Legal and regulatory update

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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:

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INTELLECTUAL PROPERTY

Biotechnology patent litigation

The English Court of Appeal reversed on 31st July, 2002, the judgment at first instance in *Kirin-Amgen v Transkaryotic Therapies & Aventis* which had found that Aventis's erythropoietin product infringed one of the product claims of Kirin-Amgen's patent to recombinant erythropoietin. The Court also reversed the first instance finding that claim 19 of the patent was invalid.

On infringement, the Court of Appeal agreed with the Judge at first instance that there was no literal infringement of the product claims of the patent in view of the process limitations inherent in the wording of those product claims. The Aventis product had been developed with Transkaryotic Therapies' 'Gene Activation' technology, which 'switches on' the relevant gene already present within a cell so as to express the protein of interest, in contrast to traditional recombinant technology, which involves the insertion into a host cell of an exogenous gene coding for the protein of interest. However, whereas the Judge at first instance had found that the Aventis product infringed the product claim of the patent which he held valid on the application of the 'Protocol Questions' (meant to provide a means of identifying a 'middle way' as to the protection afforded by patent claims and as laid down in the Protocol to Article 69 of the European Patent Convention), the Court of Appeal disagreed, finding against Kirin-Amgen as to the answers to the first two 'Protocol Questions' – namely 'does the variant have a material effect upon the way the invention worked?' and 'would this have been obvious at the date of publication of the patent to a reader skilled in the art?' They also held that, standing back from that approach, their decision was consistent with the broad principles set out in the Protocol.

On validity, the first instance Judge had held one of the two independent product claims, claim 19, invalid as insufficient because it contained a limitation (a comparison to the molecular weight of 'urinary erythropoietin' determined in a certain way) that meant that it could not be infringed. Although accepting the primary findings of fact on which the Judge had made this finding the Court of Appeal disagreed with him as to what sources of 'urinary erythropoietin' the skilled person would have used as comparators, and so reversed his judgment as to this.

Pharmaceutical patent litigation

On 12th July, 2001, the English Patents Court found, in *BASF v SmithKline Beecham*, several of the claims of a UK patent to a particular form of SKB's paroxetine hydrochloride anhydrate (including all the product claims in issue) invalid for anticipation or obviousness. The Judge did, however, uphold the validity of part of one process claim, and also another process claim, both of which involved displacing the solvent of solvation, and observed that any product claims would have to be limited to the products of such process. Patent and Supplementary Protection Certificate Protection for the basic pharmaceutical, paroxetine hydrochloride (SEROXAT) expired in the UK in January 1999.

Napp Pharmaceutical Holdings Limited v Director General of Fair Trading

The Court of Appeal rejected the appeal of Napp Pharmaceutical Holdings Limited against a decision of the Competition Commission Appeal Tribunal, which had held that Napp had abused its dominant position in the market for sustained release morphine (SRM) tablets due to its pricing policy. This case is the first time that an appeal

from a decision of the Tribunal has come before the Court of Appeal.

The market for SRM is divided into two segments: (1) supply to community pharmacies, for patients in community or primary care; and (2) supply to hospitals for use in secondary care. The Tribunal had found that Napp had a market share in excess of 90 per cent in both segments, and was thus in a dominant position. In the community segment, Napp made a gross margin of some 80 per cent; however, in the hospital segment Napp offered discounts in excess of 90 per cent of its list prices. The object of these discounts was held by the Tribunal to be the hindering of competition in the supply of SRM tablets and capsules, particularly as Napp was found to have offered bigger discounts to hospitals where it faced or anticipated competition. It was also found by the Tribunal that the prices in the community segment were excessive.

The Court of Appeal upheld the Tribunal's findings. It was at pains to point out that parties seeking to appeal a decision of the Tribunal may only appeal on points of law, not points of fact. The Appellant must precisely identify the rule of law said to be infringed by the Tribunal by reference to European authorities, and must be able to demonstrate briefly from the Tribunal's judgment the nature of the error, by reference to the Tribunal's handling of the issue in question.

The Court of Appeal stated that this was a case of predatory pricing, and such behaviour will always fall into the category of 'methods different from those which condition normal competition'. This is so even if a rival non-dominant would-be competitor prices at the same level in an attempt to overcome the market distortions.

