Legal and regulatory update

Compiled and written by Bird & Bird

an international law firm which specialises in advising clients in:

Information technology
Intellectual property
E-commerce
Communications
Pharmaceuticals and biosciences
Sport
Media
Banking and financial services

This section is intended to be a synopsis of recent legal developments and is not intended to be exhaustive. If any issue referred to in this section is to be relied upon, specific advice should be sought. Please contact:

John Wilkinson
Bird & Bird
90 Fetter Lane
London EC4A 1JP

Tel: +44 (0)20 7415 6000
Fax: +44 (0)20 7415 6111

Legal and regulatory update

INTELLECTUAL PROPERTY

Stem cell patenting

The European Group on Ethics in Science and New Technologies to the European Commission published on 7th May, 2002, its Opinion on the ethical aspects of patenting inventions involving human stem cells (Opinion No. 16). The Opinion notes that Article 6 of the Biotechnology Directive, in listing, *inter alia*, 'processes for cloning human beings' and 'uses of human embryos for industrial or commercial processes', as being contrary to '*ordre public*' under Article 53(a) European Patents Convention, 'leaves open the question of patentability of cells obtained from donated embryos. Nor does it state precisely which embryos are subjected to this exclusion.'

The Opinion goes on to observe that isolated stem cells that have not been modified do not meet the legal requirements of patentability as to industrial application. Moreover it observes that such cells are 'so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body'. It goes on to observe that unmodified stem cell lines are not patentable either as they have no specific use. In contrast, the Opinion notes that 'only stem cell lines which have been modified by *in vitro* treatment or genetically modified so that they have acquired characteristics for specific industrial application, fulfil the legal requirements for patentability.' It also observes that 'as to the patentability of processes involving human stem cells, whatever their source, there is no specific ethical obstacle, in so far as they fulfil the requirements of patentability (novelty, inventive step and industrial application)'.

Patent litigation

The English Court of Appeal has upheld two decisions of the Patents Court finding patents in the biosciences sector invalid for lack of inventive step. Thus on 23rd January, 2002, in *Lilly ICOS LLC v Pfizer Ltd* it upheld a finding as to Pfizer's patent to the use of PDEv inhibitors for the oral treatment of male erectile dysfunction invalid for lack of inventive step and on 16th April, 2002, did the same in *Asahi Medical v Macopharma (UK) Ltd and anr* in finding Asahi's patent for an apparatus for separating blood into blood components invalid for lack of inventive step.

On 6th March, 2002, the English Patents Court, in *Cairnstores Ltd & Generics (UK) Ltd v AB Hassle*, found two AstraZeneca patents on omeprazole formulations invalid for lack of inventive step. The technical problem addressed by the patents lay in the fact that ordinary enteric coatings, if used to protect omeprazole from the acid gastric juice, would themselves react with omeprazole. The solution claimed in the patent, namely to prevent the acidic enteric coating from reacting with the omeprazole coating core by keeping them apart by using a separating layer, was however held to lack inventive step. The judgment has been appealed.

Trade marks

The issue of 'bad faith' in relation to trade mark applications for pharmaceutical trade marks was addressed by the English High Court on 9th May, 2002, in *Wyeth (formerly American Home Products Corp) v Knoll AG*. Knoll's device trade mark – a stylistic representation of a moving person against a circular background, with the limbs and body of each person consisting of single lines and their heads solid dots – was registered in classes 5, 16 and 41. The dispute centred on the registration in class 5 for 'pharmaceutical preparations and substances . . . dietetic substances adapted for medical use . . .'. Wyeth claimed that, with the exception of pharmaceutical preparations and substances for the treatment of obesity, the registrations were

