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

Legal and regulatory update

REFORM OF THE TECHNOLOGY TRANSFER BLOCK EXEMPTION

Article 81 EC

Article 81(1) of the Treaty of Rome prohibits all agreements, decisions and concerted practices that may affect trade between member states and that have as their object or effect the prevention, restriction or distortion of competition within the EU. Any agreement that is prohibited by this Article is automatically void.

Such an agreement, decision or concerted practice may be granted an exemption through a 'block exemption' because it 'contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing customers a fair share of the resulting benefit'.[1] Block exemptions are essentially 'safe harbours' and apply to practices that are considered to be very unlikely to cause competition concerns.

The proposed technology transfer block exemption (TTBE)[2]

A draft regulation was published in October 2003 for consultation. It is proposed that a new draft will be circulated to member states in February 2004 for review by the Office of Fair Trading and other national competition authorities and the final regulation will be published in March/April 2004 for implementation on 1st May, 2004.

There are two key issues that are central to the proposed draft regulation:

- **Restricted clauses**: the draft regulation contains a 'black list' of clauses, which, if contained in an agreement, will cause that agreement to fall outside the protection of the new TTBE. The draft also contains a 'grey list' of clauses that may be permissible but that will need to be assessed on a case-by-case basis. The review of EC competition law being undertaken alongside the review of the TTBE will abolish the procedure for notifying individual cases to the Commission. Therefore, analysis of whether the 'grey list' clauses are permissible will have to be made by the companies entering into the agreements. The Commission has issued guidelines alongside the draft regulation, which should assist companies to make this decision. There is no 'white list' in the draft regulation. Competitors and non-competitors will be treated differently under the black and grey-listed clauses, with the restrictions on competitors being stricter than those on non-competitors. Competing undertakings is a defined term in the draft regulation and means undertakings that compete on the relevant technology market and/or the relevant product market.

- **Market share test:** the draft regulation introduces a market share test into the TTBE for the first time. Where an agreement is between competitors and they have a combined market share of greater than 20 per cent in the relevant technology or relevant product market, the block exemption does not apply to the agreement. Where the agreement is between non-competitors, the market share threshold will be that each of the parties to the agreement must have a market share of less than 30 per cent in the relevant technology and relevant product markets. In the case of new or emerging technologies, which have not generated any sales, a market share threshold of 0 per cent will be assigned. However, the market share test is a continuing obligation and it is

clear that if a technology is highly innovative, the market share is likely to exceed the thresholds once it is placed in the market and starts generating sales. In addition, new technologies may create entirely new markets and will therefore have a 100 per cent share of the relevant technology or product market. In these circumstances any agreements will lose the benefit of the proposed TTBE. The introduction of a market share test has been heavily criticised by industry as companies benefiting from the new TTBE will be required to continually review their market position. Despite these criticisms the Commission has indicated that the market share test will be included in the final draft of the TTBE.

The new TTBE is of significant concern to the biotechnology and pharmaceutical industry. In particular, in addition to covering patent and know-how licensing agreements, the proposed TTBE will also cover software copyright licensing agreements and mixed patent, know-how or software copyright licensing agreements.

Companies that are involved in technology licensing will need to be aware of the changes being introduced with the new TTBE. There will a grace period of 18 months for licences that are already in existence but that do not comply with the new TTBE. Thus, by 31st October, 2005, all existing licensing agreements will need to be reviewed to ensure that they comply with the new rules being introduced by the proposed TTBE.

EXPANSION OF THE EUROPEAN UNION: EFFECT ON COMMUNITY INTELLECTUAL PROPERTY RIGHTS

EU expansion

On 1st May, 2004, the EU will be enlarged by the accession of up to ten new member states. The Czech Republic, Cyprus, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia signed the Treaty of Accession on 16th April, 2003, and it must now be ratified by each of the candidate countries and all of the existing member states.

Community Trade Mark

The Community Trade Mark (CTM) is a unitary right which is granted by the Office for the Harmonisation of the Internal Market (OHIM) and which applies throughout all 15 member states of the EU. OHIM has been involved in enlargement negotiations since November 1998 and, as a result, the CTM Regulation has been amended to include Art. 142A, which governs the legal implications of enlargement.

The main consequence for holders of CTMs filed prior to the date of accession (irrespective of whether they have been registered or not) is that their protection will automatically extend to the territories of the ten new member states from midnight on 1st May, 2004.

