Legal and regulatory update

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John Wilkinson,
Bird & Bird,
90 Fetter Lane,
London EC4A 1JP, UK
Tel: +44 (0)20 7415 6000
Fax: +44 (0)20 7415 6111

Frederick J Dorey,
Cooley Godward LLP,
5 Palo Alto Square,
3000 El Camino Real,
Palo Alto,
CA 94306-2155, USA
Tel: +1 650 843 5000
Fax: +1 650 857 0663

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COMMUNITY PATENT – STILL NO AGREEMENT

The Competitiveness Council of Ministers met last month to discuss the outstanding issues concerning translation of patents in the proposed community patent regime. A year ago, the Council agreed in principle that reliance, in good faith, on an inaccurate translation of a patent would allow the alleged infringer to continue using the invention for up to four years. However, in the recent meeting, the Council was unable to agree on the length of time to be allowed for filing translations into the languages of the other member states.

The Commissioner for the internal market, Frits Bolkestein, expressed disappointment that agreement had not been reached and warned that this undermined the credibility of the 'Lisbon process', which aims to make Europe the world's most competitive economy by 2010.

TECHNOLOGY TRANSFER – THE NEW LAW

The new regulation governing technology transfer, which comes into force on 1st May, 2004, together with the European Commission's guidelines, has been published online.[1]

The new regulation requires an assessment of the likely economic impact of agreements on the relevant market. Certain categories of agreement will be block exempted, so long as the undertakings that are party to it command less than a threshold level of market share. Inclusion of a listed 'hardcore' term will render the entire agreement non-exempt, rather like the function of the old black list. In addition, there are four types of 'excluded restrictions' that are neither hardcore nor block exempted, but the inclusion of which will not prevent the remainder of the agreement benefiting from the block exemption. The 'excluded restriction' terms will have to be individually assessed under Article 81 and, if found to be anti-competitive, will have to be severed from the agreement.

The European Commission is keen to promote the dissemination of technology and know-how in such a manner that competition and economic efficiency are improved. To this end, the regulation differentiates between undertakings that are competitors on the relevant market and those that are not, by setting different market share thresholds beyond which the block exemption will not apply. The market share threshold for competitors is lower than for non-competitors (20 versus 30 per cent) because the European Commission perceives that there is a greater risk of collusion, market sharing and cartel behaviour between competitors and because agreements between competitors generally have a greater market impact than agreements between non-competitors.

Agreements to which the regulation may apply

The regulation will only apply to agreements between two undertakings for the transfer of technology where the primary objective of the agreement is the manufacture of goods or the provision of services using the licensed technology. Such goods and services have been defined as *contract products* in the regulation and this terminology will be used throughout this paper. A clear link is needed between the technology transfer agreement and the contract product. The regulation can apply where some further development work is necessary prior to placing the product on the market. The block exemption will not cover licensing of a research tool that the licensee will use to carry out further research, for example. According to the guidelines, the block exemption will apply to agreements in which the licensee is allowed to sub-licence, so long as production of contract products is the primary objective of the

sub-licence. The block exemption does not apply where sub-licensing itself is the primary objective.

The agreement may exist only for as long as the licensed property right subsists or the know-how remains secret (unless divulged by the licensee). Like the old regime, the regulation will not apply to R&D agreements, or to patent pools.

The regulation will cover individual and mixed licensing of patents, and know-how. The difference under the new regime is that licensing of copyright in software in order to reproduce and distribute the protected work will also be covered. Terms in the technology transfer agreement that have effects other than licensing patents, know-how or software copyright will be tolerated only so long as the primary objective of the agreement is to transfer technology. For example, terms that license other intellectual property rights, such as trademarks, will be allowed only if directly related to the licensed manufacture or provision of contract products and providing that this is not the agreement's primary objective. Likewise, some conditions relating to the sale and purchase of the contract products, such as requiring the licensee to set up a particular distribution system, will be allowed if they comply with the competition rules governing supply and distribution agreement. This is different from the old regime whereby licences of intellectual property rights other than patents or know-how were allowed only if they were 'ancillary' to that licence.

It is important to remember that the technology transfer block exemption does not exist in isolation and so, in some cases, the block exemptions for vertical or horizontal agreements may be relevant.

Assignments of patents, know-how or software copyright, or a combination thereof will be treated as technology transfer agreements, so long as part of the economic risk of exploiting that technology remains with the assignor. For example, the assignor takes some risk where the sum payable by the licensee is dependent upon the quantity of products manufactured, or the turnover obtained, by using the licensed technology. This is the same as the position under the old regime.