invalid under sections 3(6) (precluding the registration of trade marks applied for in 'bad faith') and 32(3) (by which applicants must state they have a bona fide intention to use the mark) Trade Marks Act 1994. Wyeth alleged that Knoll had had no intention of using the mark in respect of any other goods or services at the date of the application. Wyeth based its claim on evidence that Knoll had given in parallel opposition proceedings. In these Knoll had said that it had intended to use the mark primarily on obesity products but that, if it proved successful, it might use it for other pharmaceutical products. Knoll was successful in striking out the claim in relation to the key class 5 products, although the court held that it was not appropriate at the summary stage to decide on the other products and services. It did not accept, on the wording of section 3(6) and the evidence, that Knoll had acted in bad faith. Knoll had had a firm intention to use the mark in relation to products for the treatment of obesity and contemplated that it might use the mark on other products; the products on which it intended to use the mark fell within the specification of goods; and it had not claimed all products in class 5. Therefore it could not reasonably be said that Knoll had been inaccurate in its statement made under section 32(3), let alone that it had acted in bad faith under section 3(6). The precise meaning of 'bad faith' could vary depending on the linguistic context and purpose but involved a degree of dishonesty or something approaching dishonesty. To say that an applicant intended to use a mark in connection with 'pharmaceutical substances' when intending only to use it with a specific category of pharmaceutical substances did not amount to a lack of good faith. The Act did not require that the intention concerned had to apply across the whole range of goods and services in the specification.

Parallel imports

The European Court of Justice (ECJ) has again been called on to return to the long-running controversy surrounding parallel imports of pharmaceuticals within Europe in its judgments of 23rd April, 2002, in *C-143/00 Boehringer Ingelheim KG & ots v Swingward Ltd & ots and C-443/99 Merck, Sharp & Dohme GmbH v Paranova Pharmazeutika Handels GmbH*. These both concerned the parallel import of repackaged pharmaceuticals first placed on the market by the rights holder elsewhere in the EC, into the UK and Austria respectively. The manner of repackaging varied. Some of the products had been overstickered by the defendants, some had been reboxed, sometimes using the registered trade mark for the product on the outside of the box and sometimes not. The trade mark owners in both sets of cases claimed that these activities infringed their trade marks in the country into which the parallel imports were imported. It was not suggested that the quality of the goods had been affected by the defendants' actions.

The ECJ considered firstly whether repackaging could, in and of itself, be prejudicial to the specific subject matter of the trade mark and could be opposed *per se*. The Court, following its case law (notably *Hoffmann La Roche* [1978] ECR 1139 and *Bristol Myers Squibb* [1996] ECR I-3457), held that it was not possible to take this view. Instead, a trade mark proprietor could only rely upon his or her rights to prevent repackaging by a parallel importer where by exercising those rights, he or she did not contribute to the artificial partitioning of the market. If the repackaging is *necessary* to enable the product to be marketed in the state of import *and* it is done in such a way that it respects the trade mark proprietor's rights, then to oppose the parallel importation of that repackaged product will lead to artificial partitioning of the market and so restrict trade contrary to Article 28 and 30 EC Treaty.

As to the circumstances in which repackaging would be considered *necessary* to enable the product to be placed on the market in the state of importation, the ECJ drew a distinction between

repackaging which was necessary to comply with national rules and that which solely gave the parallel importer a commercial advantage. The trade mark owner could not object to the former, but could object to the latter. Here the parallel importers had argued that repackaging was *necessary* because of consumer resistance to relabelling, but the ECJ held that consumer resistance did not always impede effective market access. However, where there was strong resistance by a substantial proportion of consumers, that should be held to be a hindrance to effective market access. What on this basis was *necessary* was an objective test and one that, ultimately, the national courts had to decide.

Finally, the ECJ held that reasonable advance notice of the repackaging must be given by the parallel importer to enable the trade mark owner to react to the intended packaging. In each case the national court must decide whether the notice period was sufficient. However, the ECJ indicated that where notice was given, together with a sample of the intended packaging, 15 working days' notice would appear reasonable.

The ECJ will have a further opportunity to consider parallel imports in *C-443/00 Aventis Pharma Deutschland GmbH v Kohlpharma GmbH & anr.* Here Aventis held, pursuant to Regulation (EEC) No. 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Evaluation Agency (EMEA), separate central marketing authorisations for packages containing respectively 5 and 10 3 ml cartridges of an insulin suspension for injection. It marketed its product in Germany in packages of 10 and in France in packages of 5. The defendants imported the product from France, repackaging it for the German market into packages of 10. Aventis objected, stating that all that the defendant should do was double up the packs of 5, overstickering as necessary. The ECJ has been asked whether, where a medicinal product is the subject of two such separate central marketing authorisations, it is permissible for that product to be marketed in a double pack. In his Opinion of 7th March, 2002, the Advocate General recommended that, because of the terms of the marketing authorisation, the product could not be lawfully marketed in a double pack, thus rendering the repackaging 'necessary'.