This extended coverage may conflict with prior national rights that are already in existence in the new member states. Extended CTMs will be enforceable in the entire EU, including all new member states; however, the holder of an earlier conflicting national right in a new member state will be able to prevent the use of an extended CTM in their territory provided that the earlier national right was obtained in good faith. In addition, the new member states will be able to prevent the use of an extended CTM in their territory where it would not be valid, under national law, on absolute grounds such as descriptiveness, non-distinctiveness, deceptiveness, morality or public policy.

Where a CTM application is filed prior to 1st May, 2004, but has not been examined before that date, there will be two regimes for determining whether the CTM should be granted. If the application is filed prior to 1st May, 2004, the application will be examined on

absolute grounds (and may only be subject to cancellation actions on such grounds) based on the situation in existence prior to enlargement. Absolute grounds for refusal or invalidity that become applicable merely because of accession will not be taken into account. Applications filed between 1st November, 2003, and 30th April, 2004, will, in addition, be subject to oppositions based on earlier rights in the new member states. OHIM has reported it has had its busiest month ever in October 2003. Typically, OHIM receives 3,000–5,000 applications per month; however, in October 2003 it received over 12,000 CTM applications. This is most likely to be due to the important rule change on 1st November, 2003, which meant that there were more circumstances in which a CTM application could be found to be invalid.

Community Designs

OHIM has also confirmed that the Community Designs (CD) Regulation will be amended by the addition of Art. 110A, which will deal with the legal consequences of enlargement. CDs filed and unregistered designs made available to the public within the Community prior to 1st May, 2004, will be automatically extended to the territory of the new member states.

The validity of a CD filed or disclosed prior to 1st May, 2004, will not be able to be challenged on the basis of grounds which come into existence due to the accession of a new member state. As for the CTM, an owner of an earlier national design right in a new member state may prevent enforcement of a pre-May CD in that member state.

Following 1st May, 2004, CD and CTM applications will be subject to the full grounds for invalidity in all 25 member states.

Community Patent

In March 2003 the Competitiveness Council published a proposal for a Regulation on the Community Patent. This proposal has yet to be implemented; however, the Competitiveness Council is due to meet again in December 2003 and it is hoped that the Regulation can be finalised at that meeting.

Under the European Patent Convention a European Patent is not a Community-wide right but is a collection of national patents. The aims of the Community Patent are to:

- introduce a unitary right granted by the European Patent Office which will stem from a new body of Community patent law and will automatically cover all member states of the EU;
- introduce an affordable system of obtaining and maintaining a Community Patent similar to costs in the USA and Japan;
- introduce an appropriate language regime (the current situation is that the claims will have to be filed in all 11 (soon to be 20) official languages of the EU); and
- allow the national, European and Community Patent systems to co-exist.

There have been significant problems with the proposed Community Patent legislation and industry representatives have indicated that the legislation as currently proposed will not be used by industry (who will prefer to use the tried and tested European Patent system). However, the current member states are pushing for the Community Patent legislation to be finalised prior to 1st May, 2004. The legislation will require the unanimous consent of all the member states before it can be adopted and therefore it will be more likely that the legislation will be vetoed following the accession of ten new member states.

Community Plant Variety Right

The extension of Community Plant Variety Rights has not been addressed in the accession treaties. The Community Plant Variety Office considers that existing rights will be automatically enforceable in the new member states; however, the extent of such enforcement is uncertain in the absence of transitional provisions.

Proposed Remedies Directive

With the addition of ten new member states the disparity between the remedies available for intellectual property (IP) infringement will increase. In addition, the expansion will increase the free circulation of goods with countries that have previously been havens for pirated goods.

The Commission has been pushing for a new directive that will lay down universal remedies for IP infringement to be available in all member states. This may be crucial if IP rights holders are to be able to enforce their rights effectively in the enlarged EU. The proposed universal remedies include:

- seizure of evidence;
- seizure of assets to protect an award of damages;
- interim injunctions;
- disclosure of information;
- recall and destruction of infringing goods;
- availability of significant damages;
- publication of judgment in newspapers;
- recurring fines for non-compliance with final injunctions; and
- criminal sanctions, including imprisonment.

PATENTS: USA BANS PATENTING OF HUMAN ORGANISMS

The House of Representatives has passed an amendment (the Weldon Amendment on Patent Applications) which bans the US Patent and Trademark Office (USPTO) from issuing any patent on a human organism at any stage of development. USPTO policy states that human beings, at any stage of their development, are not patentable subject matter under 35 USC s. 101 which states that 'Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title'.

