Legal and regulatory update

Intellectual property

Grace periods

On 14th January, 2002, the European Commission published a Report (COM (002) 2 final) entitled 'An assessment of the implementation for basic genetic engineering research of a failure to publish, or late publication of, papers on subjects which could be patentable as required under Article 16(b) of Directive 98/44/EC on the legal protection of biotechnological inventions'. The Directive had required the Commission to produce such a paper within two years of the entry into force of the Directive. The Report addresses, in the context of the biotechnology sector, the question of the grace period, by which in, for example, the USA an inventor's own disclosures does not form part of the state of the art as against a patent application filed by such inventor within a year of such disclosure.

It summarises the results of a survey undertaken in the sector of industry and academia, which, not surprisingly, adopt similar positions to those adopted at a hearing (not restricted to this sector) on the grace period organised by the Commission in October 1998. An equal disparity appears in the opinions of two experts from industry and academia whose views were requested by the European Patent Office. It notes that there is no one single model for the grace period among those countries, such as the USA and Japan, that have one, but categorises the US one, coupled with its 'first to invent' system as providing 'the highest level of ''legal uncertainty'' ', and one that 'should not serve as the ''best practice'' example' for a grace period. It concludes that efforts to define and harmonise the concept of a grace period should take place at an international level, such as by the Standing Committee on Patent Law (SCP) of the World Intellectual Property Organization (WIPO), but notes that the concept will only work if it provides the 'legal certainty' which is the major concern of industry.

Meanwhile the UK Patent Office is conducting its own consultation on the subject of grace periods[1] and responses were invited to this before 30th April, 2002.

Regulatory

Draft Directive on traditional herbal medicinal products

On 17th January, 2002, the European Commission presented its proposal (COM (2002) 1 final) for a Directive amending Directive 2001/83/EC (the Community Code relating to Medicinal Products for Human Use) as regards traditional herbal medicinal products. These would be defined as herbal medicinal products fulfilling certain criteria as to indications, method of administration, period of traditional use (in the Community for at least 30 years preceding the application date) and as to there being adequate data as to not being harmful in the specified conditions of use, with plausible pharmaceutical effects or efficacy based on long-term use and experience. The directive would provide a simplified registration procedure for such traditional herbal medicinal products allowing for their registration, and hence marketing, without requiring the conduct and reporting of tests and trials on safety and efficacy. However quality must still be shown in the conventional way, and most other provisions of the Code will also apply to such products, with certain modifications, such as on labelling to make it clear that the efficacy of the product has not been clinically proven.

At present such traditional herbal medicinal products cannot usually secure authorisation under the procedures of the Community Code, because insufficient published scientific literature exists to

demonstrate 'well established medicinal use' as required by Article 10(i)(a)(ii) of the Code. New tests and trials to safety and efficacy are too expensive and are difficult to justify where the traditional use is such as to allow sound conclusions to be drawn as to safety and efficacy. As a result, the legal and practical situation as to such products is at present the subject of considerable variation throughout the Community.

ECJ Judgment on Austria's medicines reimbursement policy

On 27th November, 2001, in Case C-424/99, the European Court of Justice (ECJ) gave its first Judgment under Directive 89/105/EEC of 21st December, 1988, relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, in holding that Austria had failed to implement Article 6(2) of the Directive. This provides that:

> Any decision not to include a medicinal product on the list of products covered by the health insurance system shall contain a statement of reasons based upon objective and verifiable criteria, including, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant shall be informed of the remedies available to him under the laws in force and of the time limits allowed for applying for such remedies.

The ECJ rejected Austria's argument that its register of automatically reimbursed medicinal products was not a 'positive list' as envisaged by this Article. It then went on to hold that the 'appeal' procedure provided by the Austrian system did not equate to one to a genuine judicial body, as envisaged by the Article. Certain other aspects of the Commission's challenge to the Austrian system were rejected, but the decision is significant as representing the furthest incursion that the Commission has yet been able to make into the jealously guarded national territory of pharmaceutical reimbursement.