REGULATORY LAW

Transparency Directive

On 18th April, 2002, the English Administrative Court rejected a challenge to the UK Government's reimbursement policy for Viagra in *R v Secretary of State for Health, Ex Parte Pfizer Ltd* under EC Council Directive 89/105/EEC (the Transparency Directive). Pfizer sought permission to apply for judicial review of a decision by the Secretary of State for Health. In June 1999 the Secretary of State made a decision restricting the circumstances in which general practitioners could prescribe Pfizer's product Viagra under the National Health Service. The Secretary of State had reasoned that the forecast cost of unrestricted prescription could not be justified. The decision letter referred to the criterion notified to the European Commission in compliance with Article 7.2 of the Transparency Directive. In October 2001 the Secretary of State reaffirmed his 1999 decision. Pfizer argued that the 2001 decision failed to conform to the requirements of Article 7.3 of the Transparency Directive in three respects. Firstly it was incumbent on the Secretary of State to identify something about Viagra that justified why it was not being reimbursed while treatments for other non-life-threatening conditions were. Secondly the Secretary of State had failed to analyse each and every treatment for non-life-threatening conditions. Thirdly there was a complete absence of any assessment of the justification for the acceptance or rejection of other

treatments of specific medical conditions. The Secretary of State argued that, having complied with the requirements of Article 7.2 of the Transparency Directive, he had equally complied with Article 7.3, both in his letter of October 2001 and in further letters in January 2002 and March 2002. The court held that Article 7 of the Transparency Directive had to be read as a whole and that Article 7.3 was not free-standing. The general reason made public so far as Article 7.2 was concerned was a legally effective compliance with Article 7.3. The letter of March 2002 demonstrated a correct understanding and application of the relevant principles of law and complied with the transparency requirements of Article 7.3 of the Transparency Directive

Fertility treatments

In *R (on the application of Assisted Reproduction and Gynaecology Centre) and another v Human Fertilisation and Embryology Authority* the English High Court held on 6 February 2002 that a decision not to authorise certain fertility treatment was not susceptible of judicial review. The authority had considered a request for advice carefully and thoroughly, had produced a decision that was plainly rational, and it was not the function of the Court to enter such scientific debates nor to adjudicate on the merits of the authorities decisions or the advice it gave.

'Morning after' pill

In *R v Secretary of State for Health & Schering Health Care Ltd & Family Planning Association)(Interested Parties) ex parte John Smeaton (on behalf of the Society for the Protection of Unborn Children)* the English High Court held on 18th April, 2002, that the supply and use of the emergency contraceptive pill (the 'morning after' pill) Levonelle did not involve the commission of the criminal offence of 'procuring a miscarriage' under the Offences Against the Person Act 1861, and thus the decision to reclassify it as a pharmacy medicine for which no prescription was required was lawful. It had been argued that as Levonelle acted to prevent implantation it was not in fact a contraceptive but an abortifacient.

PRODUCT LIABILITY

Causation

The House of Lords, on 20th June, 2002, reversing the Court of Appeal in *Fairchild v Glenhaven Funeral Services & Others, Fox v Spousal (Midlands) Ltd and Matthews v Associated Portland Cement Manufacturers (1978) Ltd*, has held that the injustice of denying an industrially injured employee (here suffering from a disease caused by exposure to asbestos) a remedy outweighed any unfairness to successive employers of such employee who had failed to protect the employee from such injury but who could not be proved to have caused the damage complained of. The Court of Appeal had held that where successive employers were each potentially liable but it could not be determined which of them was actually responsible for the condition, none of them were liable.

Duty of care

In *Amanda Claire v Secretary of State for Health (on behalf of the Committee on Safety of Medicines)* The English High Court on 15th February, 2002, held that the respondent authority had not been at fault, and had acted reasonably, in delaying a warning as to the dangers of aspirin in children under the age of 12 in order to obtain industry cooperation in disseminating the warning. In the interim the claimant, when aged 6, had suffered Reye's Syndrome as a result of taking aspirin. Moreover the respondent's decision to postpone its final decision was an act or omission that was treated in law as a discretionary or policy decision taken in the exercise of statutory powers or duties in respect of which no duty of care applied.

