

# InFocus

Life science & healthcare legal e.bulletin



## Introduction

This is the third issue of InFocus, Taylor Wessing's life science and healthcare e.bulletin. Amongst the topics in this issue is an overview of the recent amendments to German Drug Law, a look at data protection and protecting your business from extremists; mediation and why you should consider it for resolving disputes and the recent European measures to combat counterfeiting and piracy.

# Contents

## Key features [print \(pages 3-14\) for this section](#)

### [Data protection considerations when tackling threats and sabotage](#) . . . . . [more](#)

Information is the lifeblood of extremists seeking to pressurize and threaten a business. Here we look at the precautionary measures that businesses should be taking to protect employees, investors and even suppliers.

### [12th Amendment to German Drug Law](#) . . . . . [more](#)

The 12th Amendment of the German Drug Law ("Zwölftes Gesetz zur Änderung des Arzneimittelgesetzes) took effect on 6 August 2004. Here we give an overview of the amendments and their effects on practice.

## In brief [print \(pages 15-18\) for this section](#)

### [Refuse to mediate at your peril](#) . . . . . [more](#)

Mediation is not often used in Intellectual Property disputes. However recent case law suggests that refusal to consider mediation as an option could result in cost penalties. Here we look at the recent Court of Appeal judgement in Halsey

### [The Patents Act 2004](#). . . . . [more](#)

The 2004 Act could probably not be described as introducing fundamental changes to UK patent law. However, a number of the new provisions are significant and here we summarise those highlights.

## Reviewed [print \(pages 19-24\) for this section](#)

### [Counterfeiting and Piracy in the life sciences and healthcare industry](#) . . . . . [more](#)

The identification of counterfeit drugs in the legitimate supply chain in the UK in August highlights the growing problem of counterfeiting for the LSH industry. Here we review the recent harmonising legislation in the EU and other anti counterfeiting measures.

## Life science and healthcare events [print \(page 25\) for this section](#)

### [News from the LSH Group](#). . . . . [more](#)

### [Mark your calenders](#) . . . . . [more](#)

## Contacts

# Key features

## Data protection considerations when tackling threats and sabotage

Recent events have demonstrated that it is not simply businesses working in special categories such as life science and healthcare that are at risk from the intimidation tactics of extremists. As recently as August 2004, the BBC Radio 4 'Face the Facts' programme reported on a campaign targeted at a number of small businesses providing services to the owner of a village guinea pig breeding farm, including his local pub, golf club, newsagent and fuel suppliers. Also recently, Oxford University, in an attempt to prevent extremists from stopping the building of the university's new £18 million biomedical research centre, applied for and was awarded an interim injunction by the UK High Court. The injunction protects the University and its staff from possible intimidation from animal rights activists.

Information is the lifeblood of extremists seeking to pressurise and threaten a business and its employees, those who invest in it or provide services to it. Whilst no business can remove itself from the danger of those seeking to wage a concerted campaign of sabotage and harassment, there are certain basic precautionary measures that a business should be taking to prevent, or limit the extent to which information it holds about workers, investors and suppliers may be compromised.

Failure to put in place appropriate measures to secure personal data can potentially result in damage to individuals, damage to the credibility of the business whose data has been compromised and also liability arising from a breach of the Data Protection Act 1998 (the "Act"). The Act places specific obligations on data controllers to take appropriate technical and organisational measures to secure personal data for which it is responsible. The Act does not provide a definitive list of appropriate security measures, since whether any combination of measures taken is appropriate will depend upon the circumstances, the harm that might result and the nature of the data to be protected both when systems are being created and also when personal data is being processed. Ensuring the reliability of staff who will have access to personal data as well as those staff of any third party processing personal data on behalf of the business will be one important consideration.

## Staff selection and training

Applicants can have ulterior motives for wishing to work for a business and may give incomplete or inaccurate information in order to achieve their goal of getting employed. The business is entitled to take reasonable steps to verify the information they have been given and vet, where relevant, successful applicants. The applicant's attention should be drawn to the verification process, particularly where this involves approaching external bodies such as educational boards, previous employers and, where appropriate, the Criminal Records Bureau. Where, however, verification checks throw up information different from that given by the applicant, the business should not automatically assume that they are the target of an attempted deception. Further checks should be made and the applicant should be invited to explain information that is potentially inaccurate or misleading.

## Day-to-day data practices

Employers need to make sure that their staff understand the importance of data protection, in their day to day information handling practices and how this links in with their employers and their own obligations under the Act. They should be made aware of the importance of taking special precautions when responding to requests for information, when disclosing information and when disposing of information. Care should be taken to avoid accidentally revealing information, perhaps by leaving a personal database password on a post-it attached to the computer or by leaving computer print-outs lying around on desks. Computer print-outs containing personal data should be securely disposed of in the same way as other confidential waste, rather than being consigned to the ordinary waste paper basket.

Importantly, workers need to understand their potential personal liability under the business's own disciplinary policy and under the Act where they process personal data for their own purposes. This should form part of the employment contract between the worker and the business. Employees should understand that if they intentionally misuse or disclose personal data processed by the business for their own purposes then, in addition to disciplinary consequences, they may face prosecution under the Act.

### Access and technical controls

Another important consideration involves limiting access to personal information held by the business wherever practically possible, to only those key staff with a need to see it. Company disciplinary rules and training may not, individually, deter a determined saboteur, but implementing technical controls on who has access to different sets of information in the business may put obstacles in their path. Measures could include:

- Creating defined and password protected user groups with permission to access specific sets of data records;
- Implementing audit-tracking facilities to enable the business to see who has accessed what data records and what actions they performed in relation to that data at a given time;
- Limiting what employees can do with data records they are permitted to access by, for example, providing view only access, preventing data from being printed off by all but key staff and by restricting the ability of employees to change specific record fields in a database;
- Ensuring that there are measures in place to protect and control the extent of any personal data that can be exchanged to and from home-working employees and the business.

It is very important that the business has in place adequate business continuity plans to prevent or reduce damage in the event of sabotage. Back-up routines are an essential part of any sensible business continuity plan. Back-ups should be designed to ensure that any data lost or damaged as a result of an act of sabotage is capable of being fully restored.

### Monitoring employees

Employers may also be tempted to monitor their employees' activities. Once again this will bring the business up against the requirements of the Act. The Information Commissioner, whose job it is to enforce the Act, accepts that at least some forms of monitoring are an acceptable part of the employer-worker relationship, but that where information about employees is collected, processed or stored in the course of such monitoring, this must be done in a way that is lawful and fair to workers.

Examples of monitoring activities may include:

- Checking logs of web sites visited by employees;
- Gathering information at point of sales terminals to check operator efficiency;
- Listening to recordings of calls made by employees in a call centre;
- Checking telephone logs to look for excessive private use;
- Arranging for all e-mails sent or received by an individual employee to be read.

The Information Commissioner has produced specific guidance on monitoring employees at work in the form of his Code of Practice covering data protection issues in relation to employees<sup>1</sup>. Part three of the Code looks at a number of the general principles underlying the issue of employee monitoring and makes clear that the carrying out any monitoring involves striking a reasonable balance between intrusion to employees on the one hand and the risk to the employer's business on the other. The balance needs to be assessed in each individual case and, therefore, the Code does not give firm rules that are applicable to every situation.

Before carrying out any monitoring, the employer must look at the specific risks which the monitoring is supposed to address. The impact of the monitoring on the privacy and other rights of relevant employees then needs to be assessed, at the same time as assessing the likely effectiveness of the monitoring in reducing or eliminating the relevant risks. This process should be documented.

Before any monitoring is used to enforce rules and standards by the business, it is also essential that the rules and standards are set out in a policy (which must refer to any associated monitoring to support compliance with the policy). All employees then need to be made aware of the policy and understand from this that monitoring is taking place and why. The only exception to this is where covert monitoring is justified (see below).