Congress has not previously spoken on this issue. The provision passed by the House bans patents for genetically engineered human embryos, foetuses and human beings. It will not affect patents on genes, cells, tissue and other biological products and will not prevent patents for procedures or methods of creating a biological product. A report that accompanies the provision also makes it clear that the patent ban is not intended to interfere with stem-cell research.

The USPTO has stated that the amendment is 'fully consistent with USPTO's policy on the non-patentability of human life-forms'.

CONSTRUCTION OF PATENTS: APPLICATION OF THE PROTOCOL ON THE INTERPRETATION OF ART. 60 OF THE EUROPEAN PATENT CONVENTION

Summary

The case of *Merck & Co. Inc v Generics (UK) Limited*[3] tried the preliminary issue of whether the defendant's process for manufacturing monosodium alendronate infringed the claimant's patent. The High Court considered how widely a patent should be construed so as to give

protection in accordance with the Protocol on the Interpretation of Art. 60 of the European Patent Convention.

The Court held that a patent should not be construed so as to give wider protection than the patentee intended because this was not an act of fairness to the patentee and because this would not give reasonable certainty to third parties.

Background

Merck is the patentee of European Patent (UK) No. 0,402,152, which relates to a method of manufacturing monosodium alendronate. Monosodium alendronate is useful in inhibiting bone resorption and was the largest selling osteoporosis medicine in the world.

The defendant is a supplier of pharmaceutical preparations to the UK and at the end of 2002 it notified Merck that it intended to sell a pharmaceutical containing monosodium alendronate as the active ingredient. The defendant supplied Merck with a confidential process description and requested Merck to concede non-infringement.

Merck commenced proceedings for infringement based on the confidential process description and the defendant counterclaimed for invalidity. It was ordered that there would be a rapid trial on the question of infringement and that determination of the issue of validity would be stayed.

As there was no dispute as to the nature of the alleged infringing process the only issue for the Court to decide was how the Patent should be construed.

The defendant argued that its process did not infringe the Patent either on applying the three step test in *Improver v Remington*,[4] namely:

- does the variant have a material effect on the way in which the invention works?
- would the fact that the variant had no material effect have been obvious at the date of the publication of the patent to a reader skilled in the art?
- would the reader skilled in the art have nevertheless understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention?

or on applying the Protocol which states that '[a European Patent] is to be interpreted as defining a position . . . which combines a fair protection for the patentee with a reasonable degree of certainty for third parties'.

Merck contended that it met each of the three questions from *Improver* but, that if it failed on the third question, it also relied on *Pharmacia v Merck*[5] for the proposition that in chemical cases the *Improver* questions are difficult to apply and should be set to one side. Merck also argued that the fairness which the Protocol requires meant that Merck should be given a monopoly co-extensive with the invention that it had made, after the scope of the invention had been established by the skilled reader.

Decision

- The correct approach is to construe the Patent and its claims in the absence of the infringement. Only once the scope of the Patent has been determined should the infringement be considered.

- The *Improver* questions are a useful structured method of looking at infringement, but the Protocol takes precedence. Merck did not prove infringement based on this test and at a first glance the defendant's process was very different from that covered by the Patent.

- Patents are supposed to be understandable to members of the relevant field on a simple reading and it should not be necessary to hear expert evidence on the construction of a patent. Under s. 14 Patents Act 1977 (and also under the European Patent Convention) the purpose of a patent is

to clearly set out what the invention is and to describe the monopoly in unambiguous terms.

- The Protocol does not require the Court to construe the Patent so as to give a wider monopoly than was intended. This would not be an act of fairness to the patentee as 'fair protection' can be referring only to protection that the patentee intended to obtain, such intention to be assessed objectively. In addition, this would not give the public reasonable certainty. The extent to which protection exceeds what is explicitly set out in the claims will only be so wide that it does not hinder the public from being given reasonable certainty.

APPEAL AGAINST REVOCATION OF PATENTS ON THE GROUNDS OF NOVELTY AND OBVIOUSNESS: GUIDANCE ON THE APPEALS PROCESS

Summary

The Court of Appeal in *(1) Instituto Gentili SpA (2) Merck & Co. Inc. v (1) Teva Pharmaceutical Industries Limited (2) Arrow Generics Limited (3) Generics (UK) Limited*[6] upheld the decision of Jacob J in the High Court that the claimants' patents were invalid for obviousness and for lack of novelty.

The Court of Appeal suggested guidance for appellants to follow in future when appealing against findings of fact by the first instance judge.