Relevant markets

Both the 'relevant product market' and the 'relevant technology market' may be considered in determining whether the undertakings qualify for the block exemption. The existing EU case law on market definitions and market shares will form the scaffold for the new regime.

The 'relevant product market' is the market for final and intermediate products incorporating the licensed technology and products that, in the buyer's view, are interchangeable or substitutable with them. One technology may lead to several products on several different product markets and each will be assessed individually.

According to the guidelines, a licensee's share of a particular product market will be evaluated from its total sales of the relevant type of products on that market. The licensee's combined sales of those products that incorporate the licensed technology as well as its sales of competing products, which do not incorporate that technology, will be considered. The licensor's share of the product market will be this, plus its own sales on the product market (ignoring the sales of any of its other licensees).

The 'relevant technology market' comprises the licensed technology and any technology regarded by licensees as interchangeable or substitutable. Shares of the relevant technology market will be calculated from the sales on downstream product markets of products incorporating the licensed technology. Each product market will be considered separately.

Paragraph 73 of the guidelines gives some simple illustrations of how to calculate the licensor's and licensee's shares of the relevant technology and product markets. The illustrations also demonstrate that geographically distinct markets should be treated separately.

Competitors and non-competitors

Under Art. 3, competing undertakings will be able to benefit from the block exemption only if their combined market share is 20 per cent or less of the relevant technology and product markets. Non-competing undertakings will each be able to have a market share of 30 per cent or less of the relevant technology and product markets. If the parties exceed the relevant threshold, the block exemption will only continue to apply to the agreement for the two consecutive calendar years following the year in which the relevant market share threshold was exceeded.

The guidelines explain that parties who own 'blocking technologies' will be treated as non-competitors. A one-way blocking technology is one that prevents another party from exploiting its technology without obtaining a licence from the blocking party. Two-way blocking positions occur where each party requires a licence from the other in order to exploit its own technology. The European Commission will rely on objective factors, not just the subjective views of the parties, in deciding whether or not a blocking relationship exists which will allow the parties to qualify as non-competitors. Court decisions and independent expert opinion may be used, as may expert evidence submitted by the parties.

Market shares will be calculated from the previous calendar year's market sales data. If such data are not available, estimates will be made based on market sales volumes. A geographical assessment may also be required in order to determine the size of each product market.

Undertakings will compete on a relevant product market if they are both already active on that product market (actual competitors) or if they are 'potential' competitors. A potential competitor is an undertaking that, 'on realistic grounds', would incur the necessary costs in order to enter the relevant market in a timely fashion in response to a small and permanent increase in relative prices. The guidelines state that such entry to the market must be likely to occur within a short period, which would normally be one to two years. However, in individual cases, longer periods may be taken into account and a suitable yardstick would be the time undertakings would need to adjust their capacity to enter the new market.

Hardcore restrictions

Even if the undertakings are below the market share thresholds described above, the agreement will not benefit from the regulation if it contains any of the following 'hardcore' terms, or terms that have an equivalent aim. There are two different sets of hardcore terms, one for competing undertakings and one for non-competing undertakings.

Hardcore restrictions between competing undertakings (Art. 4(1))

As under competition law generally, the European Commission's aim is to prevent competing undertakings colluding to push up prices, divide markets or customers or prevent the licensee from exploiting its own technology. The following are the hardcore restrictions between competing undertakings.

- As is the case under the old regime, the agreement will not be allowed to restrict the ability of either party to determine the sale price of the contract products to third parties. The guidelines state that cross-licensing with reciprocal running royalties will be block exempted *if* the licence is bona fide and not a sham to disguise a cartel.

- Reciprocal agreements (cross-licensing) between competitors which limit output or sales will be hardcore restrictions *unless* only one of the licensees is limited in this way. Reciprocal or cross-licensing means

that each party licenses its own technology to the other party (not necessarily in the same agreement) and the licences concern competing technologies or can be used for the production of competing products.

- Non-reciprocal agreements between competitors, whereby either an undertaking licenses a competitor's technology but does grant a licence of its own technology back to that competitor, or whereby each party licenses the other's technology but the licences do not concern competing technologies or cannot be used to produce competing products, are treated more generously. In these situations, the licensee's output or sales could be limited by the agreement and this would be block-exempted. The reason for this distinction between reciprocal and non-reciprocal agreements is that the European Commission believes that non-reciprocal restrictions are less likely to be cartel-based than reciprocal limits and are also likely to enhance efficiency by integrating the licensed technology into the licensee's production methods. The European Commission is also keen to ensure that licensors have an incentive to disseminate their technology, and such a non-reciprocal quantity restriction may do that. The guidelines explain that if a non-reciprocal agreement later becomes reciprocal due to the conclusion of a second licence between the same parties, they may have to revise the first licence to avoid restrictions that are hardcore for reciprocal agreements.