One further preliminary step a business will need to take is to make sure that any intended monitoring does not involve interception of any communications where this is prohibited under the Regulation of Investigatory Powers Act 2000 (since otherwise the business will be committing a criminal offence). Broadly speaking, a business can only monitor those communications that are confined to its own private communication systems and where the monitoring is necessary (among other things):

<sup>1</sup> A copy of the code is available at [www.informationcommissioner.gov.uk](http://www.informationcommissioner.gov.uk)

- To confirm compliance with regulatory practices or procedures to the person who controls the system
- For the purpose of preventing or detecting crime;
- For the purpose of investigating or detecting unauthorised use of the system; or
- Where the communications are being monitored for the purpose of checking whether or not they are communications relevant to the business.

In any other case, whenever a business monitors its employees it must have made all reasonable efforts to inform anyone who might use the system that communications transmitted via it may be monitored.

Any monitoring activity undertaken must be the responsibility of authorised and competent employees and the number of people with access to the results must be kept to an absolute minimum. All those involved must be subject to confidentiality and security requirements and properly trained. The monitoring carried out should be specific, targeted (rather than sweeping in nature) and, as far as possible, should avoid being continuous. It will usually be sufficient, for example, to carry out spot checks made at regular intervals. Provided the employees have been informed that spot check audits will take place, then this is likely to be as effective at discouraging inappropriate access to and usage of the business systems as continuous monitoring.

In relation to covert monitoring, the Code explains that this should not normally be used in the employment context and should only be used where criminal activity has been identified and an assessment has been made that concludes that notifying the relevant employee of the monitoring would prejudice the investigation into the criminal activity concerned. Where covert monitoring is necessary it should only be used for the prevention or detection of the criminal activity at which it was originally directed. Any other information collected in the course of the monitoring should be disregarded and, wherever possible, deleted unless it reveals other criminal activity or gross misconduct.

In conclusion, data protection plays a dual role when considered in the context of businesses facing threats and sabotage. It places an obligation on businesses to ensure that organisational and technical measures exist to keep personal data secure whilst at the same time it is intended to protect employees from over zealous interference by employers into the right to respect for his or her private life.

[Back to contents](#)

## 12th Amendment of the German Drug Law

The 12th Amendment of the German Drug Law ("Zwölftes Gesetz zur Änderung des Arzneimittelgesetzes") took effect on 6 August 2004. The Amendment provides for comprehensive changes of the Drug Law (AMG), the Enterprise Regulation for Pharmaceutical Wholesalers, the Operating Laws for Pharmacies and the Pharmaceutical Enterprise Regulation. Approving the result achieved by the mediation committee the German Bundestag and Bundesrat (Federal Council and Parliament) adopted the bill on 18 June and 9 July 2004, and the new law took effect one day after its promulgation. Here we give an overview of the amendments and their effects on practice.

### Amendments of the Drug Law

#### Identifying the Pharmaceutical in Braille

The 12th Amendment of the Drug Law introduces in Sec. 10 (1b) AMG the obligation to identify the pharmaceutical in Braille. While the AMG itself does not include any transitional provisions, Sec. 8 of the 12th Amendment of the Drug Law stipulates in par. 2 No. 2 in view of the effective date that Sec. 1 No. 7 lit. a1 shall take effect only on the first day of the 25th month following the effective date of the Amendment. Accordingly said obligation is not valid from the effective date of the 12th Amendment of the Drug Law but only as of 1 September 2006.

#### Expert Knowledge of the Control Manager

The control manager will have to have at least two years' practical experience in drug control to prove the required expert knowledge. The amendment of the regulation in Sec. 15 (1) No. 2 AMG however does not affect control managers who were lawfully acting as control manager at the time the 12th Amendment took effect. In deviation from Sec. 15 (1) AMG that activity may be continued pursuant to Sec. 138 (2) AMG.

#### Drug Safety for Children

To improve drug safety for children and young persons the Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM), will establish a committee in charge of

pharmaceuticals designed for children and young persons. The amendment in Sec. 25 (7a) provides that the committee must be involved in marketing authorization procedures of drugs that may be administered to children or young persons.

Any statements issued by the committee in the course of the authorization procedure will be of relevance for the evaluation of whether the pharmaceutical to be approved is sufficiently safe for children. If necessary it will be possible to impose pertinent requirements in the authorization notice on the committee's proposal.

### Clinical Trials

Pursuant to the implementation of the Directive 2001/20/EC the administrative procedure to be conducted before the start of a clinical trial has been amended in Sec. 40 et seq. AMG. A positive assessment by the ethics committee and a permission from the BfArM are now required. The new rules provide for specific simplifications of the procedure, such as deadlines for the grant of approval or permission up to fictitious permissions in case of inactivity of the authority. The latter, however, frequently do not apply, or apply only with limitations, to biotech pharmaceuticals, in particular if they are or contain genetically engineered substances.

- The amended Sec. 4 AMG provides for certain definitions adopted from the EU Directive. The term "clinical trial" is defined in Sec. 4 (23) AMG. Furthermore the term of a "non-interventional trial" is defined, which is an observational study, as such non-interventional trial requires that subjects be treated with approved pharmaceuticals in accordance with the application specifications contained in the marketing authorization, while this is analyzed on the basis of epidemiological methods, and the treatment does not follow a previously specified trial plan.
- The terms of "sponsor" (Sec. 4 (24) AMG) and "investigator" (Sec. 4 (25) AMG) are defined. According to the new law the person of the investigator does not necessarily have to be a physician anymore; in "justified exceptional cases", also another person proving the required experience in patient care may act as an investigator. However, this is expected to be of little practical relevance. Furthermore it is now required that one investigator be designated "manager of the clinical trial" in case of multicenter studies.
- Pursuant to Sec. 42 (3) AMG the Federal Ministry of Health is authorized to pass, with the approval of the Bundesrat, a legal regulation providing for more precise details. Two bills have been submitted in this respect, the most recent one dating from 7 May 2004 (hereinafter the "Draft Regulation").
- Clinical trial data is now stored in a Europe-wide database accessible to authorities, the EU Commission and the EMEA. A so-called EudraCT Number is available from the EMEA for every clinical trial. The procedure is performed online and is explained on the EMEA website ([www.emea.eu.int](http://www.emea.eu.int)). The EudraCT number must be specified in applications addressed to the ethics committee and the BfArM.
- A positive assessment by the ethics committee is now mandatory for each clinical trial of a pharmaceutical. According to the Amendment a negative assessment of the ethics committee can no longer be replaced by a tacit approval of the BfArM. The mandatory contents of the application to the ethics committee are specified in Sec. 7 of the Draft Regulation. The internet as well provides information about the application, for example on the website of the Medical Association of Baden-Wuerttemberg ([www.aerztekammer-bw.de](http://www.aerztekammer-bw.de)).
- In the case of multicenter studies the ethics committee competent for the manager of the clinical trial is competent. Accordingly, also in the case of multicenter studies, only one positive vote is required - as it is provided in the EU Directive. However, copies of the application must be forwarded to the other ethics committees that are competent for the investigators involved in the trial. The committee competent for the clinical trial manager is in charge of the proceeding and decides "upon agreement" with the other committees. How precisely the ethics committees will coordinate remains to be clarified yet, as the competence for regulation lies with the individual federal states.
- The ethics committee may involve experts or obtain expert opinions if deemed required for the assessment of the documents filed by the sponsor. Regarding clinical trials with minors the committee is obliged to involve experts to the extent it does not have expertise in the field of pediatrics. Furthermore the ethics committee must involve experts for clinical trials with xenogene cell therapeutics or gene transfer pharmaceuticals. Xenogene cell therapeutics are defined in Sec. 4 (21) AMG as pharmaceuticals that are or contain live animal somatic cells which have been genetically modified or otherwise had their biological properties altered. Gene transfer pharmaceuticals (Sec. 4 (9) AMG) are pharmaceuticals which are or contain for the genetic modification of somatic cells by transfer of genes or gene sections specific naked nucleic acids, viral or non-viral vectors, genetically modified human cells or recombinant microorganisms, while the latter are not to be used with the aim of prevention or therapy of infectious diseases caused by same.