Background

The first appellant, Instituto Gentili, was the patentee of UK Patent 2,118,042 for 'Pharmaceutical compositions containing pharmacologically active bisphosphonates'. The specification stated that such compositions are suitable in the treatment of urolithiasis and are capable of inhibiting bone resorption. The priority date was 15th April, 1982.

The respondents challenged the validity of one or more of the claims on the grounds of lack of novelty and obviousness. They relied upon various publications including European Patent Application 0,039,033A which was published in November 1981 and which described the use of certain bisphosphonates as water softeners but stated that 'owing to their properties they are also suitable for the production of cosmetic and pharmaceutical preparations'. They also relied on the common general knowledge at the priority date.

The second appellant, Merck, was the patentee of European Patent 0,998,292 which related to an invention claimed as 'a use of alendronic acid for the manufacture of a medicament inhibiting bone resorption for treating osteoporosis . . . adapted for oral administration in a unit dosage form which comprises about 70 mg of alendronic acid'. The priority date of the patent was July 1997.

The respondents challenged the validity of the 292 patent on the grounds that it was invalid under s. 4(2) Patents Act 1977, which states that a method of treatment shall not be taken to be capable of industrial application. The respondents argued that the 292 patent was for a method of treatment by therapy. They also alleged that the 292 patent was obvious and lacked novelty.

The High Court revoked both patents on the grounds alleged and both parties subsequently appealed. Merck also sought to amend the 292 patent to delete the part of the specification relied on by the trial judge in reaching his decision that it was invalid under s. 4(2).

Decision

- The issue to be determined in respect of lack of novelty was one of fact for the judge and he was correct to hold that the direction in European Patent Application 0,039,033A was to use bisphosphonates as the active ingredient in a pharmaceutical and that the skilled man would clearly understand this, given the common

general knowledge at the time. Instituto Gentili's patent (042) therefore lacked novelty because it was anticipated by European Patent Application 0,039,033A.

- The Court of Appeal would not interfere with the judge's decision on obviousness as this was also a question of fact that he had correctly determined.

- Merck's proposed amendment would affect the interpretation of the claims of the patent and hence the deletion would add to the teaching of the 292 patent. The amendment was therefore prohibited by s. 76(3)a Patents Act 1977 which states that no amendments to the specification of a patent are permitted if they constitute added matter.

- The judge was correct that the invention claimed in the 292 patent was for a particular dosing regime, rather than for the preparation of a single dose of alendronate, and therefore the Court of Appeal agreed that the 292 patent was incapable of industrial application under s. 4(2).

Appeals against findings of fact

The appeals were both, in substance, appeals against the trial judge's findings of fact. The Court of Appeal laid down some guidelines to be followed in future cases when the appellant is seeking to challenge the trial judge's conclusions on anticipation and obviousness.

The appeal court will interfere with the trial judge's ruling only if it is shown that he has erred in principle. In future, in appeals of this nature, the grounds of appeal should contain a succinct statement of the principle or principles that the judge is said to have infringed and the authority for that principle. If such a statement is produced, it should be much clearer when complaints are unsustainable and should allow for a much more economic and focused disposal of the appeal.

TRADE SECRETS: BREACHES OF CONFIDENTIALITY, THE CONSTRUCTION OF RELEVANT LICENCES AND ESTOPPEL REMEDIES

Summary

The case of *Centria (a Pennsylvania general partnership) v Corus UK Limited (1) Sigma Coatings SA (2) and Sigma Coatings Limited*[7] related to the interpretation of a know-how licence and the rights granted in the licence and concerned the trial of the following preliminary issues in the High Court (Chancery Division):

- were the defendants liable to Centria by using the technology; and if so

- was Centria estopped from asserting their cause of action?

Lastly it should be noted that defendants (2) and (3) in the action issued Part 20 claims against defendant (1) for an indemnity. Defendant (1) issued a Part 20 claim in return.

Background

The technology in question is called Versacor. It is a coating that is used to protect metal sheets from extreme environmental conditions, and is used in building construction. This technology has always been a trade secret and has never been in the public domain.

The technology was originally owned by a US company called H.H. Robertson Co., which merged to form Robertson-Ceco Corporation (RC). RC used Versacor technology both in its own business and in its subsidiaries. In an agreement dated 20th December, 1991, RC sold some of its business to a company called United Dominions Industries Inc. (UDI).