Meanwhile Belgium introduced new reimbursement procedures from the beginning of 2002, which it is envisaged will avoid a threatened referral to the ECJ by the Commission under the same Directive.

Commission consultation on paediatric medicines

On 28th February, 2002, the Commission published a Consultation Document entitled 'Better Medicines for Children'. This outlines some suggested approaches that could be taken to address the lack of suitably adapted medicinal products for children, noting that between 50 and 90 per cent of medicinal products, depending on therapeutic areas, which are used in children have never been specifically evaluated for use in children.

The most controversial aspect of the Consultation Document is likely to be the proposals it floats for providing incentives for research, which are modelled on the 'paediatric exclusivity' provisions in the USA. These have been successful in providing an incentive for such research. Where intellectual property protection already exists on a medicinal product, it is suggested that an additional period of market exclusivity (for all indications) be added at the end of the existing period of patent or Supplementary Protection Certificate protection. Where no intellectual property protection already exists on already marketed medicinal product, it is envisaged that a period of market exclusivity (limited to paediatric indications) be granted.

UK review of the process for changing the legal status of an authorisation

The UK Medicines Control Agency (MCA) has issued a Consultation Letter (MLX 279) on a range of proposals for changes in the process in the UK by which medicines are reclassified from prescription only to pharmacy (POM to P) or pharmacy to general sale list (P to GSL). At present such changes are effected through secondary legislation, tabled twice a year, and by reference to the active substance rather than the medicinal product. Thus the status of all

medicinal products containing the same active substance in the same dose changes together. It is proposed to change this system to enable such reclassification to take place by changes to the marketing authorisation for a specific medicinal product. It is also proposed to streamline and simplify the application for reclassification, and to introduce a fee for reclassification.

Because only applications for reclassification supported by the full relevant data would be considered, such a mechanism would also give some scope for offering a competitive advantage to the first to secure a reclassification for a medicinal product containing a particular active substance. Thus it is suggested that following an initial switch relating to a particular active substance, separate applications for a switch would be required from companies holding marketing authorisations for products containing the same active substance. There would then be a period of marketing advantage of at least 90 days for the 'lead' product until a further product had been successfully reclassified.

In parallel with this, and in line with the UK government aim to make more medicines available over the counter to widen access and patient choice, the Royal Pharmaceutical Society has been asked to take the lead in identifying a wide range of therapeutic categories which might provide suitable candidates for POM to P switches. Links to these proposals are set out at the MCA web site,[2] which also sets out details of the MCA proposals for changes to the reclassification system.

Successful challenge to a UK decision suspending a pesticide authorisation

In a Judgment given on 3rd December, 2001, in *R v (1) Secretary of State for the Environment, Food & Rural Affairs (2) Secretary of State for Transport, Local Government & the Regions (Defendants), ex parte Amvac Chemical UK Ltd (Claimant) & Food Standards Agency (Interested Party) (2001)* the Administrative Court upheld a challenge to the suspension of regulatory approval for a chemical used in pesticides because the claimant had not been given notice about a new and urgent dimension to the consideration being given to its approval. Amvac had sought judicial review of a decision, communicated on 4th August, 2001, to suspend regulatory approvals for the active ingredient dichlorvos. Amvac held one qualified ('not to be marketed') approval for a fly killer containing derived from the chemical but was also a distributor to holders of others approvals for pesticides containing this chemical. On 6th August, 2001, the Court had ordered an interim stay of that decision and of its public announcement.

Amvac was not allowed to challenge the merits of the decisions on substantive grounds, but was allowed to challenge it as to whether the decision:

(i) was unlawful because:
  (a) Amvac was not adequately informed or warned of the regulatory basis upon which suspension/revocation was being made or considered; or
  (b) Amvac was not given adequate information with which to make submissions on such matters; or
  (c) Amvac was not given adequate time within which to make submissions on such matters;

(ii) was unlawful because:
  (a) the defendants were obliged to have proper regard to the 'precautionary principle' as enunciated, and its mechanisms; or
  (b) they failed to have proper regard for that principle and its mechanisms; or
  (c) they did not have or give good reason for failing to have proper regard to the principle; or

(iii) to suspend/revoke the approval was unlawful, having regard to Amvac's rights to enjoy their possession under Protocol 1 Article 1 European Convention on Human Rights.