REGULATORY LAW

Animals in scientific procedures

In the UK the House of Lords Select Committee on Animals in Scientific Procedures issued its report on the subject on 16th July, 2002. This contains of review of the existing legal framework and a study of the functioning of the Animals (Scientific Procedures) Act 1986 (implementing Directive 86/609/EEC) which regulates any experimental or scientific procedure which may have the effect of causing a protected animal (namely all non-human vertebrates and the common octopus) 'pain, suffering, distress or lasting harm', and of subsequent regulatory developments. It considers the regulatory framework in other countries and studies, in the light of developing trends in regulation, animal science and public debate, whether human beings have the right to experiment on other animals and whether animal experiments work. It makes a number of specific recommendations within the framework of the existing law but its main conclusions are that it is morally acceptable for human beings to use other animals, but that it is morally wrong to cause them unnecessary or avoidable suffering, and that there is at present a continued need for animal experiments both in applied research and in research aimed purely at extending knowledge.

Proposed Directive on standards for human tissues and cells

On 19th June, 2002, the Commission adopted a proposal for a Directive setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells. The proposed Directive would provide a legislative framework for human tissue engineering and tissue engineered products. It would not apply to blood or blood products (as these are already regulated by Directives 2000/70/EC and 2001/83/EC and a new proposal as to these is also already under separate discussion). Nor would it apply to research using human tissues or cells (such as when used for purposes other than application to the human body), the transplantation of human organs, or tissues

and cells used as an autologous graft within the same surgical procedure.

Implementation of Clinical Trials Directive

The Commission is undertaking a consultation exercise on the detailed guidelines for the implementation of Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use, and published several draft guidelines on its web site in July 2002. Member states have until 1st May, 2003, to prepare national provisions for complying with the Directive and must adopt such provisions by 1st May, 2004.

Cartagena Protocol on Biosafety and its implementation in Europe

On 25th June, 2002, the Council of Ministers approved the Cartagena Protocol on Biosafety to the Convention on Biological Diversity on behalf of the European Community. The Protocol, which was adopted on 29th January, 2000, is stated in one of the recitals to the Decision to provide 'a framework, based on the precautionary principle, for the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation, and sustainable use of biological diversity, taking into account risks to human health and specifically focussing on transboundary movements.' In consequence the Commission is proposing a Regulation on the transboundary movement of genetically modified organisms (GMOs) to implement into Community law the provisions of the Protocol not covered by existing Community law. The Commission takes the view that Directive 2001/18 on the deliberate release into the environment of GMOs is consistent with the relevant provisions of the Protocol, and needs no modification to implement the Protocol in the Community. However, new Community legislation is required to implement certain other aspects of the Protocol that have no existing counterparts in EC legislation, and in particular those concerned with the export of GMOs.

Implementation of Directive 2001/18 on the deliberate release into the environment of GMOs

The Commission has undertaken a number of initiatives in preparation for the entry into force on 17th October, 2002, of this Directive, and which will repeal Directive 90/220/EEC. Firstly it has sent to the Council of Ministers proposals for two Council Decisions. One, in relation to Part B of the Directive, would establish the summary notification information format for prior notifications to the competent national authority concerning the deliberate release of GMOs into the environment other than for placing on the market. The other would establish guidance notes supplementing Annex VIII to the Directive, addressing the issue of monitoring. Secondly it has, by Commission Decision of 24th July, 2002, established guidance notes supplementing Annex II to the Directive. These relate to the objective, elements, general principles and methodology of the environmental risk assessment referred to in Annex II. In the UK the Department for Environment, Food and Rural Affairs has undertaken two rounds of public consultation and published a draft of the Genetically Modified Organisms (Deliberate Release) (England) Regulations 2002 which would implement the Directive by amending the Environmental Protection Act 1990 and repealing the Genetically Modified Organisms (Deliberate Release) Regulations 1992.

Antibiotics in animal feeds

The Court of First Instance of the European Court of Justice gave judgment

in September 2002 in T 13/99 *Pfizer Animal Health v Council of Ministers* and T 70/99 *Alpharma v Council of Ministers*, upholding the decision of the Council to ban certain antibiotics (virginiamycin and bacitracin zinc) in animal feed because of the risk of resistance developing in humans. The applicants had argued that the Council had failed to conduct a thorough risk analysis, but the Court accepted that preventative measures, as long as they had some scientific basis and were not based on mere conjecture, could be taken under the 'precautionary principle', without awaiting the reality and seriousness of perceived risk to become apparent.

Food Supplements Directive

Directive 2002/46/EC on the approximation of the laws of member states relating to food supplements completed its passage through the Community legislative system on 10th June, 2002. The new Directive, which is to be implemented by 31st July, 2003, will harmonise national laws as to most vitamins and minerals which are marketed as foodstuffs for supplementing the normal diet and are presented as such. It will establish purity criteria, labelling provisions and maximum levels of vitamins and minerals that can be used in such supplements. It will not apply to medicinal products so in effect will serve to limit the maximum levels of vitamins and minerals that can be used in supplements unless such supplements are authorised as medicinal products.