A term of the agreement dated 20th December, 1991, was that an Intellectual

Property Licence Agreement would be executed. This agreement was to be in the same terms as the term sheet. An important section of the term sheet was that a licence was to be provided to use the know-how in the USA only. In January 1992 an Intellectual Property Licensing Agreement was executed between the parties. However, this agreement differed from the term sheet. In the new version there was a worldwide exclusive licence to the know-how and a restricted licence to use the trade marks in the USA. The parties also agreed to share improvements under the licence. However this was useless if an exclusive licence had been granted.

In 1996 Centria acquired the business involving the Versacor technology from UDI. Centria asserted that they have the exclusive worldwide right to the technology. The defendants claimed that Centria only have exclusive rights in America (and other defined territories) to the technology.

The defendants are those companies whose interests in Versacor can be traced back to RC's subsidiaries. These companies are involved in the manufacture, sale and supply of products that incorporate Versacor technology.

Reasons for the opinion

Hart J expressed the opinion that that 1992 Licence was poorly drafted. In constructing the agreement he concentrated on the wording of the Licence and what made commercial sense at the time of drafting the agreement. The judge did not allow Centria to infer complex ideas into the document for which there was little evidence.

Hart J remarked that the worldwide exclusive licence to use the know-how but only a licence to use the trade marks within the USA was a 'commercial puzzle' and explained the meaning of an exclusive licence and that fact that it was at odds with the rest of the agreement.

Also, RC was never in a position to grant an exclusive licence because certain of its overseas subsidiaries were already licensed to use the know-how. This fact was well known to the parties at the time.

The judge ruled that the phrase 'the right to use the Shared Know-How only within the American Territory' was unambiguous and fatal to Centria's claim. Hart J concluded that Centria's claim failed simply because the right to which it succeeded was, as a matter of construction, a right to use the technology only within the USA. The defendants had not infringed the confidentiality of the agreement by marketing Versacor in territories other than America. The defendants had not infringed any other obligation to Centria.

Hart J suggested that the doctrine of estoppel by acquiescence should apply to Centria. This was because they did not assert their claim to an exclusive worldwide right until 2000. The 1992 Licence was executed in 1992. Centria were aware that the defendants were using the technology outside America for eight years and Centria allowed them to do so. Hart J believed that Centria should be estopped by acquiescence despite the fact that the claimant did not know it had a claimed right. Hart J suggested that in this case it would be enough for the claimant to have no excuse as to his lack of knowledge.

Although estoppel was discussed, it was not relevant to the ruling once the first issue had been decided.

THE MARKET AUTHORISATION OF GENERIC MEDICINAL PRODUCTS – INTERPRETATION OF THE ABRIDGED PROCEDURE

Summary

Astrazeneca A/S v Lægemiddekstyrelsen participant: Generics[8] examined the following preliminary issues:

- whether an application for a marketing authorisation for a generic medicinal product can be made when the marketing authorisation for the

reference product has been withdrawn; and

- whether an application for a marketing authorisation for a generic medicinal product can be granted when the marketing authorisation for the reference product has been withdrawn.

Background

A product called Losec Entero (Losec) was developed by the Astra Group. In February 1997 Astrazeneca (which was formed on the merger of the Astra Group with Zeneca plc) applied to Lægemiddekstyrelsen for a marketing authorisation for a variation of the Losec Entero product.

On 23rd February, 1998, Generics applied to the Lægemiddekstyrelsen for marketing authorisation of a medicinal product in capsule form called Generics Entero. Losec is the reference medicinal product for Generics Entero. On 6th April, 1998, Astrazeneca withdrew the requested marketing authorisation for Losec. On 30th November, 1998, Generics was granted a marketing authorisation for its product.

Astrazeneca brought an action against Generics claiming that

> the marketing authorisation of the reference medicinal product must be in force not only at the time when the application for marketing authorisation of the generic medicinal product is made but also at the time when the marketing authorisation of the generic medicinal product is granted.

Guidance was sought on the interpretation of the abridged procedure for market authorisation used where the applicant product is very similar to another product called the reference product, and set out in Council Directive 65/65/EEC.

Reasons for the opinion

It was stated that the primary purpose of the Directive was to protect public health. In the current case the reason that the marketing authority was withdrawn from the reference product was nothing to do with its safety.

It was held that the Directive intended the marketing authorisation of the reference product to be in force on the date when the application for the generic product was made. It is not necessary for the marketing authorisation of the reference product to be in force on the date the application was granted.

