Legal and regulatory update

Compiled and written by Bird & Bird
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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:

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

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

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Regulatory

Borderline Products

In *Optident Ltd and Ultradent Productions Inc. v Secretaries of State for Trade & Industry and for Health* the House of Lords on 28th June, 2001, upheld a decision of the English Court of Appeal, reversing that at first instance, and holding that on a proper construction of the relevant EC Council Directives, the claimants' gel for whitening teeth was a cosmetic product rather than a medical device. Thus its marketing was prohibited under cosmetics legislation because it contained more than the permitted amount of a particular bleaching agent. The defendant regulatory bodies were therefore entitled to take steps to prevent its sale in the United Kingdom, notwithstanding that it had been treated as a medical device elsewhere in the Community and had the CE mark applied to it.

Challenge to change of classification from prescription to pharmacy

The Society for Unborn Children (SPUC) has secured leave to bring proceedings for a judicial review challenging the UK delegated legislation which reclassified the emergency contraceptive levonorgesterol (the 'morning after' pill) as a pharmacy medicine rather than a prescription-only medicine. SPUC argues that the drug is instead an abortifacient and that therefore only doctors can authorise its use under the Abortion Act 1967, and that anyone else doing so would be committing a criminal offence. The application is likely to be heard in the summer of 2001.

Intellectual property

Biotechnology patents

Mr Justice Neuberger in the English Patents Court gave judgment on 11th April, 2001, in the joined cases of *Kirin-Amgen v Transkaryotic Therapies and others* and *Kirin-Amgen v Roche Diagnostics and others*. The action concerned two patents for the naturally occurring protein erythropoietin (EPO), which is used to treat anaemia in patients with kidney failure. One independent product claim (claim 19) of Kirin-Amgen's patent EP (UK) 0 148 605 B2 and those claims that were dependent on it was found invalid on the ground of insufficiency, but the EPO from the differing processes used by Transkaryotic Therapies (TKT) and from Roche were each found to infringe another independent product claim of the patent (claim 26), and Roche's process for the production of EPO was also found to infringe an independent process claim of the patent (claim 27). Roche's patent EP (UK) 0 411 678 B, on which they had sued Kirin-Amgen, was found invalid on the grounds of obviousness and lack of novelty.

Claim 19 was to:

> 19 A recombinant polypeptide having part or all of the primary structural conformation of human or monkey erythropoietin as set forth in Table VI or Table V or any allelic variant or derivative thereof possessing the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells to increase hemoglobin synthesis or iron uptake and characterized by being the product of eukaryotic expression of an exogenous DNA sequence and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources.

The Judge found that the variability of EPO (a consequence of its variable glycosylation) was such that there was no difference between 'recombinant EPO' as a class and EPO 'isolated from urinary sources', rendering the claim not only incapable of infringement but also insufficient.

Despite this finding of fact he then went on to find claim 26 valid, and not

anticipated by EPO isolated from urinary sources:

> 26. A polypeptide product of the expression in a eukaryotic host cell of a DNA sequence according to any of Claims 1, 2, 3, 5, 6 and 7.

His reason for so finding was, notwithstanding that there was no difference in properties between such EPO as a class and that isolated from urinary sources, that the process of producing such EPO was a limitation not in the prior art and which conferred novelty on the claim. This finding runs counter to the established case law of the European Patent Office, which only considers that such 'product by process' claims (whether expressed as 'produced by') or 'producible by' are allowable and novel where the process of production confers on the product some new property which differentiates it from the prior art.

The Judge also found claim 26, as a result of its relationship with claim 1, not enabled across the scope of the claim, in that it did not enable expression in human host cells. However, despite this finding of 'classical insufficiency' he then went on to find that the patent disclosed a principle of general application (namely the sequence that coded for EPO) and that this rendered claim 26 valid, apparently applying in reverse the principle established in *Biogen v Medeva*. Biogen established that where the claims reflect the invention of a general principle, it may suffice for the inventor to disclose one example. However, *Biogen* was a case where there was no finding of 'classical insufficiency' and so this further principle was applied to find the patent in that case insufficient. Here, rather than finding that claims had to be both classically sufficient and *Biogen* sufficient, he in effect held that classical insufficiency was irrelevant if the claims were *Biogen* sufficient.