European Parliament votes to tighten rules on labelling of GM food

On 3rd July, 2002, the European Parliament approved a proposal of the Parliament's Environment Committee to introduce stricter labelling requirements for food containing GM ingredients. The proposals apply to both food intended for human consumption, and also to animal feed.

The proposals are as follows:

- full traceability and labelling of all foods containing GM ingredients or derivatives. This includes GM derivatives that do not necessarily show up in testing, such as sugar or oils; and

- lowering the percentage threshold of GM ingredients in foodstuffs for labelling purposes from 1 to 0.5 per cent. Any food containing GM ingredients in excess of this threshold would need to be appropriately labelled.

However, the Parliament did not agree to calls from some MEPs to extend the labelling requirements to milk, meat and eggs from animals reared on GM feed. Likewise, a proposal by the UK government for the establishment of a 'GM-Free' label was not agreed.

The proposals still need to be agreed by EU environment ministers if they are to become law. While the proposals have been welcomed by environmental groups such as Greenpeace and Friends of the Earth, the US government is arguing that the tougher rules would lead to an unfair barrier to its food trade with the EU.

Labelling of medicinal products

The Court of First Instance of the European Court of Justice gave judgment on 3rd July, 2002, in Case T-179/00 *A Menarini v EC Commission*, overturning the decision of the Commission rejecting the request by Menarini, as a local distributor in Italy, to include its logo in the 'blue box' of the packaging of OPTRUMA, a pharmaceutical product registered under the centralised authorisation procedure established under Regulation 2309/93, which centralised registration was in the name of Eli Lilly. The 'blue box' sets out information specific to a member state. Although the packaging guidelines set out in Volume 2C of the Notice to Applicants, established under Article 6(5) of Regulation 2309/93, and consistently with Directive 92/97 on the labelling of medicinal products for human use and on

package leaflets, allows the name of the local representative to be listed, they make no reference to the logo of the local representative. The Court did not consider the Commission's decision to have been an administrative decision which was the result of a complex assessment in the medico-pharmacological field, which would have been subject only to a limited judicial review, and so felt able to address the issue effectively *de novo*. It considered that the inclusion of the local representative's logo would be useful for health education with the meaning of Article 2(2) of Directive 92/97, and rejected the Commission's argument that this would create a risk of additional confusion for consumers to whether to contact the local representative or the holder of the marketing authorisation, as the scope for such confusion was already there.

PARALLEL IMPORTS

Regulatory aspects

In its decision in Case C-172/00 *Ferring v Eurim-Pharm*, the European Court of Justice held on 10th September, 2002, that the grant of a marketing authorisation for a parallel import of a medicinal product from elsewhere in the Community could not be frustrated by withdrawing the marketing authorisation for the reference product in the country of importation, and that this was not affected by the fact that a new version of the withdrawn medicinal product had been placed on the market in the country of importation, unless there was a risk to public health arising from the coexistence of two versions of the same medicinal product on the market. Meanwhile the Commission has requested Italy to modify its procedures for the authorisation of parallel imports because they currently represent an obstacle to free trade.

Repackaging

In its decision in Case C-433/00 *Aventis Pharma Deutschland v Kohlpharma & MTK Pharma*, the European Court of Justice held on 19th September, 2002, that, in the context of the centralised authorisation procedure established under Regulation 2309/93, the Regulation precluded a medicinal product which was the subject of two marketing authorisations, one for packs of five items and the other for packs of two items, from being marketed in a package consisting of two packs of five items which have been joined together and relabelled. The consequence of this is that Aventis, which markets its INSUMAN product in packs of five in France and in packs of ten in Germany, cannot argue that it is not 'necessary' for parallel importers from France into Germany to repackage, as opposed to simple 'bundling'. Thus such parallel importers ought to be able to repackage, as opposed to 'rebundling', under the case law in Case C-443/99 *Merck Sharpe & Dohm* as to the extent to which repackaging and relabelling of parallel imports of medicinal products can be undertaken without infringing trade marks.

PRODUCT LIABILITY

National implementation of the Product Liability Directive

In its Judgment of 25th April, 2002, in Case C-183/00 *Sanchez v Medicina Asturiana SA,* the European Court of Justice held that the Product Liability Directive 85/734/EEC had superseded member states' national laws as to defective products, and thus a Spanish citizen who had brought an action in respect of a transfusion with blood alleged to have been infected with hepatitis C could not rely on the more extensive rights for consumers which were available under an earlier Spanish law as to defective products and which was still in force.