- The ethics committee may withhold a positive assessment only if the documents filed by the sponsor remain incomplete after a reasonable deadline set for completion, if the documents are not conform to the state of the art of scientific findings, or if the general requirements as to clinical trials are not met. This includes the information of patients, the patients' consent to participation in the trials and processing of data, the appropriate qualification of investigators, and patient insurance, which will be addressed below.
- The ethics committee must decide about the application for a positive assessment within 60 days of receipt of the documents. The Draft Regulation provides for a reduction or extension of that period, for example for a reduction in the case of single-center studies, or an extension in the case of trials of pharmaceuticals containing genetically engineered organisms. There is no such time limit with respect to clinical trials of xenogene cell therapeutics.
- As mentioned above, aside from the positive assessment of the ethics committee it is mandatory to obtain permission from the BfArM, which must be applied for by the sponsor. The application has to include the results of the analytical and pharmacological-toxicological examination, the trial plan, and clinical information about the pharmaceutical. The application for BfArM permission can be filed parallel to the ethics committee application for positive assessment. BfArM permission may be withheld only, first, for the same reasons the ethics committee may withhold its positive assessment. Secondly, BfArM permission may be withheld where the sponsor or his representative are not domiciled in a EU Member State or the European Economic Area, where the risk/benefit analysis produces a negative result, or where no state of the art pharmacological-toxicological examination has been performed. In the case of xenogene cell therapeutics permission may also be refused for lack of sufficient insurance also covering third party risks, while it remains to be clarified precisely which third party risks need to be covered.

Unless the BfArM transmits to the sponsor within 30 days of receipt of the documents substantiated objections, permission is deemed granted. If the sponsor receives substantiated objections within said period and fails to amend his application accordingly within 90 days, the application is deemed refused. Details are specified in the Draft Regulation. The fictitious permission deemed to be granted in case of inactivity of the BfArM exceeding 30 days does not apply to the following pharmaceuticals:

- Pharmaceuticals according to Part A of the Annex to the EU Regulation 2309/93, i.e. pharmaceuticals manufactured using one of the following biotechnological processes:
  - recombinant DNA technology;
  - controlled expression of genes coding for biologically active prokaryotes and eukaryotes including transformed mammalian cells; hybridoma and monoclonal antibody methods
  - Somatic cell therapeutics, xenogene cell therapeutics, gene transfer pharmaceuticals;
  - containing genetically engineered organisms;
  - whose active substance is a biological product of human or animal origin, or contains biological components of human or animal origin, or whose production requires any such components.

A written permission of the BfArM is always required for the above pharmaceuticals. The BfArM has to decide on applications relating to pharmaceuticals of the above points 2 - 4 within 60 days of receipt of the documents, while this does not apply to xenogene cell therapeutics. The deadline does not apply to pharmaceuticals according to the first bullet point either, in relation to which the Draft Regulation partly provides for reduced or extended deadlines.

The BfArM may revoke a once granted permission (Sec. 42a AMG) if it turns out that the requirements for the grant had not been met, or are no longer met, or if there are facts that give reason to doubt the scientific basis of the trial. The sponsor must be heard before the grant is revoked. The trial must be discontinued afterwards. Court action against the revocation has no suspensive effect, in other terms the trial must be interrupted until a decision to the contrary is taken.

- The terms of patient information and consent have now been regulated in detail. Patients (referred to as "subjects" in the law) usually have to be of age and capable of comprehending the significance and consequences of a clinical trial (special provisions apply to minors). The subject has to be fully informed in view of the clinical trial, which has to be done by an investigator, who has to be a physician. The information must include the right of the subject to terminate his or her participation in the clinical trial at any time. Moreover the law now expressly requires that a "generally comprehensible information document" must be handed over to the subject. Accordingly the information letters should not include any technical terms, if possible. The subject must be given the opportunity of a further consultation with the investigator about other conditions of the clinical trial, for example funding and insurance. The subject's consent,

- Sec. 40 (4) AMG provides for special regulations relating to clinical trials with minors, which are admissible only if the pharmaceutical to be tried is designed for the diagnosis or prevention of diseases in minors, and the administration of the pharmaceutical to minors is medically indicated. Another requirement is that a clinical trial with adults or alternative trial methods are not likely to produce sufficient findings. These provisions are followed by terms relating to the consent of the legal representative and the consideration of objections raised by the minor.
- Sec. 41 AMG comprises provisions about clinical trials involving adults suffering from a disease which is intended to be treated with the study drug. Such a clinical trial may only be performed if the administration of the study drug is indicated according to the findings of medical science to save the life of the person, restore his or her health, or alleviate his or her ailments. Moreover the clinical trial is now also admissible if it entails a direct benefit for the entire group of patients suffering from the same disease. Accordingly a so-called group benefit is sufficient. It is therefore sufficient if it is anticipated that the study drug is likely to have positive effects in the treatment of a specific disease in persons other than the study subjects. An individual benefit for the individual study participant is no longer mandatory.

Clinical trials involving minors have to meet additional, strict requirements. Under certain conditions, a group benefit of the above described kind is sufficient, in particular, the research must entail only a minimum risk and minimum stress for the subject, in other words a very minor and only temporary impairment of health and inconvenience.

The provisions relating to the group benefit do not apply to clinical trials involving adults who are not capable of giving consent, and minors who will not be capable of giving consent after they have come of age, that is to say the individual benefit remains a mandatory requirement in these cases.

- The manufacture and importation of study drugs are subject to the provisions of the Pharmaceutical Enterprise Regulation (please see section B below for its amendments). Sec. 5 of the Draft Regulation furthermore includes detailed provisions as to the required labeling of study drugs.
- The transitional provision of Sec. 138 AMG stipulates that clinical trials where the required documents were filed with the ethics committee competent for the manager of the clinical trial by 6 August 2004 (effective date of the Amendment), are subject to the previous regulations of the AMG. Therefore, for instance, no BfArM permission or amended subject consent are required in these cases.

## Wholesale License Sec. 52 a

### Definition of "Wholesale"

The 12th Amendment of the AMG for the first time provides for a legal definition of wholesale trade with pharmaceuticals. Pursuant to the amended Sec. 4 (22) wholesale trade with pharmaceuticals means every professional or commercial activity performed for the purpose of trade comprising the procurement, storage, dispensing or exportation of drugs, with the exclusion of dispensing of pharmaceuticals to consumers other than physicians, veterinarians or hospitals. This exception in particular affects pharmacies where they dispense drugs directly to the ultimate consumer, but not where they supply pharmaceuticals to physicians, veterinarians or hospitals or also other pharmacies.

### License

Wholesale trade with pharmaceuticals or materials containing a drug or to the surface of which a drug is applied (Sec. 2 (2) No. 1 AMG), test sera or test antigens, will in future be subject to a license pursuant to Sec. 52a (1) sent. 1 AMG. This excludes wholesale of gases for medicinal purposes, and finished drugs approved for trade outside pharmacies which are plants or parts thereof or pressed juices from fresh plants or parts thereof designated with their customary German name and generally known in their effects, unless they were manufactured with a solvent other than water, or medicinal waters and their salts in their natural mixing ratio or their reproductions.

Pursuant to Sec. 52a (7) AMG no license is required for the activities of pharmacies qualifying as customary pharmacy operations. That provision in its present form was adopted upon a proposal of the Bundesrat, since the entire customary pharmacy operations should remain exempt from the license requirement. The legislative history of the Amendment states that customary pharmacy operations in particular also include all activities permitted under the German Drug Law, Pharmacy Law, Social Security Code V and the Operating Laws for Pharmacies, as well as the new forms of care under the modernization act of the Law relating to Statutory Health Insurance. The legislative intent states that pharmacies, based on the license under Pharmacy Law, may dispense pharmaceuticals to consumers as well as physicians and hospitals, handle returns, or purchase drugs in purchasing pools or forward them to other pharmacies.

## InFocus

No wholesale license is required if a manufacturing license according to Sec. 13 AMG is given. Pursuant to Sec. 52a (5) AMG the manufacturing license according to Sec. 13 AMG also includes the license for wholesale trade with the pharmaceuticals covered by the manufacturing license. However, this applies only for the company specified in the manufacturing license. Where other subsidiary companies within a group which do not hold a manufacturing license perform wholesale trade, a license is required.