On infringement, the Judge found Roche's product, and their process for making it, literally to infringe claim 26 and claim 27:

> 27. A process for production of a polypeptide having at least part of the primary structural conformation of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells and to increase hemoglobin synthesis or iron uptake, which process is characterized by culturing under suitable nutrient conditions a prokaryotic or eukaryotic host cell transformed or transfected with a DNA sequence according to any of Claims 1, 2, 3, 5, 6 and 7 in a manner allowing the host cell to express said polypeptide; and optionally isolating the desired polypeptide product of the expression of the DNA sequence.

TKT's process for making their product was not alleged to infringe claim 27, and the Judge found that its product did not literally infringe claim 26. However he found that the product infringed claim 26 on an application of the principle of 'purposive construction', and despite the evidence showing that the skilled person would not have believed that the TKT process would work. After Judgment was given it was drawn to the Judge's attention that in so finding he had apparently overlooked a binding Court of Appeal authority (*AHP v Novartis)* that one could not purposively infringe unless it was obvious that the variant in issue would work. However in a further Judgment given on 9th May, 2001, the Judge, although agreeing that it was likely that he had overlooked such authority, held that on considering it it did not alter his Judgment on such point.

Biotechnology Directive

On 14th June, 2001, Advocate General Jacobs delivered his opinion in Case C-377/98 in which Netherlands seeks the annulment of the Directive on the legal protection of biotechnological inventions (Directive 98/44) by the European Court of Justice (ECJ). He recommended that the action be dismissed and rejected the grounds of the challenge – including those that the Directive infringes the principle of legal certainty, is incompatible with international obligations (including the TRIPs Agreement and the European Patent

Convention) and breaches fundamental rights.

Supplementary protection certificates

On 10th May, 2001, the ECJ gave judgment in one of the cases on SPCs currently before it – *BASF* (Case C-258/99), holding:

1. The concept of a product within the meaning of Article 3 of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products covers chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process, which have general or specific action against harmful organisms or on plants, parts of plants or plant products.
2. Two products which differ only in the proportion of the active chemical compound to the impurity they contain, one having a greater percentage of the impurity than the other, must be regarded as the same product within the meaning of Article 3 of Regulation No 1610/96.
3. The fact that a marketing authorisation must be obtained for the new plant protection product which has a different proportion of active chemical compound to impurity from that of the former plant protection product is not relevant for the purposes of establishing whether or not the constituent products of those plant protection products are the same.
4. The conditions laid down in Article 3(1)(a) and (d) of Regulation No 1610/96 are, in any event, not all satisfied where a product, as a plant protection product, manufactured according to a patented process and the subject of a marketing authorisation, differs from a previously authorised product, as a plant protection product, only in the proportion of the active chemical compound to the impurity it contains, the percentage of impurity being greater in the older product than in the new one, and where that process patent has been designated as the basic patent.

In so finding the ECJ largely followed the opinion of the Advocate General – an applicant could not secure an SPC for purer material by treating such purer material as a new product.

European patent law reform

On 29th June, 2001, the French government signed the London Protocol concerning the language system for European patents, which has already been signed by Germany and the UK and several other European Patent Office (EPO) member states. Had they failed to do so by the end of June the Protocol would have been abandoned. This marks a major move towards reducing translation costs associated with the European patent. Under this agreement those signatory countries having English, French or German as a national official language would no longer require any translations of the entire specification of the patent under Article 65 of the European Patent Convention. Those signatory countries not having one of these three languages as a national official language would have to nominate one of English, French and German and would then no longer require translations of the entire specification in that language into a national official language. However, these countries could still require (and no doubt would require) translations of the claims of the patent into a national official language irrespective of whether the claims are in English, French or German. This would not affect the right of signatory countries to require full translations into the national official language in the case of legal proceedings concerning the patent, such as infringement proceedings.

Meanwhile work continues on drafting the 'European Patent Litigation Protocol' by which signatory countries would agree to an integrated judicial system, including harmonised rules of procedure and at least a common court of appeal, for litigation concerning European patents. However, the European Commission is now questioning the competence of EC member states to negotiate such a measure, maintaining that competence in such matters has now passed to it as a result of Regulation 44/2001 on

Jurisdiction and Enforcement of Judgements, which will replace the Brussels Convention for all of the EC (with the exception of Denmark) from May 2002.