It was decided that this interpretation best fits the objective of saving the time, repetition and expense of gathering the results of clinical and other trials, but if the authorities of individual member states have any concerns about an individual product it is open to them to refuse to acknowledge marketing authorisations granted under the abridged procedure.

A person who makes an application for marketing authorisation of a generic product is under an obligation to update the competent authority on new issues that might be important to his application.

CONTRACTING OUT OF INSOLVENCY AND ACQUIESCENCE

Summary

This is the case of *(1) Michael Bruce Fraser, (2) Agatha Shuk-Yee Wong-Fraser, (3) Davidson Tools Limited and (4) Sankey Product Developments Limited v (1) Oystertec PLC, (2) Paul Anthony Davidson, (3) Adrian Philip Binney and (4) Easyrad Limited*. The claimants sought summary judgment on the following issues:

- that any assignment of the contested Patent No. 2314391 was void because it was based on an attempt to contract out of the insolvency laws;

- the assignment was not effective because no court had made an insolvency finding; and

- that the assignment did not apply to the Patent.

The defendants maintained that Mr Davidson owned the Patent. They also submitted that the claimants acquiesced in the assignment of the Patent and were therefore barred from making this claim.

Background

The claimants were creditors of Easyrad Limited. Mr and Mrs Fraser invested in Easyrad because it was able to acquire the Patent, which it did, from Lancashire Fittings Limited for £50,000, but the consideration was deferred and was to be treated as an interest-free loan from Lancashire to Easyrad to be repaid when and if Easyrad had made a profit of £500,000. Mr and Mrs Fraser lent Easyrad £48,000, which was also interest-free and to be repaid when and if Easyrad had made a profit of £500,000. Easyrad did not make the profit required to trigger either of the loans.

Mr Binney acting for Easyrad then assigned the Patent from Easyrad to Mr Davidson. This assignment was made under an insolvency agreement. The insolvency agreement contained clauses by which the Patent assigned to Easyrad would be assigned to Mr Davidson in the event of termination of the agreement which could be brought about on the basis that Easyrad became unable to pay its debts within the meaning of s. 123 of the Insolvency Act 1986.

Oystertec PLC then held itself out as owning the Patent. This was because Mr Davidson and Mr Binney were directors of Oystertec. It was due to the supposed ownership of the Patent that Oystertec was successfully floated on the stock market in February 2001.

Mr and Mrs Fraser and Davidson Tools Limited (DTL) submitted that the assignment was not lawful because no special resolution authorising the assignment had been signed by the requisite amount of shareholders in Easyrad, as per the shareholders' agreement in force at the date of the assignment.

The defendants have argued that the Insolvency Agreement executed prior to the shareholders agreement gave Mr Binney the power to execute the assignment on behalf of Easyrad.

Reasons for the opinion

The judge commented that the effect of the assignment would be to divest the company of the asset that creditors expected to be available to satisfy their debts. He concluded that the creditors were right to have such expectation because the Patent was presented to the outside world as an asset of Easyrad without qualification.

There was a general principle that there could not be a 'valid contract that a man's property shall remain his until his bankruptcy, and on the happening of that [event] go over to someone else, and be taken from his creditors.' It was decided that the agreement was void because the agreement had the effect of depriving the creditors of Easyrad of Easyrad's assets on insolvency. He stated that the key to understanding the enforceability of such a provision was how the asset in question appeared to the outside world.

It was held that the Easyrad assignment was not effective to divest Easyrad of the Patent.

It was further held that the claimants would not be granted declaratory relief that Easyrad owned the Patent. This was because the claimants had allowed the Oystertec flotation to take place knowing that Oystertec held themselves out as owning the Patent.

THE ABILITY OF THE COURT TO GRANT RELIEF FROM LIABILITY TO NON-EXECUTIVE DIRECTORS

Summary

The case of *The Equitable Life Assurance Society v Roger Bowley, Peter Davis, Christopher Heddon, Shaun Kinnis, Peter Martin, Alan Nash, Jennifer Page, David Price, Roy Ranson, John Sclater, I. Peter Sedgwick, Jonathan Taylor, David Thomas, Alan Tritton, David Wilson*.[9]

This matter dealt with the application for summary judgment by the non-

executive directors of the Equitable Life Assurance Society. The non-executive directors claimed relief from the court under s. 727 of the Companies Act. This section allows the courts to grant relief from negligence claims by a society against its directors.

Background

On 22nd December, 1993, Equitable adopted a differential terminal bonus policy (DTBP). This allowed Equitable to pay less in bonuses to the higher earning of its two pension policies. It was decided in the House of Lords on 20th July, 2000, that Equitable was not entitled to adopted the DTBP. This decision led to Equitable having liabilities of £1.5bn.