### Application

The application for the wholesale license must be filed with the competent authority of the country where the establishment is located or intended to be located, for that establishment. Pursuant to Sec. 52 (2) AMG the application has to include the following:

- specify the establishment for which the license is requested;
- proof of suitable and sufficient premises, equipment and facilities for a due and proper storage and distribution and, where required, due and proper repackaging, packaging and labeling of pharmaceuticals;
- identify a person in charge who has the expertise required for performing the activity; and
- a statement in which the applicant undertakes to comply with the regulations applicable to the due and proper operation of a wholesale business.

The authority has to decide about the application within three months; however, if the authority invites the applicant to provide further information the period is suspended until the required additional information has been made available to the authority. Pursuant to Sec. 52a (4) AMG grant of the license may be refused only if the above described requirements are not met or if there are facts which justify the assumption that the applicant or the person in charge do not have the reliability required for the performance of their activity.

If one of the reasons for refusal is given the license must be revoked subsequently. The license has to be revoked by the authority if the requirements for the grant are no longer met; the authority may also order a suspension of the license.

### Transitional Periods

Anyone who is lawfully engaged in the wholesale trade of pharmaceuticals on the effective date of the Amendment and has filed an application for a license by the fourth month following the effective date may continue the wholesale trade until a decision has been taken on the application.

### Wholesale Trade with Pharmaceuticals Designed for Animal Use

With respect to wholesale trade with pharmaceuticals designed to be administered to animals serving the production of food, which are not approved for trade outside pharmacies, the previous Sec. 9 of the Enterprise Regulation for Wholesale Businesses required the official approval of the competent authority for specific establishments. Sec. 9 has been repealed. Where such an official approval has been granted, it is pursuant to Sec. 138 (5) AMG deemed a license within the meaning of Sec. 52a AMG. The holder of the official approval however has to file the documents and statements required under Sec. 52a (2) AMG with the competent authority on or before the first day of the seventh month following the effective date of the Amendment.

### Authorization to Improve Drug Safety Sec. 63b

The Amendment introduces a new Sec. 63b relating to duties of documentation and notification of the holder of the marketing authorization. The new section comprises the notification duties in the area of pharmacovigilance in consideration of the new requirements under European law (Art. 104 and 105 Directive 2001/83/EC and 75 and 76 Directive 2001/82/EC), which had previously been included in Sec. 29 (1) sent. 2 to 8.

### Certificates Sec. 72 a

The regulation of Sec. 72a (1) AMG now also includes active substances of a microbial origin as they have a similar risk potential as the already covered active substances. The previous regulation contained an authorization to prohibit by ordinance the importation of active substances or drugs which are blood or blood preparations. This prohibition is now extended to all drugs, active substances and other substances designated to be used in drug manufacture which are of human or animal or microbial origin or which have been manufactured applying gene technology, since, according to the legislative intent, the same safety concept applied to them.

## The Pharmaceutical Enterprise Regulation

### Approval Sec. 7

Pursuant to Sec. 7, aside from the signing of the manufacturing and trial protocol, the approval of a pharmaceutical now also requires the written confirmation of the control manager that the particular batch of pharmaceuticals has been duly manufactured and examined in accordance with the applicable legal provisions and the requirements specified in the marketing authorization. The control manager has to enter the batches into a continuous register or comparable document to ensure they can be traced back. That provision correlates with the other provisions of the Pharmaceutical Enterprise Regulation and those of the Enterprise Regulation for Pharmaceutical Wholesalers, which are intended to provide for an improved possibility to trace back batches.

### Distribution and Importation Sec. 13 (3)

Sec. 13 (3) requires that the examination of the pharmaceutical quality of drugs pursuant to Sec. 6 has to be performed in the area of applicability of the Drug Law, in other words in Germany. Besides a full qualitative and quantitative analysis the additional examinations set forth in Sec. 13 (3) have to be conducted to guarantee the quality of the pharmaceutical. The examination is not required if the pharmaceutical was already subjected to a pertinent examination in another Member State of the European Union and pertinent examination documents are available there. The amendment of Sec. 13 (1) is based on Sec. 51 (1 b) of the Directive 2001/83/EC. The examination provisions of Sec. 13 (3) do not apply to pharmaceuticals designated for clinical trials involving humans. Furthermore the examination is not required where the requirements pursuant to Sec. 72a sent. 1 No. 1 are met, in other terms the pharmaceutical quality of the imported drug has been verified by pertinent certificates. According to the meaning and purpose of the provision such a certificate is not required for reimports. According to the meaning and purpose of the provision reimported pharmaceuticals will further not be subject to the examination provisions of Sec. 13 (3) Pharmaceutical Enterprise Regulation. Certificates pursuant to Sec. 72a (1) No. 1 AMG have to be issued by the competent authority of the exporting country. Regarding pharmaceuticals designated for administration to humans or containing active substances of human or animal origin or active substances manufactured applying gene technology, mutual recognition of the certificates must be assured based on bilateral or multilateral treaties with the exporting country. This applies, among others, to countries that are parties to the Pick-Up Agreement. Furthermore there are bilateral treaties with Japan. The US and the EU also concluded an agreement about mutual recognition.

## The Enterprise Regulation for Wholesale Traders

### Compliance with the EU Guidelines on Good Distribution Practice

The amendment provides for a new wording of Sec. 1a of the Enterprise Regulation for Pharmaceutical Wholesale Businesses. Businesses and institutions will have to comply with the EU guidelines on Good Distribution Practice of pharmaceuticals and for that purpose operate a functioning quality assurance system that is adequate in view of their activities. Such quality assurance system in particular has to ensure that pharmaceuticals are purchased only from, and delivered only to, authorized businesses and institutions. With that clarification of the admissible distribution channel the legislator intended to contribute to the improvement of drug safety, and in particular hinder counterfeit pharmaceuticals from entering the regular distribution channel.

### Purchase only from Businesses and Institutions Holding Manufacturing and/or Wholesale Licenses

That requirement also follows from the new Sec. 4a relating to the purchase of pharmaceuticals, according to which pharmaceuticals may be purchased only from businesses and institutions holding a manufacturing license according to Sec. 13 AMG or a wholesale license according to Sec. 52 AMG. Businesses and institutions holding a manufacturing license or a license under Pharmacy Law and/or otherwise entitled to dispense drugs to ultimate consumers may also take back pharmaceuticals.

Deliveries have to be checked upon acceptance for any damage to the packaging, conformity of the delivery with the order, and confirmation of the supplier including specification of the issuing authority and date of issue that he holds the required permission.

### Delivery only to Businesses and Institutions Holding Manufacturing or Wholesale Licenses or otherwise Authorized to Dispense Drugs to Ultimate Consumers

Pursuant to the new Sec. 6, not only the purchase but also the delivery of pharmaceuticals may be effected only to businesses and institutions holding a manufacturing or wholesale license or authorized to dispense drugs to ultimate consumers. The businesses and institutions listed in Sec. 47 AMG are authorized in that respect, as pointed out in the legislative intent.

### **Batch documentation**

Pursuant to the new Sec. 6 (2) delivery must in future be accompanied by detailed documents stating in particular the date of delivery, the name and quantity of the pharmaceutical, and the names and addresses of the supplier and the recipient. If delivery is effected to other businesses and institutions holding a wholesale license the batch identification must also be specified. This requirement applies also where pharmaceuticals are dispensed to pharmaceutical enterprises, hospital pharmacies, and pharmacies supplying hospitals, for the purpose of supplying hospitals. The batch must be identified also in the case of dispensing of blood preparations, sera from human blood and blood components produced with gene technology, which replace lacking components, and specifically also in case of delivery to businesses and institutions for dispensing to the ultimate consumer. Batch documentation is further required where drugs designed for administration to animals are dispensed. Furthermore the supplier has to confirm, by specifying the issuing authority and the date of issue, that he holds a wholesale license. The batch-related documentation for drugs designed for animal use is based on stipulations set forth in EU law. By introducing batch documentation also for drugs designed for human use the legislator intended to improve drug safety. Batch-related documentation for drugs designed for human use is also based on the EU Guidelines for Good Distribution Practice.

### **Separate Storage of Counterfeit Pharmaceuticals**

The new Sec. 5 (3) also serves the goal of ensuring a safe and fast removal of counterfeit pharmaceuticals from the distribution network. The provision sets forth that counterfeit pharmaceuticals must be stored separately and securely, and that the competent authority has to be notified promptly.