- The parties to the agreement will not be allowed to allocate markets or customers under the regulation except that:

  – the licensee may be restricted to production in certain technical fields of use or product markets – this applies in both reciprocal and non-reciprocal agreements;

  – in non-reciprocal agreements only, either party may be restricted from use in certain technical fields, product markets or exclusive territories which have been reserved for the other party;

  – the licensor may be prevented from licensing the technology to another licensee in a particular territory;

  – in non-reciprocal agreements only, either party may be restricted from active and/or passive sales into exclusive territories or to exclusive customer groups reserved for the other party;

  – in non-reciprocal agreements only, the licensor may restrict the licensee from active sales into the exclusive territory or to the exclusive customer group which the licensor has allocated to another licensee – provided that the licensee to whom that territory or customer group has already been allocated was not a competitor of the licensor at the time that licence was concluded;

  – the licensor may impose a 'captive use restriction' whereby the licensee can exploit the licensed technology only to make products for its own use and for spare parts for its own products. The licensee may not be restricted from selling (either actively or passively) the contract products as spare parts for its own products; and

  – in non-reciprocal agreements only, the licensor may restrict the licensee to produce contract products only for a particular customer, so long as the licence was granted specifically to create a

'second source of supply' for that customer.

- The licensor will not be able to restrict the licensee's ability to exploit or license its own technology. Nor will the parties be able to restrict the other's ability to carry out research and development unless the term is indispensable to prevent licensed know-how from being disclosed to third parties.

Hardcore restrictions between non-competitors (Art. 4(2))

Where the parties to an agreement are not competitors at the time the agreement is concluded, but become competitors later, the list of hardcore restrictions for non-competitors shall continue to apply throughout the term of the agreement *unless* the agreement is amended in any material respect.

The following terms are hardcore for non-competing undertakings.

- As for competing undertakings, price restrictions may not be imposed on either party when selling contract products. Recommended and maximum prices may be allowed, so long as this does not amount to fixed or minimum sale prices as a result of pressure from, or incentives offered by, either party.

- The parties to the agreement will generally not be able to restrict the customers to whom, or territories in which, the licensee may sell *passively*. However, the following list of such terms will be allowed:

  – The restriction of passive sales into an exclusive territory or to an exclusive customer group reserved for the licensor.

  – The restriction of passive sales into an exclusive territory or to an exclusive customer group which the licensor has allocated to another licensee. This restriction will only be allowed during the first two years of sales by the licensee to whom that territory or group was allocated (note that restrictions on active sales by the licensee would be block exempted even if no exclusive territories or customer groups had been allocated).

  – A 'captive use restriction' whereby the licensee can exploit the licensed technology only to make products only for its own use and for spare parts for its own products. The licensee may not be restricted in selling the contract products actively and passively as spare parts for its own products.

  – A 'second source of supply' restriction whereby the licensee may only produce contract products only for a particular customer. The licence must have been granted specifically to create that second source of supply for that customer.

  – The licensor may set up a selective distribution system and restrict sales to unauthorised distributors.

- The licensor may set up a selective distribution system, but may not restrict licensees who operate at the retail level from active or passive sales to end users. The licensor could prohibit members of the selective distribution systems from operating out of 'unauthorised' places of establishment.

Excluded restrictions (Art. 5)

There are four types of restrictions that will be neither hardcore restrictions nor block exempted. Unlike hardcore terms, which render the whole agreement illegal and unenforceable, where these terms can

be severed, the block exemption could still apply to the rest of the agreement. Individual assessment of the 'excluded' terms, taking all the relevant facts into account, will be required to decide whether their overall effect is pro- or anti-competitive. The rationale for this differentiation from hardcore terms is that terms that may reduce the licensee's incentive to innovate are excluded from block exemption.

However, whether or not a term can be severed from an agreement will be judged under national law. In the UK it is extremely difficult to 'blue pencil' a contract and sever terms, so the best advice is to avoid this situation arising. It will therefore be very important to consider this issue when drafting technology transfer agreements.

The following terms are excluded from the block exemption in agreements between competitors and non-competitors.