Some progress is also being made with the proposed Community patent; some consensus was reached by Ministers meeting at the European Community Internal Market Council on 31st May, 2001. They agreed to guidelines which would provide for:

- the EPO to play a central role in the granting and administration of Community patents;
- national patent offices also to play a role, including advising applicants, receipt and forwarding of applications to the EPO and the dissemination of information on Community patents;
- applicants remain free to have applications fully processed by the EPO;
- maintenance of costs at a competitive level;
- a percentage of annual renewal fees distributed among member states/ national patent offices;
- a jurisdictional system being set up in accordance with Articles 225a and 229a of the EC Treaty as adopted at Nice;
- appeals to be heard by the ECJ Court of First Instance.

It was also agreed to call for a Diplomatic Conference to be convened to yet further revise the 1973 European Patent Convention, in order to accommodate the Community Patent.

Competition law and free movement of goods

Parallel imports

The European Commission has determined that Glaxo's Spanish dual pricing mechanism, aimed at compensating for the effect of parallel exports from Spain to elsewhere in the Community (by charging higher prices to wholesalers on drugs intended for export), is contrary to Article 81 of the EC Treaty, notwithstanding that the price differentials which drive such trade are a consequence of government price control. The scheme was notified to the Commission, thereby avoiding the liability for fines that is otherwise a common consequence of such a finding It remains to be seen whether Glaxo will appeal the finding to the Court of First Instance, it is entitled to, and thereafter to the ECJ, as these bodies have tended to take a stricter view than the Commission of the circumstances in which Article 81 applies.

Competition law and minor agreements

The European Commission has issued a draft of a new Notice on Minor Agreements that would replace the 1997 Notice. Apart from restructuring the Notice for example to bring it line with the Guidelines on Vertical Restraints and the Guidelines on Horizontal Cooperation Agreements, the most significant feature of the Notice is the increase in the thresholds below which the Commission does not consider that Article 81(1) will generally apply. Thus the threshold of 5 per cent in aggregate of the relevant market for horizontal agreements would be increased to 10 per cent, and the 10 per cent threshold for vertical agreements would be increased to 15 per cent. As before, this would not apply to agreements that have as their object the fixing of prices, limiting production or sales, sharing markets or sources of supply, or which confer territorial protection.

Domestic UK competition law

Resale price maintenance (RPM) for over the counter (OTC) medicines has ended in the UK as a result of the Community Pharmacy Action Group abandoning its defence when the Judge hearing the matter in the Restrictive Practices Court said on 11th May, 2001, that it had presented insufficient evidence to support the allegation that a substantial number of independent community pharmacies would close and reduce the range of products available to the public if RPM ceased. The exemption for OTC medicines from the Resale Prices Act 1964 (now replaced by the Competition Act

1998) dates back to 1970, but the Office of Fair Trading, considering that the situation had changed since then, had applied to the Restrictive Practices Court for an order discharging the exception.

Data protection

Health and Social Care Act

The Health and Social Care Act has received Royal Assent. The controversial proposals allowing restrictions to be introduced on the pharmaceutical sector's use of anonymous patient data for promotional purposes were dropped at the 11th hour. However, the Act does still address the difficulties that data protection and the General Medical Council's revised guidelines on confidentiality pose for cancer registries and organisations such as the Public Health Laboratory Service (PHLS).

Section 60 allows the Secretary of State to introduce secondary legislation, permitting the disclosure of patient information (despite duties of confidentiality), where this is 'necessary' or 'expedient' in the interests of improving patient care or in the public interest. Regulations made under this section will specify the types of information involved and the bodies to whom the data may be released. They may also require the recipients of the information to give appropriate undertakings (for example as to security).

Where confidential information will be released at an identifiable level, then the Secretary of State is not permitted to introduce regulations if it would be 'reasonably practicable' having regard to the 'cost of and the technology available' to achieve the same purpose through other means. The Secretary of State must re-assess this on an annual basis. Before making regulations the Secretary of State must consult with organisations representing persons affected by the regulations and with a new Patient Information Advisory Group.

Data protection

The Data Protection Directive (implemented by the Data Protection Act 1998) introduces a prohibition on organisations transferring personal data to countries outside the European Economic Area (EEA) that, in broad terms, do not have European-style data protection obligations. On 18th June the European Commission approved model contractual clauses which organisations may use as a way around this ban. The terms require the data importer to comply with European-style data protection provisions and allow individuals to whom the data relate to enforce certain of their provisions. The terms will be effective as from 3rd September.