### **Regulatory Offenses**

The catalog of regulatory offenses in Sec. 10 has been complemented by the new provisions.

### **Operating Laws for Pharmacies**

#### **Separate Storage of Counterfeit Pharmaceuticals, Duties of Notification**

The Operating Laws for Pharmacies have been adjusted in Sec. 21 in accordance with the new regulation of Sec. 5 (3) of the Enterprise Regulation for Pharmaceutical Wholesalers. Pharmacies as well have to store counterfeit pharmaceuticals that have been identified in the distribution network separate from marketable pharmaceuticals and in a secure place until a decision has been taken on the further procedure. The counterfeit products must be clearly marked as such. The competent authority has to be notified promptly.

#### **Batch Documentation for Deliveries to other Pharmacies**

Pharmacies as well will have to document and inform the recipient about the batch name of the pharmaceutical in question in the case of deliveries of pharmaceuticals to other pharmacies, or purchase of pharmaceuticals from other pharmacies. For that purpose a new paragraph 1a is inserted in Sec. 22.

[Back to contents](#)

# In brief

## Refuse to mediate at your peril

Mediation has much to recommend it. The life science industry is tightly knit and a means of alternative dispute resolution ('ADR') that is relatively cheap, has a high success rate, allows a party to retain confidentiality and yet maintain ongoing business relationships would seem to be highly attractive. Nevertheless, some organisations remain suspicious of a scheme that involves showing one's hand at an early stage.

Intellectual Property (IP) disputes represent only about 3% of the work of the Centre for Effective Dispute Resolution (CEDR). In an effort to promote ADR as an effective means of resolving IP disputes, the UK patent Office is considering ways in which IP owners could be encouraged to make more use of ADR.

Recent case law relating to the cost sanctions for failing to mediate, however, has meant that parties should think carefully before abruptly dismissing an offer of mediation. In a long awaited ruling, the Court of Appeal in *Halsey v Milton Keynes NHS Trust*<sup>2</sup> has attempted to provide clarification and guidance as to the factors that the courts should consider in determining whether to refuse to award a successful party its costs if it declines to mediate. Parties to any dispute, therefore, need to pay careful heed to these guidelines when faced with any offer to mediate. Failure to do so may prove financially detrimental in the long run. Companies that doggedly proceed with litigation on principle or that have a standard hard line response to disputes, for example, may find that they bear their own costs as a result, even if they are successful.

*Halsey* is an important successor to cases such as *Dunnett v Railtrack plc* [2002]<sup>3</sup> and *Hurst v Leeming* [2002]<sup>4</sup> which were seen as a major endorsement of Lord Woolf's plea to solicitors, in his 2002 report on civil justice reform, to mediate more and litigate less.

In *Dunnett*, the Court of Appeal denied Railtrack its costs in successfully resisting an appeal, as it had rejected an offer to mediate. Railtrack had considered that mediation would have involved an extra payment of money, which it was not willing to contemplate, over and above the sum that it had already offered to the claimant in settlement. This was not a valid excuse, however, for refusing to mediate, particularly given an earlier recommendation in the case by a Lord Justice that the case was suitable for mediation. Brooke LJ used the opportunity to warn parties of:

*"... the possibility that, if they turn down out of hand the chance of alternative dispute resolution when suggested by the court, they may have to face uncomfortable consequences."*

By contrast, in *Hurst v Leeming* the defendant was awarded its costs even though it had refused mediation, as the attitude and character of the claimant was such that mediation was unlikely to succeed.

In *Halsey*, the Court of Appeal acknowledged that there had been a measure of uncertainty as to the approach that should be adopted by the courts in determining when the court should impose a costs sanction against a successful litigant for refusing to take part in mediation. It noted that a measure of the significance of the question was demonstrated by the fact that there were four interveners to the case, the Law Society, the Civil Mediation Council, the ADR Group and the CEDR.

As a primary issue, the Court of Appeal confirmed that a court has no power to order ADR against the wishes of a party. To do so would be contrary to a party's right to access to court laid out in Article 6 of the European Convention on Human Rights. On a practical basis, they also accepted that if a party objected to ADR, ordering them to take part might simply increase costs by adding another process to the equation. The judge should explore the reasons for opposition, but if at least one of the parties remained intransigently opposed to ADR, it would be wrong of the court to compel it. Nevertheless, the Court of Appeal concluded that where a successful party refuses to agree to mediate despite the court's encouragement, that is a factor which will be taken into account when deciding the costs issue. A party that actively wants to engage in mediation with the other side, therefore, would be advised to seek an ADR order of the kind sometimes made in the Commercial Court at an early stage in proceedings, which stops short of actually compelling the parties to undertake ADR, but which strongly encourages the parties to do so. In *Halsey*, the Court of Appeal suggested a party who rejects an offer to mediate despite such an order will run the risk that his refusal is unreasonable on that basis alone.

<sup>2</sup> (2004) EWCA (Civ) 576 (together with *Steel v Joy*)

<sup>3</sup> 1 WLR 2343

<sup>4</sup> Lloyds Rep PN 508

Essentially, the Court considered that an order depriving a successful party of his costs is an exception to the general rule that the losing party pays the winner's costs. As such, the Court determined that burden is on the unsuccessful party to show why there should be a departure from the general rule. Importantly, such a departure will not be justified unless it is shown that the successful party acted unreasonably in refusing to agree to mediation. Aside from the factor described above, namely a particular recommendation by the court concerned that mediation be undertaken, the Court of Appeal listed a number of factors that were relevant in determining whether a party's decision to reject mediation was unreasonable:

- The nature/subject matter of the action. Some cases are intrinsically unsuited to mediation, such as actions for fraud or breach of confidentiality, where an injunction may be needed or where legal precedent is sought;
- Whether the refusing party reasonably believed that it would win on the merits at trial. If the position were otherwise, there would be considerable scope for a claimant to use the threat of costs sanctions to extract a settlement from the defendant even where the claim is without merit. The Court of Appeal acknowledged that "large organisations ... are vulnerable to pressure from claimants who, having weak cases, invite mediation as a tactical ploy. They calculate that such a defendant may at least make a nuisance-value offer to buy off the cost of a mediation and risk of being penalised in costs for refusing a mediation even if ultimately successful". A clear cut case is likely to be one where the party in question is likely to succeed on a summary judgment application. In true border-line cases, however, mediation is likely to be appropriate unless there are "significant countervailing factors which could tip the scales the other way";
- The extent to which other settlement methods have been attempted. This is subject to the view, however, that mediation can often succeed where previous efforts to settle have failed;
- Whether the costs of the mediation would be disproportionately high. This factor is highly relevant where the sums at stake in the litigation are comparatively small and mediation is likely simply to increase overall sums spent;
- Delay i.e. where mediation is offered late in the day and acceptance would have the effect of delaying trial, or where substantial costs had already been incurred;
- Whether mediation had a reasonable prospect of success. The burden of showing this lies with the unsuccessful party who desired mediation, not on the refusing party who succeeded at trial. This factor, for example, was relevant in the case of *Hurst v Leeming* above, where the claimant's attitude was such that he was incapable of the objectivity required to achieve successful mediation.

That is not to say that there is now little scope for refusal of mediation. In *Halsey* itself, the Court of Appeal were seemingly generous in their interpretation of the above criteria. The defendant NHS Trust successfully defended a claim relating to the death of the claimant's husband arising out of its allegedly negligent treatment of him. The Trust were able to recover their costs despite a refusal to mediate on the basis that the sums involved were too low to justify further NHS expenditure, the attempt at mediation was "somewhat tactical" and the Trust had reasonable grounds to believe it had a strong defence. It was felt that the claimant's proposals were generally unrealistic and, therefore, the mediation was unlikely to succeed. Arguably, however, mediation could have been achieved at little extra cost and may have resulted in giving the claimant the chance to air her grievances and understand the Trust's claims against her.

Overall, the Court of Appeal emphasised that, in many cases, no single issue will be decisive and the above factors should not be regarded as an exhaustive check list. Nevertheless, the list is useful when considering an offer to mediate. Indeed, the judgment is the essential reference guide in this context.