- Obligations on the licensee to license *exclusively* any severable improvements to the licensed technology back to the licensor will have to be individually assessed. Severable improvements are those which can be exploited without infringing the licensed technology or making use of the licensed know-how. In contrast, a *non-exclusive* grant-back obligation, such as one whereby the licensor and licensee will both be able to exploit or license the improvement, will be capable of block exemption. This is different from the old white list provision whereby such non-exclusive grant back obligations are allowed so long as the licensor also undertook to license its own improvements back to the licensee.

- Similarly, obligations on the licensee to assign improvements or new applications of the licensed technology to the licensor will require individual assessment. However, according to the guidelines, for obligations of this type and of the type mentioned above, the payment of a purchase price or royalty by the licensor may perhaps tip the outcome of the individual assessment towards it being pro-competitive because the licensee still has an incentive to innovate.

- Obligations on the licensee not to challenge the validity of the licensor's intellectual property rights or contest the secrecy or substantiality of the know-how will need to be assessed individually. The guidelines inform us that this is to ensure undistorted competition by eliminating invalid intellectual property rights. However, the same does not apply to terms whereby the licensor can terminate the agreement if the licensee does any of those things. This is the same as the current position and the risk of continuing to use the licensed technology thereafter will then lie on the former licensee.

For non-competitors, terms in a technology transfer agreement that limit the licensee's ability to exploit its own technology or that limit either party's ability to carry on research and development will not be block exempted unless indispensable to prevent the disclosure of the licensed know-how to third parties.

Withdrawal of the benefit of the regulation (Art. 6)

The European Commission will be able to deny individual technology transfer agreements the benefit of the block exemption, should it find that the agreement is incompatible with Art. 81(3) of the EC Treaty.

Some examples are given where this might be the case. One is where third parties' technologies are not able to access the market due to the cumulative effect of parallel networks of similar restrictive agreements that prevent licensees from using third parties' technologies. Another example is where potential licensees are prevented from accessing the market by a

parallel network of similar agreements which prohibit licensors from licensing to other licensees. A third example is where the parties do not exploit the licensed technology and have no objectively justifiable reason for not doing so.

In contrast to the old regime, the regulation will give the same power to withdraw the benefit of the block exemption to the competent authorities in each member state. This power will be limited to cases where the market has a distinct geographical area that falls within, or encompasses solely, that member state.

Transitional period (Art. 9)

Agreements that complied with the repealed Regulation 240/96 and came into force before 30th April, 2004, will have the benefit of a transitional period lasting until 31st March, 2006, before they will have to comply with the new regime.

Innovative technology

The guidelines provide little comfort for innovative undertakings that seek to license new technology for which there is no existing or potential competition in the relevant markets. After the first year of licensing, for which the market share will be zero, the undertaking is likely to have a market share too high to qualify for the block exemption. The agreement will have to be individually assessed against Art. 81 to see whether it falls within the exemptions of Art. 81(3). Paragraphs 130–235 of the guidelines attempt to enlighten us on the application of these provisions to agreements that are outside the block exemption, beginning with the pacifier that, provided that no hardcore terms are included, there is no presumption of illegality in agreements that fall outside the block exemption.

Paragraph 131 of the guidelines unhelpfully states Art. 81 is unlikely to be infringed where there are four or more independently controlled technologies available that may be substitutable for the licensed technology and at a comparable cost. This is unlikely to benefit the licensor of new technology for which no equivalent exists.

Paragraph 164 discusses the situation where a research institute or small research-based undertaking lacks the production and distribution capabilities to put the licensed product on the market effectively. Even if the licensor and licensee were competitors on the technology market, the guidelines state that an exclusive, non-reciprocal licence would be unlikely to infringe Art. 81.

Paragraph 165 discusses the exclusive licensing between non-competitors. Where such an exclusive licence is necessary to induce the licensee to invest in new technology and bring products to the market 'in a timely manner', the agreement is likely to fulfil the requirements of Art. 81(3), even in cases whereby the licensee has to make large investments in developing the licensed technology.

These statements are not clear or definite enough to rely upon however, and only time will tell how the new block exemption and guidelines will be interpreted by the courts.

EU MEDICINES LEGISLATION

The package of measures known as the 'Future Medicines Legislation', having completed its passage through the EU legislative process, has now been published as:

- Directive 2004/27/EC, amending Directive 2001/83/EC on the Community code relating to medicinal products;
- Directive 2004/28/EC, amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products;
- Regulation (EC) No. ref/2004 laying down Community procedures for the authorisation and supervision of

medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA).

The new Regulation replaces, with extensive amendments, Regulation (EEC) No. 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (EMEA).