COMPANY/COMMERCIAL LAW

Non-executive directors

A consultation document was issued at the beginning of June inviting views on the role and effectiveness of non-executive directors following the announcement of an independent review of these issues by the Secretary of State for Trade and Industry on these issues. The intention is that clarifying the position of non-executive directors will promote further good corporate governance in the UK, and make it easier to identify the sorts of people who would be best suited to the job and most likely to perform to a high standard.

The term 'non-executive director' under English law has no special meaning. It represents all directors who do not perform an executive function within a company. No distinction is made on the register of UK companies if a director holds an executive position or has a service agreement with the company such as a managing or finance director. Executive directors generally have day-to-day control of the running of the business. However, important decisions are generally referred to the board as a whole, where non-executives can exert influence on a range of matters relating to the company. Non-executives can exercise a measure of control over the company, provide alternative views and help to protect the interests of shareholders through their involvement on the board.

Non-executives may be valued for their business sense and industry knowledge, or for skills used 'behind the scenes' in promoting the company. They can attract investors by virtue of their reputation and experience. Non-executive directors can represent the company, enter into negotiations and sign documents as appointed officers, although these activities are usually the responsibility of the management team.

The review will consider all aspects of the role and position of non-executives. Particular consideration will be given as to whether the role of non-executive directors should be different for smaller companies. Appropriate recommendations will be made to Government. It is possible that the review may lead to legislative changes but it is more likely to result in the introduction of a code of practice relation specifically to non-executive directors. The consultation document can be obtained from the DTI at http://www.dti.gov.uk/cld/non_exec_review or by calling +44 (0) 20 7215 3917. Responses are requested by 6th September, 2002, and a report to the Secretary of State is expected by the end of the year.

CASES

Director's fiduciary duty and director's competing interests: in *Plus Group Limited & Ors v Pyke (2002)*

Reference: (2002) EWCA Civ 370

In general, a director's fiduciary duty means that they must act at all times in the best interests of the company and must not make any secret profit from their connection with the company. In the absence of restrictions there is no absolute rule preventing directors from setting up in competition. If a director has an interest that conflicts with the interests of the company they will be required to notify the company of that interest. The articles of association of the company may then permit them to continue to be involved in decisions relating to that matter or may require them to abstain from voting on such issues. It is usual for directors' service contracts to include an undertaking from the director (known as a restrictive covenant) that they will not be involved or otherwise interested in a business that competes with the company of which they are a director. This case is unusual because there were no restrictive covenants placed upon the director.

The Court of Appeal held that a director was not in breach of fiduciary duties in setting up a company in

competition with another company of which they were still a director.

Relations between the defendant director and the company had broken down after he suffered a stroke and he had been effectively excluded from all decision making and participation in the company affairs. One year after his illness the defendant established a new company in competition with the claimant company. The defendant was not removed as a director of the claimant company until a further nine months later.

The Court of Appeal supported the first hearing decision that there was no alleged breach of fiduciary duty. The defendant had been effectively excluded from the companies over six months before he had established the competitive business. The continued connection with the claimants was not of the director's making and did not give rise to any fiduciary duty towards them on his part.

Responsibility for signing-off accounts: *Barings plc (in liquidation) & Anor v Coopers & Lybrand & Ors (2002)*

Reference: (2002) EWCH 461

A director must sign the balance sheet and a director or secretary must sign the directors' report of the company's annual accounts as a mark of the approval of the board. The signature on the balance sheet confirms that the accounts give a true and fair view of the state of affairs of the company for the preceding financial year and that they comply with the relevant statutory provisions. If accounts are approved by the board but do not comply with the requirements of the Companies Act 1985, every director who is a party to their approval, either knowing that they do not comply or reckless as to whether they comply, is guilty of an offence and liable to a fine.

This case arose as part of the litigation following the collapse of Barings Bank. A finance director was not deceitful in signing representation letters for the purpose of his company's annual audit even though various statements in the representation letter were factually incorrect.