[Back to contents](#)

### The Patents Act 2004

The Patents Act 2004 (the "2004 Act") received Royal Assent on 22 July 2004. It amends the current statute governing the patent system in the United Kingdom, the Patents Act 1977 (the "1977 Act"). The primary purposes of the 2004 Act are:

- to bring the UK patent system into line with the revised European Patent Convention ("EPC 2000")<sup>5</sup>; and
- to introduce new measures directed to the enforcement of patent rights and in resolving patent disputes.

It may be some time before the full impact of the new law can be fully assessed since (i) all but one of the new provisions are yet to enter into force<sup>6</sup>, and (ii) as discussed further below, in some cases the primary legislation only establishes the framework, leaving it to yet to be drafted regulations and/or judicial interpretation to "fill the gaps".

The 2004 Act could probably not be described as introducing fundamental changes to UK patent law. In particular, the amendments introduced by the 2004 Act do not effect what ultimately is or is not patentable, nor do they effect what is or isn't an infringing act. However, a number of the new provisions are significant and what follows below is a summary of those highlights.

### Changes related to EPC 2000

#### Method of treatment or diagnosis claims

Under the current provisions of the 1977 Act, claims directed to the treatment or diagnosis of the human or animal body are deemed not patentable inventions by virtue of not being capable of industrial application. The amendment to be introduced by 2004 Act removes this rather nonsensical "legal fiction" and such inventions are now included along with others (such as discoveries, presentation of information, inventions contrary to public policy or morality, etc) which are simply deemed as not patentable per se. This better reflects the position that the exclusion of methods of treatment from patentability is based on policy grounds.

#### Second medical use claims

The amendments to be introduced by the 2004 Act will have the effect that second or subsequent medical uses for a previously disclosed compound may be patentable without having to dress the claims up as process claims in the somewhat unwieldy "Swiss" form. A second medical use will be novel as long as that specific use does not form part of the state of the art. Of course, the second medical use must still be inventive to be patentable.

#### Post-grant amendment

The ability of a patentee to amend the specification of a patent after grant is currently subject to the Court (or Comptroller, in the Patent Office) exercising its discretion to allow the amendment. In exercising that discretion, the conduct of the patentee plays a central role.

Although the idea of removing entirely the UK Court's discretion with respect to claim-limiting amendments was considered, the discretion on post-grant amendment will remain. However, the amendments to be introduced by the 2004 Act do provide that in exercising that discretion the Court must "have regard" to any relevant principle that is applicable in amendment proceedings under the EPC<sup>7</sup>. With this obligation in mind, it should be noted that EPC 2000 provides a new central procedure for proprietors of European Patents to voluntarily limit their patent by amendment of the claims at the EPO.

The Implementing Regulations for EPC 2000 concerning a patentee's request for post-grant amendment by limitation do not provide any guidance as to what elements of the patentee's conduct, if any, should be taken into account. Consequently, it remains to be seen whether or not, or to what extent, the UK courts will continue to consider the conduct of the patentee when the patentee is seeking purely claim-limiting amendments.

#### Relief for amended/partially valid patents

Damages for pre-amendment infringement or for infringement of a partially valid patent are only currently available where the patent was drafted in good faith and with reasonable skill and knowledge.

The amendments to be introduced by the 2004 Act add an additional hurdle for the patentee in that damages will only be available in these situations if the Court is satisfied the infringement proceedings were brought in good faith. It is hoped that these provisions will deter patentees from asserting broad claims that they know or ought to know are invalid.

<sup>5</sup> Revisions to the current European Patent Convention were agreed by the contracting states in November 2000 and the revised text was subsequently adopted and published by the Administrative Council of the European Patent Organisation on 28 June 2001. EPC 2000 will come into force two years after ratification by 15 contracting states, or on the first day of the third month following ratification by the last of all contracting states, whichever is earlier

<sup>6</sup> the only provisions to enter into force to date are amendment to sections 120 and 123 of the 1977 Act - this gives the comptroller the power to give directions regarding certain procedural matters which were prescribed by rules made by the Secretary of State under the original provisions of the 1977 Act.

<sup>7</sup> the principles may be derived from, for example, regulations made under the EPC, any relevant guidelines produced by the EPO, decisions of the Opposition Division and Boards of Appeal

### Central amendment at EPO as condition of relief

Under the amendments to be introduced by the 2004 Act, if a European patent is found partially invalid, the Court may make it a condition of granting relief for infringement that the proprietor of a European patent limit the claims to the Court's satisfaction at the EPO. Similarly, the Court may make an order that a partially valid European patent be revoked unless the proprietor limits the claims to the Court's satisfaction at the EPO.

It is immediately apparent that the outcome of proceedings in the UK where the validity of a European patent is in issue may have an impact on the scope of the patent in all the designated territories. In the context of the pharmaceutical sector, the possibility of such an outcome is, perhaps, going to increase further the attraction of the UK courts for generics wishing to challenge the validity of pharmaceutical patents.

### Other provisions of the 2004 Act

#### Threats

The 2004 Act will introduce amendments to the 1977 Act that further limit the circumstances in which a claim for groundless threats can be brought.

Under the amendments to be introduced by the 2004 Act, threats will be able to be made against a primary infringer (i.e. a party who is making or importing a patented product or is using a patented process) not only for those primary acts of infringement, but also with respect to any other infringing activity being carried out by the primary infringer. Therefore, provided it is clear the party has made or imported the patented product, threats will also be able to be made with respect to the selling, offer to sell, stocking, etc of the product.

The amendments to be introduced under the 2004 Act also provide a means for a patentee to threaten alleged secondary infringers with infringement proceedings. The patentee will have a defence to a claim for groundless threats against a secondary infringer if he can establish that he has made his best endeavours to discover the identity of the primary infringer, but has failed. The secondary infringer must be notified of the attempts the patentee has made to trace the primary infringer. Consequently, it will be possible under the provisions of the 2004 Act to threaten retailers or distributors with infringement proceedings.

Under the current threats provisions of the 1977 Act, relief for groundless threats will be available if the patent asserted is found to be invalid. The amendments to be introduced by the 2004 Act provide the patentee with a defence in that even if the patent is eventually held to be invalid, relief will not be available if the patentee can establish that (i) the act of "infringement" did, in fact, take place and (ii) he did not know and did not have reason to suspect at the time of making the threat that the patent was invalid.

The 2004 Act also enlarges the definition of acts which do not constitute threatening another with proceedings for infringement:

- providing any purely factual information about the patent;
- making enquiries solely for the purpose of discovering if there has been primary infringement (and if so, by whom);
- making assertions about the patent for the purposes of making such enquiries.

Of course, what will and will not in fact constitute a threat will depend on a consideration of all the circumstances. Therefore, it will still be advisable to tread carefully. This includes solicitors, who will remain "on the hook" in the event that an actionable threat comes in the form of, for example, a solicitor's letter.

#### Patent Office non-binding opinions

The provisions of the 2004 Act will introduce a new procedure whereby any person can request the Patent Office to issue a non-binding opinion on the validity of a patent (with regard to novelty and inventive step only) or on whether an act infringes the claims of a patent.

The detail of this new procedure will be set out in yet to be drafted Patent Office rules and, as such, much of the procedure is yet to be revealed. It is, however, envisaged that the procedure will be quick and simple, most probably involving only an exchange of written submissions. It is also likely that the Patent Office opinion will be open to public inspection.

It is hoped this procedure will be useful in assisting parties seeking to reach settlement of a patent dispute without resorting to full proceedings. Given the current general obligation on parties to litigation to explore other means of

resolving their dispute, it will be interesting to see to what extent parties will embrace this new procedure. In the absence of a "knockout" prior art novelty reference that was simply not brought to the examiner's attention during pre-grant examination, it is perhaps easy to envisage parties to most disputes, particularly where the issues are very technical or complex in nature, preferring to keep their evidential powder dry for a more comprehensive examination in court.

### Litigation costs

Under the 1977 Act, when making an award of costs in an action for compensation for employees' inventions under section 40, the Court is obliged to have regard to the financial position of the parties. The amendments to be introduced by the 2004 Act extend this obligation to all proceedings in which infringement is in issue<sup>8</sup>. The amendment is not intended to interfere with the Courts' overall discretion on costs under the Civil Procedure Rules, but merely adds to the list of factors that should be taken into account when awarding costs.