At the time of writing, however, these measures have been published only on the internet and not in the *Official Journal*, so the day on which the Directives enter into force is not yet known. The importance of this will be in establishing when the changes in substantive law made by these measures (for example as to the periods of regulatory data protection, harmonising these according to the '8 + 2 + 1' formula) must take effect in member states, as this will take place 18 months after such publication. This date will also constitute the date of entry into force of most of the Regulation (for example, adding further types of medicinal product for which the centralised authorisation procedure under the Regulation will become obligatory), except for those provisions relating to the EMA (the new name for the EMEA) itself.

Also published with these is Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products. This will provide, for certain such products that have been in medicinal use for at least 30 years, a simplified registration procedure relaxing the requirements of safety and efficacy – thus it need merely then be shown that the product proves 'not be harmful in the specified conditions of use' and that its 'pharmacological effects or efficacy . . . are plausible on the basis of long-standing use and experience'.

PARALLEL IMPORTS
ECJ rules Bayer's clamp-down on parallel imports was not anti-competitive

In the early 1990s, Bayer's British subsidiary lost very substantial amounts of turnover due to parallel importing of cheap batches of its 'Adalat'/'Adalate' branded cardiovascular drug by Spanish and French wholesalers. This trade was driven by Adalat's large international price differential, which resulted from the relevant competent national authorities fixing the drug's price at up to 40 per cent less in Spain and France than its price in Britain.

Bayer's Spanish and French subsidiaries responded to this loss of profit by reducing the supply of Adalat to the Spanish and French wholesalers. Consequently, the wholesalers were only able to supply their domestic markets and stopped parallel importing into Britain. They complained to the Commission which investigated the matter in 1996.

Commission

Even though it was the wholesalers who had complained, the Commission decided that they had entered into an anti-competitive agreement with Bayer, contrary to Art. 81 EC Treaty (Commission Decision 96/478/EC). The Commission found that Bayer had colluded with the wholesalers to prevent parallel imports of Adalat into Britain. The fact that the wholesalers stopped exporting to Britain while continuing to do business with Bayer (in order to supply their respective domestic markets) constituted their tacit acceptance of Bayer's export ban. Bayer was fined and ordered to stop its infringement of Art. 81.

CFI

Bayer successfully appealed to the CFI, which ruled that the Commission had failed to prove the existence of an anti-competitive agreement. Bayer's actions were unilateral and not agreed to by the wholesalers. The conduct of the parties

did not constitute an agreement just because they continued to do business with one another and the Commission had failed to demonstrate that Bayer had imposed an export ban. The Commission appealed.

ECJ

In January 2004, the ECJ upheld the CFI's ruling. Bayer's conduct and the wholesalers' attitudes did not constitute an agreement. Although it would be possible to deduce an agreement from the conduct of the parties, Bayer's actions had been put into effect without help from the wholesalers, who had opposed the reduction in their supply of Adalat. None of the evidence showed that Bayer had intended to impose an export ban or that supplies of Adalat were conditional upon compliance with the alleged ban.

To prove that an agreement was concluded by tacit acceptance, the Commission would have had to show that Bayer had invited (either expressly or impliedly) the wholesalers to jointly fulfil Bayer's goal of an export ban, particularly as the export ban is not, at first sight, in the interests of the wholesalers.

On a cautionary note, although Bayer has been vindicated in this instance, manufacturers who seek to reduce parallel importing by limiting supplies to wholesalers in other EU member states will have to be careful to avoid infringing Art. 82, which prohibits the abuse of a dominant position.

Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted – COM (2003) 839 final

This Communication, issued by the Commission on 30th December, replaces its 1982 Communication on the same subject to take account of developments in ECJ case law since then. Its overall aim is to give guidance on practical application of the principle of the free movement of goods within the EU to the national measures relating to parallel imports, from one EU member state to another, of proprietary medicinal products for which marketing authorisations have already been granted in the member state of destination.

Such measures include not only those as to trade marks, which cannot be used to contribute to the artificial partitioning of the internal market, so that the parallel importer may, where 'necessary' repackage a proprietary medicinal product and reaffix the trade mark or indeed replace it with the trade mark used in the market of destination, provided that repackaging does not adversely affect the original condition of the product or the reputation of the trade mark and its owner, but also the regulatory framework. As discussed below however, there are still issues to be clarified by the ECJ as to the application of the principle in relation to trade marks.