Equitable is pursuing actions for negligence and breach of fiduciary duty against directors and argued the following:

- in 1996, 1997 and 1998 the directors failed to get legal advice on the DTBP policy before putting it into action;
- in 1999 and 2000 after the problem had been identified and legal advice obtained they failed to make existing and prospective policy holders aware that the Equitable would face substantial costs if they lost the litigation outstanding against them; and
- that the directors improperly used the discretion granted to them under Art. 65.

Reasons for the opinion

Langley J decided that the claim could not be dismissed on a summary application. The claims against the non-executive directors could not be said to have no real prospect of success.

Previously a non-executive director was 'justified in trusting [an] official to perform [their] duties honestly'. It was held that this is no longer the case. Now a company can expect to rely on non-executive directors for 'independence of judgement and supervision of the executive management'.

On the point about s. 727 Langley J laid out the following conclusions:

- s. 727 does contemplate a situation where an officer of the company can act both negligently and sufficiently reasonably to justify the court excusing the officer from liability;
- s. 727 does contemplate that a court could relieve an officer of liability without a full trial; and
- that in the current circumstances a case would have to be exceptional for the court to grant relief.

The officer would have to demonstrate to the satisfaction of the court that he had acted 'reasonably' and was aware of 'all the circumstances' before a court could relieve him of liability. In Langley J's opinion this is very unlikely to occur in a summary application.

CONFIDENTIALITY AGREEMENT BETWEEN THE FOOD AND DRUG ADMINISTRATION AND EUROPEAN COMMISSION'S DIRECTORATE GENERAL ENTERPRISE AND THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

On 12th September, 2003, letters setting out confidentiality undertakings were exchanged between the Food and Drug Administraion (FDA) and the European Agency for the Evaluation of Medicinal Products (EMEA) and the European Commission. The idea behind these letters is to facilitate an exchange of non-public information between Europe and the USA regarding legislation proposals and the development of regulations by these bodies. Under these arrangements there is provision for non-public information to be disseminated to individuals visiting the

respective bodies. In particular, both letters highlight a key benefit that is anticipated by the arrangements, namely the sharing of information relating to the review and evaluation of information relating to investigational and marketing applications with the hope that this will reduce the time taken for new products to become available to patients.

COUNCIL CONCLUSION (2003/C250/01) REINFORCING THE COMPETITIVENESS OF THE EUROPEAN-BASED PHARMACEUTICAL INDUSTRY

The European Council's conclusions in respect of the reinforcement of the competitiveness of the European-based pharmaceutical industry were published in the *Official Journal* of the European Union on 22nd September, 2003.

In this document the Council highlights the importance of the pharmaceutical industry and stresses the need to reinforce its competitiveness. The Council invites member states to actively participate in the implementation of key actions, suggested by the Commission, in particular benchmarking, by providing appropriate information on legislative and non-legislative measures that could have an impact on the pharmaceutical sector.

The Council invites the Commission to organise an EU-wide reflection on different approaches to pricing and reimbursement for pharmaceutical products. Furthermore, the Council invites the Commission to report to it regularly on the state of competitiveness of the pharmaceutical sector on the basis of the results of the benchmarking exercises and information supplied by member states.

IDEC PHARMACEUTICALS CORPORATION AND BIOGEN INC.

On 14th August, 2003, the Office of Fair Trading, having concluded that a relevant merger situation had not been created under the Enterprise Act 2002, cleared the anticipated acquisition by IDEC Pharmaceuticals Corp. of Biogen Inc.

AAH AND EAST ANGLIAN PHARMACEUTICALS

On 3rd December, 2003, the Office of Fair Trading (OFT) made a reference under the Enterprise Act 2002, to the Competition Commission (CC) in respect of the anticipated merger of AAH and East Anglian Pharmaceuticals.

The decision to make a reference to the CC was a consequence of the OFT's concerns that the merger would result in a substantial lessening of competition in the supply of pharmaceutical products to dispensing doctors, retail pharmacies and hospitals in the region of East Anglia, and also parts of the East Midlands and South East England. The OFT concluded, therefore, that further investigation is required in order to assess whether competition from other pharmaceutical suppliers operating in these areas would be sufficiently effective.

The CC must decide on the case by 19th May, 2004.