It was held that in order for the director to be guilty of deceit the claimant would have had to show that the director had signed the representation letters either:

- knowing that the statements in the letters were untrue, without an honest belief in their truth, or indifferent as to whether or not they were true; or

- knowing that he had no reasonable grounds for making the statements, without an honest belief that he had such grounds or indifferent as to whether he had or not.

The case turned on the facts as the finance director was not in a position to verify the statements, which had been made by managers in other offices. Although he may have been negligent he did not necessarily lack an honest belief in the truth of the statements.

Directors' service contracts to be approved by shareholders: *Knopp v (1) Thane Investments Ltd (2) Denbrae Ltd*

Reference: LTL 29/05/2002

The articles of association of a company frequently require that service and other agreements must be approved by the shareholders. Even if the directors and shareholders are the same people, as is often the case in small companies, these requirements must still be strictly observed.

The Directors in this case had entered into service contracts without shareholder approval. The court held that the company was lawfully entitled to terminate the contracts on this basis and also for breach of fiduciary duty.

The two defendant companies had the same two directors. The directors passed board resolutions approving very generous service contracts between themselves and the companies. Each abstained from voting on the entering

into of their own service contract but the contract was approved by the other. The two directors proceeded to run the company in a manner that was for their own personal benefit rather than the interests of the company.

The companies terminated the contracts on the basis that (1) the directors had breached their fiduciary duty to act in the best interests of the company and (2) the terms of the agreements had not been agreed by the companies in a general meeting of the shareholders.

The judge held that there had been serious breaches of fiduciary duty and therefore the contracts could be terminated on that ground. The judge further stated that the contracts could have been terminated in any event. Where there is a requirement for something to be agreed or approved by a company in general meeting and that does not take place it can be ratified only if all the shareholders agree. In this case the consent of all the shareholders was never sought. The directors' executive service contracts were therefore avoidable at the instance of the company as they had not been validly entered into.

A memorandum of understanding can be legally binding: *Bunn v Rees (2002)*

Reference: LTL 19/04/2002

It is open to a party to produce evidence to show that an agreement was made without any intention to create legal relations. However, in commercial relations this is a difficult burden to discharge.

The terms of the document in this case were consistent with a commercial agreement that was intended to be legally binding. It was described as an agreement for the sale and purchase of the defendant company's share capital and was signed by the parties. The expectation that the parties would enter into a further, more detailed agreement was not consistent with an intention to create legal relations in respect of a preliminary document. The court found that the defendants were experienced business people and fully understood the consequences of signing the document and the agreement was held to be binding on the defendants.

It is crucial when entering into commercial negotiations to know whether there is an intention to create legal relations, as the evidential burden of proving there was none is a difficult one. Biotechnology companies may be involved in negotiations over the assignment of intellectual property rights, licensing or distribution and collaboration in research and development. The company must be aware of the potential consequences of signing any document, including a memorandum of understanding or heads of terms. If the terms in an agreement are sufficiently clear and determine the roles and obligations of each of the parties, an intention to create legal relations may easily be found.

Appointment of financial intermediary: *Vernon-Kell v (1) Clinch and (2) Fairfield Imaging Limited (2002)*

Reference: LTL 14/05/2002

This case concerned the raising of funding for a company (the second defendant) for use in the development of its computer-based techniques of cancer diagnosis and prognosis. The claimant alleged that, under an oral agreement, the company had agreed to pay him £30,000 for introducing an investor to the company and a further 10 per cent of any finance raised. The first defendant agreed that an oral contract had been made but that it was only required to make these payments if cash was received or shares were issued by the company.

The eventual outcome was quite different from that originally envisaged involving a reverse take-over of the company. The first defendant argued successfully that the final outcome was a completely different transaction from the negotiations in which the claimant had been involved. The agreement related only to certain outcomes of negotiations

as then contemplated by the parties. Accordingly the claimant was not entitled to any further payment from the company.

Companies should think carefully about their obligations to all parties when entering into arrangements with financial advisers. Investment and funding are critical to the success of the development of a company and can take many forms. A third party intermediary engaged to assist in raising finance should always be employed subject to a written agreement which clearly sets out the terms and conditions of any commission to be received.