As to regulatory barriers to such parallel imports the Communication notes for example that the ECJ has ruled that when the marketing authorisation in the member state of destination has been withdrawn for reasons other than the protection of public health, this does not affect the validity of the parallel import authorisation. Again, however, there are still issues to be clarified by the ECJ as to the application of such principle. Thus, on 1st April, 2004, in *Case C-112/02 Kohlpharma v Bundesrepublik Deutschland*, the ECJ relaxed these principles further by holding that it was not necessary that the product authorised in the member state of destination have a common origin with the product in the member state from which it was imported – the assessment of safety and efficacy carried out for the medicinal product which was already authorised could be used in the application for a marketing authorisation for the second, imported medicinal product without any risk to public health.

(1) *Boehringer Ingelheim KG* (2) *Boehringer Ingelheim Pharma Gmbh & Co KG v Swingward Ltd*

(1) *Boehringer Ingelheim KG* (2) *Boehringer Ingelheim Pharma Gmbh & Co KG* (3) *Boehringer Ingelheim Ltd v Dowelhurst Ltd*: *Glaxo Group Ltd v Swingward Ltd*: *Glaxo Group Ltd v Dowelhurst Ltd*

(1) *Smithkline Beecham Plc* (2) *Beecham Group Plc* (3) *Smithkline & French Laboratories Ltd v Dowelhurst Ltd: Eli Lilly & Co v Dowelhurst Ltd*

On 5th March, 2004, the English Court of Appeal, on appeal from the Judgments of Mr Justice Laddie of 28th February, 2000, and 6th February, 2003 (the latter as to the consequences of an ECJ decision of 23rd April, 2002, in response to a referral made on 28th February, 2000), in actions for infringement of registered trade marks for importing pharmaceuticals from elsewhere in the EU and restickering (relabelling) and reboxing (repackaging) them, held, primarily in relation to the appeal by the parallel importers from the second judgment, that certain further questions should be referred to the ECJ. These questions, which were left to the parties to formulate, were as to whether the test of 'necessity' as it applied to the reboxing of parallel imports of pharmaceuticals concerned only the act of reboxing or extended further, and as held by Mr Justice Laddie, to the details of the presentation of the reboxed product. However the Court also held, in the context of cross-appeals on the restickering issue, that clear guidance was also required as to the precise form of allowable restickering, and also ordered a reference to the ECJ as to these.

The Court of Appeal also upheld an appeal by the parallel importer as to the period of notice that must be given to the rights owner of the intention to sell parallel imported goods the original packaging of which had been altered or discarded, holding that this should be 15 working days, rather than the seven working days in the case of restickered goods as held in the second judgment of Mr Justice Laddie. However the Court largely dismissed an appeal by the trade mark owners against the first of his judgments, as to reboxing having been shown, in the cases before it, to be necessary to overcome the resistance met to sale of the product when it was simply restickered. Another cross-appeal as to passing off, brought by one of the trade mark owners, was also dismissed.

Glaxo Group Ltd v Dowelhurst Ltd and Richard Taylor

On 15th March, 2004, the English Court of Appeal dismissed an appeal by Glaxo from the judgment of Peter Prescott QC, who had refused to grant summary judgment to them in a trade mark infringement action in respect of 15 out of 16 batches of Glaxo product parallel imported from outside the European Economic Area (the EEA – the European Union plus Iceland, Liechtenstein and Norway). The Court also allowed an appeal against his grant of summary judgment on the remaining batch. The factual issue which it was held could not be determined in summary proceedings was whether or not the batches had been 'put on the market' in the EEA with the consent of Glaxo where these had originally been sold under contracts identifying an ultimate destination in Africa but not, it would appear, preventing the purchaser from selling in the EEA, and where ownership of the batches may first have passed within the EEA. In an interim decision in Germany a Hamburg Court, in similar circumstances and in another action brought by Glaxo, had held that goods were 'put on the market where the buyer has the power of disposal within the market'. Glaxo instead argued in the English Court that the correct position should be that adopted by the European Commission in its 'Guide

to the Implementation of Directives based on the new Approach and the Global Approach', which had observed that 'placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community'. The Court also held that it would be premature to make a reference to the ECJ until the full facts had been determined, as the detail which would emerge on so doing might matter if there was a grey area between putting on the market in and out of the EEA.

CASES

Genzyme guilty of 'market squeeze' abuse for orphan drug

On the 11th March, 2004, the Competition Appeal Tribunal (CAT) rejected Genzyme Limited's appeal against a £6.8m fine imposed by the Office of Fair Trading (OFT) in March last year for breach of Chapter II of the Competition Act (1998). Chapter II is modelled on Art. 82 of the EC Treaty and prohibits the abuse of a dominant market position. The OFT's decision had been criticised for imposing an unfairly high burden on innovative companies who undertake a very high investment cost in order to develop 'orphan' drugs to treat diseases that affect only a very small number of people. Although the CAT reduced Genzyme's fine by more than half to £3m on the basis that the OFT had not proved its findings before May 2001, the CAT's ruling has robustly rejected those criticisms.