ECJ RULING IN THE BAYER/ADALAT CASE EXPECTED SHORTLY

The European Court of Justice's judgment in the *Bayer/Adalat* case, in which the European Commission is appealing against a decision made by the European Court of First Instance (CFI) against it, is expected early in 2004. The decision is important as its outcome is widely expected to influence the future parameters of parallel trading, which has particular importance to the pharmaceutical industry.

The decision of the CFI significantly increased the standard of proof necessary for the existence of an 'agreement' for the purposes of Art. 81 EC, by stating that the mere continuation of commercial relations between a supplier and distributor after the adoption of a unilateral policy aimed at restricting

exports (in this case Adalat, a medicine manufactured and marketed by Bayer AG) is not sufficient to establish the existence of an agreement regarding an export limitation policy of the supplier. Rather it is necessary to show a 'concurrence of wills' between the parties regarding the restriction of exports. The form in which this is manifested is unimportant.

Apparently unilateral conduct that is claimed by an aggrieved party to be part of an agreement cannot be so treated unless there is evidence of actual acquiescence by distributors in the policy adopted by a supplier.

The Advocate-General on 22nd May, 2003, reached the same conclusions as the CFI but on a slightly different basis, holding that in order to establish the existence of an agreement on such a point, there must be at least a 'proposition' by one party to another, which the other party can either accept or reject. The Advocate-General's opinion, although not binding on the judges of the ECJ, is likely to be influential.

Refusals to supply exporter wholesalers could also be attacked under Art. 82 EC, but only where the supplier is dominant in the relevant market. Therefore in essence, if the conduct of a non-dominant pharmaceutical manufacturer in limiting supplies is unilateral and does not reflect the shared intentions of two or more parties, then neither Art. 81 nor Art. 82 EC would apply. As the CFI held, such a non-dominant supplier faced with an event harmful to their interests, would have the right to adopt a supply policy which they consider necessary, even if, by the very nature of its aim, for example, to hinder parallel imports, the implementation of that policy may entail restrictions on competition.

IMPLEMENTATION OF THE CLINICAL TRIALS DIRECTIVE IN BELGIUM

The Belgian Minister for Public Health has recently published a draft law intended to implement the clinical trials directive (EU Directive 2001/20) in Belgium. To a large extent, the draft law simply carries over the provisions of the Directive. There are though certain features that should be noted.

Most important among these is the fact that the provisions apply to 'experimentation', which is defined as 'every study, trial or investigation conducted in man with a view to developing biological or medical knowledge'. This appears to be broader than the definition of 'clinical trial' set out in the Directive and to which it applies. In fact, the Directive's already comprehensive definition seems to cover the majority of situations that are encountered in reality and so the likelihood of this difference having practical consequences remains to be seen. The law will apply to all new trials commencing in Belgium; existing trials will not be affected.

Interestingly, the draft makes special provision for non-commercial trials, which is a trial in which the sponsor – a university, hospital, academic research institution or other authorised body – does not own a patent covering the drug under investigation and will retain any intellectual property in the results of the trial. The sponsor of a non-commercial trial does not have to file preclinical data with the government authority when applying for authorisation in respect of a previously registered drug, does not have to pay any ethics committee fees and may be excused from certain labelling requirements. The draft law also provides that a patient cannot be involved in more than one Phase I trial simultaneously.

It should be noted that the draft introduces some fairly short time limits for both the competent ethics committee and the government authority to complete their respective reviews, with a period of 15 days applying in both cases to Phase I trials and 28 days for all other trials. Once the trial is underway, the primary obligation lies with the ethics committee to monitor protocol compliance (the

Directive simply requires that this is done by the member state).

Finally, it should be noted that criminal sanctions will be introduced for failure to comply with the basic preconditions for undertaking a trial, such as a favourable ethics committee report, informed patient consent and appropriate insurance arrangements. Investigators can be prohibited from conducting trials for certain periods of time if found to have committed such infringements.

The draft law will be introduced into the Belgian parliament early in 2004, although it is not known whether it will be passed in time for the 1st May deadline set out in the directive.

References

1. Article 81(3) EC.
2. Draft Commission regulation on the application of Article 81(3) of the Treaty to categories of technology transfer agreements 2003 *OJ* C 235/10.
3. [2003] EWHC 2842 (Pat).
4. [1990] FSR 1.
5. [2002] RPC 775.
6. [2003] EWCA Civ 1545, [2003] All ER (D) 62 (November).
7. [2003] EWHC 2395 (Ch).
8. C-223/01.
9. QBD Case No: 2002 Folio 406.