The purpose behind this amendment is to put small and medium enterprises engaged in a patent dispute against a larger, wealthier party in a better position when it comes to costs. Although a noble idea in theory, how this potentially delicate balance will actually work in practice remains to be seen.

### Compensation for Employee Inventions

Under the 1977 Act, an employee may be awarded compensation for an invention if the patent for that invention has been of outstanding benefit to the employer, i.e. the benefit to the employer must have been derived from the existence of the patent, rather than the underlying invention itself.

Under the amendments to be introduced by the 2004 Act, although an invention must still be patented before an employee can become entitled to compensation, it is no longer necessary that the benefit flow from the patent itself, i.e. benefit (which must still be "outstanding") derived from the invention for other reasons can be taken into account when assessing an employee's entitlement to compensation.

### Conclusion

It is probably fair to say that the provisions to be introduced by the Patents Act 2004 add some interesting gloss to the existing statutory regime rather than introducing fundamental changes to current patent law in the UK.

[Back to contents](#)

---

<sup>8</sup> The principle will not apply to proceedings where validity only is in issue, but will apply to awards of costs on issues of validity raised in proceedings where infringement is also in issue

## Reviewed

## Counterfeiting and Piracy in the life sciences and healthcare industry: A review of the EU and UK legislation

Counterfeiting and piracy is a serious issue that affects all intellectual property right holders. However, counterfeiting in the life sciences and healthcare industries can have particularly grave consequences. Companies, which are the victims of counterfeiting, will inevitably suffer financially. However, there is also an acute risk to the health of the public from, for example, counterfeit medicinal products.

In August this year counterfeits of a Lilly ICOS product and an Abbott Laboratories product were found in the legitimate supply chain in the UK. Both companies have been working closely with the regulatory authorities in the UK to recall the products and further to establish how counterfeits of their products entered the supply chain. The presence of counterfeit medicines in the legitimate supply chain in the UK is unusual. The last incident was Azantac in 1994.

Counterfeit medicines are a global problem and tackling the problem is a priority for the international regulatory bodies and the pharmaceutical industry. Here we look at some of the legal measures available to assist in tackling this global issue.

### International Treaties and Conventions

At an international level, measures and procedure for enforcing IP rights were, in effect, the subject of harmonisation by the entry into force of the Agreement on Trade-related Aspects of Intellectual Property (the TRIPS agreement). However, the legal situation in the European Community (EC) was such that right holders did not benefit from equivalent protection throughout the EC.

### The EU Directive on the Enforcement of Intellectual Property Rights

Directive 2004/48/EC on the Enforcement of Intellectual Property Rights (the "Directive") came into force on the 29 April 2004. The Directive is an attempt to harmonise IP rights enforcement across the Member States so that the EU will be a level playing field for IP owners. The Directive also aims to stem the loss of confidence in the internal market associated with counterfeiting, and the consequent reduction in investment and innovation. It is also hoped that the Directive will tackle the link between infringements of intellectual property rights and organised crime. In short, the Directive, which came into force on 29 April 2004, was intended to send out a clear political signal "in support of a strong stance against counterfeiting and piracy ...".

The Directive is stated to be "without prejudice" to any Community or national legislation, in so far as such legislation contains provisions that are more favourable to right holders.

### General Obligation

There is a general obligation on Member States to provide effective, proportionate and dissuasive measures, procedures and remedies to ensure the enforcement of intellectual property rights.

### Evidence

Article 7 of the Directive recognises the need for an effective means of presenting and obtaining evidence of infringement:

- any specific, reasonably available evidence identified by the applicant as being in the control of the opposing party and which is claimed to substantiate the applicant's claims. The competent judicial authority may order the production by the opposing party of [...?];

1 CPR 1.1(1)

2 CPR 26.6 - basically claims for £5000 or less. Disclosure in the Small Claims track is governed by CPR 27.4(3)(a)(i) which provides that each party shall at least 14 days before hearing file and serve on each other copies of all the documents that they intend to rely on

3 CPR 26.6 - when the small claims track is inappropriate, i.e. when the value of the claim is not more than £15,000, the court considers that the trial will not last for more than one day, and oral expert evidence at trial will be limited to one expert per party in relation to any expert field; and expert evidence in two expert fields

4 CPR 26.6 - when the small claims and fast tracks are inappropriate

5 In the case of intellectual property rights, this is PD 63 para 5

6 i.e. the documents which adversely affect his own case; adversely affect another party's case; or support another party's case

7 r. 31.7(2)

8 r.31.10(5 to 9)

9 CPR 31.10 and PD 31 paras 2 - 5

## InFocus

- similarly, for infringement carried out on a commercial scale, the competent judicial authority must be permitted to order the communication of banking, financial or commercial documents under the control of the opposing party, where appropriate.

Production of such evidence and documents will be subject to the protection of confidential information.

Article 6 of the Directive goes further and allows the court to order measures to preserve evidence of infringement even before proceedings have been initiated.

In addition, the competent judicial authority may order the production of information on the origin and distribution networks of the goods and services which infringe IP by the infringer and any other person found in possession of infringing goods on a commercial scale. This is known as the Claimant's "Right of information" and is contained in Article 8 of the Directive.

## Remedies

The Directive provides for a number of "provisional and precautionary" measures enabling the prevention of further alleged infringements before the substance of a case is decided:

- Article 9 of the Directive allows a court to order an interim injunction, and where the infringement is on a commercial scale, the seizure of the infringer's property, including the blocking of his bank accounts;
- Article 11 of the Directive allows a final injunction to be ordered.

In addition to precautionary measure, the Directive also includes "corrective" measures, for example:

- the recall from sale of infringing goods, or their destruction;
- an order for pecuniary compensation may be made if the infringement is unintentional and not negligent, and where it would be disproportionate for the court to apply other remedies (Article 12);
- the court may also order the infringer to pay the right holder damages to compensate him for his loss. The court is required to take into account the right holder's loss of profits and any unfair profits made by the infringer (Article 13).

Article 10(3) of the Directive emphasises the need to balance the seriousness of the infringement and the remedies ordered, and the interests of third parties.

## The Shortcomings of the Directive

The Commission initially proposed criminal sanctions for serious intentional infringements committed for commercial purposes. These were not included in the Directive. However, Article 16 states that "Member States may apply other appropriate sanctions in cases where intellectual property rights have been infringed", leaving Member States free to impose criminal sanctions if they chose to do so.

In most instances, the competent judicial authorities have a wide discretion in relation to implementation of some provisions. It has been argued that, for this reason, the Directive does not go far enough towards harmonisation.

## The UK

Many of the enforcement methods specified by the Directive are already available to life science and healthcare companies in the UK, where IP right holders are able to seek interim and final injunctions, orders for delivery up and destruction of infringing goods. However, whilst the UK has experience of such measures, the Directive makes them much more widely available across a range of intellectual property cases. The House of Lords European Scrutiny Sub-Committee E (Law and Institutions) commented on 11 June 2003 that there would have to be a detailed assessment of the compatibility of Articles 7-9 (evidence and the right of information) with domestic law and the challenges they pose for human rights.

The existence in UK law of many of concepts included within the Directive, and an apparent reluctance to exercise the broad discretion given by the Directive in relation to the exercise of the remedies, means that the Directive is unlikely to have a marked effect on a national level.

### Watch Notices

In addition to the measures set out in the Directive, EC regulations permit IP right holders to ask Customs and Excise to keep a watch for counterfeit or pirated goods. If Customs identifies any, it will detain them for inspection, possible seizure and destruction. Although there is no searchable register of "watch notices" in force, these notices are increasingly used by UK IP right holders. Such notices could be used for example, to get Customs to intercept active ingredients or finished product thought to infringe Intellectual property rights when they enter the UK.

### Other anti-counterfeiting measures

Until relatively recently, counterfeit pharmaceuticals were perceived as an issue facing developing countries. However, the US Food and Drug Administration has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about five per year through the late 1990s. A similar upsurge in counterfeit pharmaceuticals has been noted in the UK notably the two incidents in August this year and as a result, the Counterfeiting Intelligence Bureau, a part of the International Chamber of Commerce, introduced the CIB Counterfeit Pharmaceuticals Initiative in August. The primary objective is to increase the dissemination of evidence on counterfeit materials and increase investigation and protection efforts on a number of fronts.