Genzyme Limited, a UK subsidiary of Genzyme Corporation, the US biotechnology company, supplies 'Cerezyme' (imiglucerase) in the UK for the treatment of the rare enzyme deficiency disorder 'Gaucher's disease' (pronounced 'go-shay'). There are only around 190 sufferers in the UK who are treated with Cerezyme. Of these, 170 receive infusions of the drug at home, and 115 of these patients (or their parents) have been trained to infuse the drug themselves. The remainder require nursing assistance.

This case concerns delivery of Cerezyme to patients' homes in the UK and the provision of associated home care services, such as nursing support, patient training, the provision of an emergency help line, the supply of fridges and needles and the disposal of waste. Genzyme sold Cerezyme to the National Health Service (NHS) at a single list price which included home delivery and associated home care services. After terminating the agreement it had with its exclusive distributor, Genzyme supplied both the drug and the home care services to Gaucher's patients itself and, from that date onwards, would supply Cerezyme to third parties only at the NHS list price (which included home care services). This effectively eliminated any margin that third party home care service providers, including Genzyme's former distributor, could make and so cut them out of the 'downstream' market for the provision of such services.

The OFT ruled that Genzyme's pricing strategy was an abuse of its dominant position in the 'upstream' market for the supply of drugs to treat Gaucher's disease with a 'market squeeze abuse'. The CAT upheld the OFT's findings regarding market squeeze, but it rejected the finding that Genzyme had also abused its position by 'bundling' the drug with the services for one price on the NHS list. Such bundling was not, of itself, an abuse of a dominant position, although the practice facilitated the market squeeze. The CAT also found that Genzyme's abuse had been going on for a shorter time than the OFT found and reduced the fine imposed on Genzyme accordingly. Genzyme has also been ordered to negotiate a new pricing strategy for the drug and the home care services with the NHS and other third party service suppliers.

This is an important competition case for drug companies and healthcare service providers to note, as it affects not only the prices which they may charge the NHS,

but also the products and services which may be bundled by the monopoly holder.

Cyprotex Discovery Ltd v The University of Sheffield

This case concerns an appeal by Cyprotex Discovery Ltd and is an important ruling on the ownership of intellectual property rights arising out of research project between a university and a commercial sponsor.

The University of Sheffield had developed a series of algorithms, databases and associated computer software to assist in the prediction of how potential new drugs would be absorbed in the human body. The university then entered into a multi-party research agreement to develop a program that would utilise the information into a user-friendly model which would turn it into a commercially exploitable product. Cyprotex was one of the sponsors and provided sponsorship in the form of the services of one of their employees.

The multi-party research agreement was poorly drafted and when the relationship between Cyprotex and the university broke down there was a dispute over copyright ownership of the computer program. The agreement did not expressly deal with ownership of the computer program but only improvements to the program. The agreement also provided that the university would grant licences to the sponsors.

The Cyprotex employee was provided with background information necessary to write the program and he went on to solely write the software code. The court stated that in the absence of a contract to the contrary then Cyprotex would be adjudged to be the owner of the copyright in the program as the employer of the author of the copyright work. However, the court looked at the surrounding circumstances and contractual background and gave a commercial interpretation to the wording of the research agreement. The university was, among other things, able to rely on the existence of an 'informal' oral agreement between the parties prior to completion of the research agreement under which it was claimed that Cyprotex had agreed that copyright should be vested in the university. The court stated that it was the intention of the parties that the program would belong to the university. The court's decision was also based on the fact that the responsibility for the provision of a computer programmer was the University's and the University would normally have been expected to engage either as a consultant or as an employee to do this. However, Cyprotex provided a programmer in lieu of a financial contribution to the project. The important message from this case is that the important terms relating to collaborative research should always be set out clearly in writing in advance.