Causation

On 29th July the English High Court dismissed actions brought against Schering, Organon and Wyeth by claimants who had asserted that the 'third generation' Combined Oral Contraceptives (COC3s) supplied by

these defendant companies had caused a range of cardiovascular injuries, collectively classified as venous thromboembolism (VTE), and were thus defective within the meaning of the Consumer Protection Act 1987, which implements in the UK the Product Liability Directive 85/374/EEC. It was alleged that the synthetic progesterones in the COC3 carried a substantially increased risk of causing VTE when compared with the synthetic progesterone in the defendants' second generation contraceptives (COC2s). However, after an extensive review of the evidence from ten epidemiological experts, the Court held that as a matter of probability there was no increased risk of VTE associated with any of the COC3s supplied to the claimants by the defendants as compared with the COC2s. Thus, the claimants having failed on the issue of causality, the Court did not go onto consider other issues such as whether the products were 'defective' within the meaning of the Act or whether the 'development risks defence' had any application.

MODERNISING UK COMPANY LAW: THE GOVERNMENT'S WHITE PAPER

On 16th July, 2002, the Government published a white paper entitled 'Modernising Company Law'. Comments on the white paper are required by 29th November, 2002. It is intended that the draft clauses will be incorporated into a Companies Bill. The white paper contains over 200 draft clauses – a summary of the main recommendations are set out below.

Small and private companies

- Abolishing the requirements to appoint a company secretary (though it will be open to private companies to appoint a company secretary if they choose to do so).

- Shortening the time limit for filing accounts from the present ten months to seven months after the year end.

- Removing the requirement for private companies to hold AGMs, lay accounts in general meeting or appoint Auditors annually (again unless they choose to do so, or a member demands that the company does so). This would make the present elective regime the norm for private companies.

- Replacing 'Table A' with a simplified model constitution.

- Extending the small company accounting regime to cover companies with turnovers of no more than £4.8m, balance sheet totalling no more than £2.4m, and no more than 50 employees.

- Simplifying the procedure for private companies to take decisions by written resolution and standardising notice periods for meetings to 14 days for all meetings. The existing right to call a meeting at short notice would be retained.

- Abolishing the requirements for shareholder authorisation to allot relevant securities.

- Creating an arbitration scheme specifically to deal with shareholder disputes.

Shareholders' powers

- Enhancing the powers of proxy voters by allowing them to speak at meetings and vote on a show of hands.

- New rights for a sufficient body of members to require a scrutiny report on resolutions voted on by way of poll.

- Requiring quoted companies to publish their annual financial statements on a web site at least 15 days before circulation of the AGM Notice. The aim of this is to improve shareholder access to quoted company information, and give sufficient time for them to

assess the information and if necessary raise resolutions.

Directors' duties and contracts

- Codification of directors' duties by way of statute. This will be a codification of the directors' duties currently found principally in the common law, and will be based around the directors' core duty to 'promote the success of the company for the benefit of its members as a whole'. This will also require directors to recognise, where appropriate, the impact of the company on the community and on the environment, to foster relationships with its employees, customers and suppliers, to maintain a reputation for high standards of business conduct, and achieve outcomes that are fair as between its members.

- Abolishment of corporate directors. This would bring the UK into line with other European jurisdictions where directors must be individuals.

- Extension of shareholders rights to inspect directors' service contracts.

Company reporting/audit

- Requiring directors of all companies to volunteer information to auditors. Dishonest failure to do so would be made an offence.

- Requiring all public and also very large private companies to publish an operating and financial review as part of their annual report. This would comprise an auditor-reviewed view of the business including all information that the directors judge necessary for understanding of the business.

- Requiring quoted companies which make a preliminary announcement to publish it on a web site and communicate it electronically to shareholders immediately after it is released to the market.

- Requiring quoted companies to make their full annual report and account available on a web site within four months of the financial year end.

- All public companies would be required to lay the accounts in general meeting and file them at Companies House within six months of the financial year end.

Regulatory and institutional framework

- The establishment of a Standards Board based on the current accounting standards board but with a suitably adapted constitution and membership. This board would have the power to make rules regarding detailed company reporting and disclosure on matters such as the form and content of financial statement, requirements for the operating and financial review, and the form and content of the summary statement which listed companies are required to provide to shareholders.

- Establishment of a successor body to the financial reporting review panel, with a broader remit and with powers to run concurrently with the powers of the secretary of state to enforce compliance with form and contents rules by companies.

Other changes of note

- Companies formed under the new legislation would have unlimited capacity. This would remove the need for a large objects clause, and would mean that those entering into contracts with such a company need not concern themselves with whether the company has capacity to enter into the transaction.

- Simplification of the capital maintenance rules and share capital in general.

- Modernising the process of forming a company by replacing the

Memorandum and Articles of Association with a single constitutional document.

- Providing a separate form of incorporation designed specifically for charities.
- Modernising and clarifying criminal and civil law sanctions for directives and codifying the civil sanctions against directors.
- Strengthening the criminal law for dishonesty offences.