Directors' service address (for public record) as well as residential address filed at Companies House. Directors' residential addresses kept on separate and secure register	ss163 - 167 & ss240 - 246
■ No longer requirement to file details of other directorships at Companies House	s163
<b>Share capital</b>	
■ Removal of concept of authorised share capital	
■ No authority to allot shares required for private company with only one class of shares (unless articles require it)	s551
■ Company may re-denominate share capital into foreign currency, by ordinary resolution unless articles restrict this power or require a higher majority	s622
■ New solvency statement procedure for reduction of capital by private companies with share capital – alternative to court approved procedure which will remain	s626
■ No longer requirement for specific authorisation in articles to reduce share capital – company can reduce its capital unless specific restriction in articles	s641
<b>Shareholders</b>	
■ A single member may form a public company	s7
■ Members' addresses no longer needed in annual return (except for members holding 5% or more in listed companies)	ss855 - 856
<b>Company capacity and constitution</b>	
■ Company's objects treated as moved into articles. Objects of new companies will be unrestricted unless articles provide otherwise. General commercial objects of existing companies treated as restriction on company's objects	ss28 & 31
■ Memorandum will be historical document relating to formation	s8
■ Company can execute a deed by single director in presence of witness (in addition to execution by affixing seal or by two authorised signatories)	s44
<b>Financial assistance</b>	
■ Prohibition on giving of financial assistance by private company for purchase of its shares and whitewash procedure abolished	ss677 - 680
■ Prohibition retained for financial assistance given by public company (or by subsidiary (public or private) of public company for acquisition of shares in public company)	ss677 - 680
<b>Auditors</b>	
■ Auditors able to limit their liability by agreement with company (provided fair and reasonable)	ss534 - 535
<b>Striking off and restoration to register</b>	
■ Voluntary application for strike off extended to public companies	s1003
■ Time limit of six years from dissolution for court application for restoration	ss1029 - 30
■ New procedure – company may be restored by Companies House without court application	ss1024 - 28

**Further information**

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# Life science and healthcare news and events

## News from the LSH Group [Back to contents](#)

Partner, and Head of Regulatory, [Marjan Noor](#) spoke on "SPCs - Scope and Development" at the C5 Conference [EU Pharma Law and Regulation](#) on 18 and 19 September 2007.

Associate [Tim Worden](#) spoke on "Resolving disputes in R&D agreements" at the conference "[Drafting and Enforcing R&D Contracts](#)" organised by Hawksmere in London on 20 September 2007.

Partner [Dr Wolfgang Rehm](#) spoke on international issues at the American Bar Association's "[Emerging issues in Biotechnology Law](#)" conference on 6 and 7 September 2007 in Washington, DC, USA.

Head of Regulatory [Marjan Noor](#) ran a legal quiz at the ABPI legal Day on 24 September 2007.

Taylor Wessing LLP was a Platinum sponsor of [BioPartnering Europe 2007](#) at the QEII Conference Centre in London on October 7 to 9 2007. If you would like more information on this event please contact partner [Daniel Pavin](#).

Partner [Malcolm Bates](#) attended the [ERBi Bench2Boardroom](#) conference on Wednesday 17 October 2007.

## Mark your calendars [Back to contents](#)

Partner, and Head of Regulatory, [Marjan Noor](#) will speak on "Assuring patent term extensions in Europe and how they compare to the US regime" at the European [Pharmaceutical Law Forum](#) organised by Informa Life Sciences in Washington, DC, USA on 23 and 24 October 2007.

Associate Gareth Morgan is speaking on "Special strategies for licensing to and from JVs" at the Falconbury conference "[International Technology Licensing Agreements](#)" on 16 November 2007

Associate Tim Worden is speaking on "Maintaining and exploiting the value of IP rights in licensing and collaboration deals" at the Falconbury conference "[Negotiating, Understanding and Drafting Commercial Contracts for the Pharmaceutical Industry](#)" on 28 – 30 November 2007 in London.

Members of the LSH group will be attending the [GENESIS](#) conference at the Queen Elizabeth Conference Centre in London on 13 December

Partners Simon Cohen, Marjan Noor and Nigel Staote and associates Philip Carey and Gareth Morgan are speaking at the Management Forum conference, [Successful Patent Litigation in the UK and Europe](#), at the Rembrandt Hotel, London, on 17 December 2007.

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# Contacts

For further details on any of the topics discussed in this bulletin please contact the editors or your usual contact in the LSH group. If you would like to be taken off the recipient list, or add a colleague's name, please send an email to [h.cline@taylorwessing.com](mailto:h.cline@taylorwessing.com). If you are asking to be taken off the recipient list please insert 'Unsubscribe' in the subject line.

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