The mode clauses do, however, have drawbacks. The data exporter must accept joint liability for the acts of the importer; if sensitive data are involved (including health data) then individuals must be notified before the transfer takes place and some member states will require the clauses to be deposited with supervisory authorities and to include supplemental details.

Company/commercial law

Legislation

Directors' addresses

The government has tabled an amendment to the Criminal Justice and Police Bill to allow private addresses of directors who are at serious risk of violence to be kept secure on the Companies House register. Under the current legislation, all directors are obliged to file their home address at Companies House. This information is available for inspection by the public. The proposed amendment will allow directors who are at serious risk of violence or intimidation to apply to the Secretary of State for Trade and Industry for a confidentiality order. The order will allow the director to file a service address instead of their home address. A home address will still have to be provided but this will be kept separate on a secure register, which would only be available for inspection by certain privileged bodies (such as the police). The proposal would take the form of an amendment to the Companies Act 1985.

Comment In light of recent high-profile intimidation of certain directors, the new clause (introduced to a standing committee of the House of Commons on 6th March, 2001) was generally welcomed. It was noted, however, that the new clause would initially only benefit new directors or directors who have moved house as it would be impossible to delete existing records at Companies House.[1]

Boardroom pay disclosure

The Department of Trade and Industry (DTI) is to introduce new boardroom pay disclosure requirements which are aimed at improving the connection between performance and pay at the same time as giving the shareholders of a company more power.

The proposed secondary legislation follows the recommendations of the DTI consultation paper on directors' remuneration. This paper requested greater transparency so that shareholders have full access to the information they may require to enable them to understand the company's general policy on executive remuneration and the complete remuneration packages of individual directors. In March 2001 the Secretary of State for Trade and Industry announced reforms to the disclosure requirements on boardroom pay.

The new provisions, to be introduced under the Companies Act 1985, will require companies to disclose all aspects of directors' remuneration within a single report, which forms part of the company's annual reporting requirements. The remuneration report will have four main elements:

- Justification by the board of matters relating to directors' remuneration. The provisions will require disclosure of information on: the membership of the remuneration committee; whether the board has accepted the committee's recommendations without amendment; and the name of each firm of remuneration consultants that has advised the committee.
- A statement of the company's policy on directors' pay packages. Specific disclosure requirements will include: details of performance criteria for long-term incentive and share option schemes; details of comparative group(s) of companies; and details of the company's policy on contract and notice periods for executive directors.
- Details of each director's remuneration in the preceding financial year. Companies will be required to present the information in a prescribed, tabular format to facilitate comparison between companies.
- Performance graphs. These will provide historic information on the company's performance. The requirement will be modelled on a typical US performance graph as set out by the US Securities and Exchange Commission.

It is anticipated that these changes will come into force by 31st December, 2001.[2]

Codification of the Unanimous Consent Rule

The Company Law Committee of the Law Society has responded to a consultation letter issued by the Company Law Review Steering Group on the formalisation of the unanimous consent rule. The unanimous consent rule broadly states that members of a company may, by their unanimous agreement, bind or empower their company to do anything within its capacity, irrespective of any limitation in its articles of association. Originally, the Steering Group was against the codification of the rule ('Modern company law for a competitive economy: Developing the framework'). However, it has now changed its view and is proposing that the rule should be codified.

The Committee, among other responses:

- generally supported the Steering Group's proposal for codification and agrees that it is sensible to include alongside the statutory provisions setting out formalities for meetings any additional provisions, such as a unanimous consent

rule whereby such formalities may be overridden;
- raised issues on the need for careful consideration of when the unanimous consent rule should not apply (ie the right of preference shareholders to receive notices but only to vote in limited circumstances should not be capable of being overridden by a statutory unanimous consent rule).[3]

References

1. DTI press release, 2nd March, 2001; House of Commons Standing Committee F debate on the Criminal Justice and Police Bill, 6 March 2001 available at URL: www.publications.uk/pa/cm/stand.htm
2. 'Directors' Remuneration', July 1999, available at URL: www.dti.gov.uk/cld/condocs.htm; DTI press release, 7 March 2001.
3. Memorandum of the Company Law Committee of the Law Society: 'The Unanimous Consent Rule: Codification', April 2001, No. 417.