NOTES FROM THE USA

Biotech companies face new regulations under the Sarbanes–Oxley Act

Now that more and more privately owned biotechnology companies are looking to secure public funding, such companies should take proactive steps to ensure compliance with the Sarbanes–Oxley Act of 2002 as well, especially when considering either an initial public offering (IPO) or a merger with a public company. Responding to a wave of US corporate and accounting scandals that resonated around the globe, President Bush signed the Act into law on 30th July, 2002, and, now that public markets are opening up, it is a key compliance issue for biotechnology companies. The Act applies to all companies that file periodic reports with the US Securities and Exchange Commission (SEC), including all publicly held biotechnology companies. The Act includes several new changes that affect the rules regarding company loans to directors and officers, the composition and role of audit committees, and officer certification of reports filed with the SEC. Some of the major changes are discussed as follows,

along with steps biotech companies can take to promote compliance with the Act.

Loans to directors and executive officers

Section 402 of the Act prohibits a public corporation from granting personal loans to its directors and executive officers. This prohibition applies to any personal loans granted directly or indirectly, including loans granted through any subsidiary. Loans existing at the time the Act was enacted are grandfathered,[2] provided there is no material modification to any term of the loan, or any renewal of the loan at the time of enactment or any time thereafter. For private companies, this prohibition can come into play in two different situations. First, if a private company goes public, the prohibition applies upon filing any registration with the SEC. Secondly, if a private company merges with a public company, the prohibition applies if an individual becomes an executive officer or director with the public company. If a private company has any loans that would be subject to the prohibition under s. 402, the loans must be unwound or paid off before the company goes public or is acquired by a public company. Although the Act does not specifically address loans by private companies, any private biotechnology company considering a public offering or merger with a public company should consider developing a plan to resolve any of these issues well in advance.

Independence and expertise of audit committee members

With respect to audit committee members, the Act requires that each member of the audit committee be 'independent'. To be considered independent under the Act, the audit committee member (1) cannot accept any additional consulting, advisory or other compensatory fee from the company, other than that company's normal director or committee fees, and (2) cannot be an 'affiliated person' of the company or its subsidiaries. The term 'affiliated person' is not defined in the Act, but the Act notes that any director who holds a controlling interest in the company's stock is disqualified from serving as a member of the audit committee. The SEC may grant limited exceptions to this independence requirement.

The Act also directs the SEC to issue rules requiring companies to disclose whether the audit committee has at least one member who is a 'financial expert'. The Act does not define 'financial expert', but rather directs the SEC to define the term. In forming its definition, the Act requires that the SEC consider whether the person has acquired an understanding of generally accepted accounting principles through education and experience. If the company does not have a financial expert on their audit committee, the company must disclose and explain the deficiency.

Private biotechnology companies considering an IPO or public company merger should consider recruiting independent financial experts to their boards as soon as possible. Individuals with significant financial and accounting experience and little or no previous ties to the company should be identified as candidates. This will provide a smoother transition from private to public company, will help ensure compliance with the Act, and will avoid the difficulties associated with recruiting independent directors immediately prior to an IPO.

The role of the public company audit committee

Under the Act, the audit committee is directly responsible for the appointment of a registered public accounting firm that will serve as an external auditor, oversight of any work the accounting firm performs for the company, and its compensation. This structure encourages increased communication flow between management, the audit committee, and the external auditor. From the point a biotech company becomes public, its management should engage in open and

frank discussion with both the audit committee and the external auditors regarding the risks faced by the company, the financial condition of the company, and the quality of accounting principles to be applied.

Certification of financial statements

Section 302 of the Act requires public company CEO and CFO certification of all quarterly and annual reports filed with the SEC. Officer certification means that based on his or her knowledge, (1) the report does not contain any untrue statement of a material fact or omit to state a material fact that makes the statements misleading, and (2) the financial statements and other financial information included in the report fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of and for the periods presented in the report. Fines and criminal penalties may be imposed for making the certification knowing that the periodic report does not comply with the Act. To avoid this liability, senior management should ensure the company has strong internal controls, develop control documentation as new systems and improved processes are initiated, and institute a strong quarterly close process right from the beginning.

Conclusion

The Act's new regulations impose major changes with respect to corporate loans, audit committees and officer liability. These changes will place significant burdens on all public companies, as well as any private companies considering an IPO or public merger. Avoiding loans to corporate officers, recruiting high-quality independent audit committee members, and implementing strong internal auditing controls are all proactive steps that private biotechnology companies can take to ensure a smooth public transition.

Reference and note

1. URL: http://europa.eu.int/comm/competition/antitrust/legislation/entente3_en.html#licensing
2. In the context of the new regulations, the term 'grandfathered' means that if a loan was issued legally under the previous regulations, that loan will remain valid, even if it would be considered illegal under the new regulations. In other words, the new regulations on loans only affect those loans issued after the regulations were enacted, not those already in existence at the time of enactment.