Amvac applied for the hearing to take place in private, with only judgment being given in open court, on the basis that public

reference to possible risks from dichlorvos, prior to a reasoned judgment stating the court's conclusions, could cause irreparable damage to the market for such products. However, it was held that no sufficient grounds for a hearing in private had been made. A public hearing would not defeat the object of the hearing. No confidential information of significance had been identified and there was no special reason to fear that any reporting of the case would be unbalanced.

The decision challenged was held to be procedurally flawed as to the notice given to Amvac and so succeeded on ground (i). Amvac had not been notified promptly after the relevant meeting of the Advisory Committee on Pesticides of the new and urgent dimension to the consideration being given to dichlorvos, leaving it with insufficient time to comment before the decision to suspend the approvals. However, the challenge to the decision failed under grounds (ii) and (iii). There was no settled, specific or identifiable mechanism of risk assessment in the field of pesticide approval on which Amvac could rely on as part of the 'precautionary principle'. In any event, the present decision had not been made purporting to apply the precautionary principle as a term of art or any settled, specific or identifiable mechanism or methodology. Neither could an approval of the qualified kind held by Amvac be a 'possession' under Protocol 1 Article 1 of the European Convention on Human Rights as the suspension of the licence had no direct economic effect on Amvac. Neither did its economic interest in the other approvals constitute such a 'possession'.

Taxation

Substantial shareholdings – tax exemption regime

From 1st April, 2002, a disposal by a trading company of all or part of a substantial shareholding in another trading company (or a holding company of a trading company) will be exempt from capital gains tax. Where the exemption applies any gain on the disposal of shares will not be chargeable to tax and any loss will not be available to set against gains.

The key features of the new exemption are as follows:

- a company will be regarded as having a substantial shareholding in another company if it held 10 per cent or more of the ordinary shares of the other company for a continuous period of at least 12 months during the two years before the disposal;
- the company disposing of the shareholding must be a trading company or a company which is a member of a trading group;
- the shareholding must be in another company which is a trading company or a holding company of a trading group;
- special rules will apply for aggregating holdings by members of groups of companies;
- when the exemption applies no claim is necessary; and
- where a company satisfies the conditions for the substantial shareholding exemption (as summarised above) and also owns an asset related to shares in the company invested in (ie options over, or securities convertible or exchangeable for, shares), any gains on the disposal of the asset relating to the shares will also be exempt from capital gains tax and any loss will not be available to set against gains on the disposal of the asset.

Full details of the new regime can be found on the Inland Revenue web site.[3]

New corporation tax relief for intangible assets

The Inland Revenue has announced that a new regime to provide relief for the cost of intangible assets including intellectual property and goodwill will take effect from 1st April, 2002.

The new regime will provide for companies to obtain tax relief for the cost of intangible assets (including goodwill and intellectual property), in most cases based

on the amortisation reflected in their accounts. There is also provision for tax allowances at a fixed rate of 4 per cent per annum to provide for relief in the case of indefinite or longer life assets.

The new rules will apply to expenditure on the creation, acquisition and enhancement of intangible assets (including abortive expenditure), as well as expenditure on their preservation and maintenance. Relief under the new regime will therefore be available for the cost of internal development, as well as acquisition, of intangible assets.

Payments for the use of intangibles will also be within the scope of the new regime. The charge on income rules will no longer apply to royalty payments and relief will be given in line with the accounting treatment. The taxation of royalty receipts will also follow the accounts.

Disposals of intangible assets will be taxed on an income basis under the new regime. A roll-over relief will apply where disposal proceeds are reinvested in new intangible assets within the regime.

Full details of the new relief can be found on the Inland Revenue's web site.[3]

References

1. URL: http://www.patent.gov.uk/about/consultations/grace/section1.htm
2. URL: http://www.mca.gov.uk/whatsnew/consultletters/reclassification.htm
3. URL: http://www.inlandrevenue.gov.uk/news/press.htm