Also in August, an IP Crime Strategy developed by the Patent Office was launched. The Strategy brings together brand owners, police, trading standards and customs to share intelligence, improve training, ensure co-ordination of the relevant agencies, and produce an annual national enforcement report to monitor progress and success.

The new Directive and the strategies recently implemented in the UK show that the developed world is taking the issue of counterfeiting and piracy seriously. In theory, at least, life science and healthcare companies should find that enforcing their IP rights in EU is a more straightforward and effective exercise, which will be of particular importance in the context of an enlarging EU.

[Back to contents](#)

# Life science and healthcare events

## News from the LSH Group

Members of the LSH group in Cambridge took part in this year's **Chariots of Fire relay race**, to raise money for Papworth Hospital. There were 400 teams competing this year, the highest number yet, with each team member having to run the 1.7 mile route around the colleges of Cambridge. Although the Taylor Wessing team were by no means the fastest team (they came in at 53 minutes!), they all managed to run reasonable times with an overall finishing time of 1 hr 17 mins. This meant we came in at a very respectable 163rd. Well done Cambridge!

Taylor Wessing's LSH group is working in association with Melville Consultants. Melville Consultants can provide life science companies with "In-House" legal support on an ad-hoc basis depending on the companies needs. Legal support can be provided on a project basis or on an hourly, daily or weekly basis. The principle Suzanne McLean has over 20 years in-house experience in the pharma/bio sector. Melville consultants can be contacted at telephone: 0207 348 6070; Mobile: 07787 550035; Email: [suzannemclean@melvillelegal.com](mailto:suzannemclean@melvillelegal.com).

Taylor Wessing sponsored the 2nd Annual Celebration of Biotechnology in Cambridge on 28 September 2004 at King's College, Cambridge, UK

Mark Hodgson, LSH group partner, spoke with Tony Rollins of Merck and Harrie Temmink of the EU Commission on the Community Patent at Euro Legal's 13th International Patent litigation Conference on 29-30 September 2004 in London.

## Mark Your Calendars

LSH partner Dr Malcolm Bates, will be speaking with Christopher Thornham at the **BioArrays Europe 2004** conference in Brighton on 8 October.

Taylor Wessing is sponsor of the **12th annual BioPartnering Europe** event at the Queen Elizabeth II conference Centre, London on October 10-12 2004. Simon Walker, LSH partner, is chairing a BioPartnering Leadership Session "The Quest For Funding: Relative Merits of Raising Funds Through the Issue of Capital or Partnering Arrangements". Daniel Pavin and Dr Malcolm Bates are presenting a workshop entitled "University Challenge".

On October 20, the LSH Group are giving an **ABPI Breakfast Briefing** on "EU Enlargement: 6 months on". The briefing for members of the ABPI will include discussion on how the 'specific mechanism' for parallel imports from accession countries is operating in practice; what problems, if any, have been experienced in obtaining adequate SPC protection in the accession countries; the environment for pre-patent expiry clinical trials within the expanded EU; obtaining data exclusivity protection within the accession countries. Please contact the ABPI or Mark Hodgson for more details.

LSH partner Dr Malcolm Bates will be speaking on IP due diligence in BioPharm licensing transactions at the **Euro Legal Conference "BioPharm Licensing"** on Monday 29 and Tuesday 30 October in London.

Taylor Wessing partners Richard Price and Sabine Rojahn and Finnegan & Henderson partner Mike Elmer are running a seminar **"International Patent Litigation - why it is worth it"** at the Institute of Electrical Engineers Savoy Place London on 8th November. If you would like an invitation to this seminar or any future seminars please contact Mark Hodgson or your usual contact in the LSH Group.

Sally Annereau, will be speaking on data protection - considerations when tackling threats and sabotage, at a one day conference at the British Standards Institution ("BSI"), London W4 on 7 December 2004. The BSI conference will be looking at the wider issues surrounding employee security. For further information visit [www.bsi-global.com/seminars](http://www.bsi-global.com/seminars).

# 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.

## Editors:

Helen Cline - email: [h.cline@taylorwessing.com](mailto:h.cline@taylorwessing.com)

Mark Hodgson - email: [m.hodgson@taylorwessing.com](mailto:m.hodgson@taylorwessing.com)

## Contributors:

Sally Annereau - email: [s.annereau@taylorwessing.com](mailto:s.annereau@taylorwessing.com)

Thomas Carl - email: [t.carl@taylorwessing.com](mailto:t.carl@taylorwessing.com)

Philip Carey - email: [p.carey@taylorwessing.com](mailto:p.carey@taylorwessing.com)

Helen Cline - email: [h.cline@taylorwessing.com](mailto:h.cline@taylorwessing.com)

Emily McGee - email: [e.mcgee@taylorwessing.com](mailto:e.mcgee@taylorwessing.com)

Anoushka Myers - email: [a.myers@taylorwessing.com](mailto:a.myers@taylorwessing.com)

Julie Simpson-Day - email: [j.simpsonday@taylorwessing.com](mailto:j.simpsonday@taylorwessing.com)

Dr Wolfgang A Rehmann - email: [w.rehmann@taylorwessing.com](mailto:w.rehmann@taylorwessing.com)

[www.taylorwessing.com](http://www.taylorwessing.com)

## Taylor Wessing offices

### Berlin

Jägerstrasse 51  
D-10117 Berlin

Tel +49 (0)30 88 56 36 0  
Fax+49 (0)30 88 56 36 46

### Brussels

Trône House  
4 Rue du Trône  
B-1000 Brussels

Tel +32 (0)2 289 6060  
Fax+32 (0)2 289 6070

### Cambridge

24 Hills Road  
Cambridge CB2 1JW

Tel +44 (0)1223 446400  
Fax+44 (0)1223 446401

### Düsseldorf/Neuss

Königsallee 92a  
D-40212 Düsseldorf

Tel +49 (0)211 83 87 0  
Fax+49 (0)211 83 87 100

Am Krausenbaum 42  
D-41464 Neuss

Tel +49 (0)2131 7 40 30 0  
Fax+49 (0)2131 7 40 30 50

### Frankfurt a. M.

Senckenberganlage 20-22  
D-60325 Frankfurt a. M.

Tel +49 (0)69 971 30 0  
Fax+49 (0)69 971 30 100

### Hamburg

Neuer Wall 44  
D-20354 Hamburg

Tel +49 (0)40 3 68 03 0  
Fax+49 (0)40 3 68 03 280

### London

Carmelite  
50 Victoria Embankment  
Blackfriars  
London EC4Y 0DX

Tel +44 (0)20 7300 7000  
Fax+44 (0)20 7300 7100

### Munich

Isartorplatz 8  
D-80331 Munich

Tel +49 (0)89 2 10 38 0  
Fax+49 (0)89 2 10 38 300

### Paris

42 avenue Montaigne  
75008 Paris

Tel +33 (0)1 72 74 03 33  
Fax+33 (0)1 72 74 03 34

### Representative offices:

#### Alicante

Paseo Explanada de España No.  
1, 4-Izda E-03002 Alicante, Spain

Tel +34 (0)96 51 42 805  
Fax+34 (0)96 52 00 248

#### Shanghai

15th Floor United Plaza  
Unit 1509  
No. 1468 Nanjing West Road  
200040 Shanghai,  
China

Tel +86 (21)6247 7247  
Fax+86 (21)6247 7248

### Associated office:

#### Dubai

**If you would like to receive a copy of our other newsletters please contact us on:**

**[london@taylorwessing.com](mailto:london@taylorwessing.com)**

This bulletin is correct to the best of our knowledge and belief at the time of going to press. It is however written as a general guide, so it is recommended that specific professional advice be sought before any action is taken. We are required by law to protect personal data. Please write to Carmelite, 50 Victoria Embankment, Blackfriars, London EC4Y 0DX if you no longer wish to receive any of our future publications and we will amend our records accordingly.

© 2004 Taylor Wessing

All rights reserved