
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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REGULATORY DATA PROTECTION FOR MEDICINES

Pending the coming into force in November 2005 of the changes to the regulatory data protection regime under European Medicines Legislation to be effected under the 'Future Medicines Legislation', the European Court of Justice (ECJ) continues to deal with cases referred to it concerning the existing law of regulatory data protection. Thus it gave Judgment on 29th April, 2004, in *The Queen (on the application of Novartis Pharmaceuticals UK Ltd) v The Licensing Authority established under the Medicines Act 1968 (acting by the Medicines Control Agency)*, and the Advocate General gave his Opinion on 8th July, 2004, in *Approved Prescription Services v The Licensing Authority (acting by the Medicines Control Agency)*.

Both cases concerned situations where an abridged authorisation (not requiring full clinical data) had been sought by demonstrating 'essential similarity' to a product that had been authorised for less than the full data protection period (ten years in most of the Community, but at present six years in some countries) but where such product contained an active ingredient which had been authorised, albeit in a different formulation but in the same pharmaceutical form (as in *Novartis*) or in a different pharmaceutical form (as in *Approved Prescription Services*) for the full such period. In *Novartis* the ECJ held that such an authorisation could be validly granted, even though the product for which authorisation was sought was not 'essentially similar' to the product which had been authorised for the full data protection period, and in *Approved Prescription Services* the Advocate General has recommended the same approach, noting also that so doing is consistent with the new law.

ONCOMOUSE PATENT UPHELD

At the end of June 2004, the European Patent Office upheld a Harvard University patent granted in 1988 on a mouse genetically altered to develop cancer (the first patent to be granted on a transgenic animal), but further restricted the wording of the claims so that it now applies only to mice and not to all species of rodents.

The European patent, granted in 1992, which was intended to facilitate research into the treatment of tumours in humans, claimed a method of producing the animals. But the ruling, which closes a years-long legal battle with environmental groups, added further qualifications to an earlier ruling given in 2001 that had limited the claims of the patent to rodents, rather than mammals in general as originally filed.

EMEA LAUNCHES CLINICAL TRIALS DATABASE

At the beginning of May the European Agency for the Evaluation of Medicinal Products (EMA) announced the launch of EudraCT. EudraCT is a database of clinical trials currently taking place in Europe. While the Medical and Healthcare products Regulatory Agency (MHRA) has access to the database, companies and the public do not have access rights. Companies will simply download forms (which are available on the EMA website) and will then send completed filings to regulatory authorities on disk feeding to the relevant body the information about proposed trials. The regulatory authorities will enter the information in the secure database, allowing them to keep up to speed on trials taking place across Europe.

As stated above, EudraCT will not be made public. However, there are plans to

include parts of EudraCT in another public database on medicinal products, although no time scale for this has yet been set. It is envisaged that the information that would be available to the public would in any case relate to products that are already on the market and probably not to first indications trials. The public database has yet to be built and it is expected that the European Commission and the member states will work together to determine which portions of EudraCT it would be appropriate to disclose.

ACTION TO SPEED UP MEDICINE DEVELOPMENT OF MEDICINES

The Department of Health announced the establishment of the UK Clinical Research Collaboration (UKCRC). The mission of this new body is to work to speed up the availability of new treatments for patients who suffer from some of the most common and debilitating conditions and also to promote research into less common conditions. The body will initially work on increasing the number of clinical trials with the aim of speeding up the development of new medicines and treatments from the laboratory to the patient.

The reasoning behind this approach is derived from the achievements of the cancer research sector (and has the support of the National Cancer Research Institute). It is hoped that by replicating the structure of bringing together public, private, charitable and voluntary sectors into specific treatment-focused networks, more clinical trials can be undertaken and more patients can take part.

The Department of Health reported that the UKCRC will consist of representatives of the main funding bodies for clinical research in the UK, namely, government research funding bodies being the Departments of Health – England, Scotland, Wales and Northern Ireland, Office of Science and Technology and the Medical Research Council. It will also include the

Association of Medical Research charities, the Wellcome Trust, representatives of the related industry sectors, the Academy of Medical Sciences and the Academy of Medical Royal Colleges, the NHS Confederation, MHRA and the National Institute for Clinical Excellence (NICE) and members of the public, including people affected by the relevant conditions.

A budget of £31m has been allocated. Although some of the funds will be used to promote networks and clinical trials generally, the larger part of this will be used in the setting up of networks that will focus on Alzheimer's, strokes and diabetes and also on the broader categories of mental health and children's medicine. The Department of Health expects to publish more information on how the funding will be used to support the work of the UKCRC later this year.

REFUSAL TO LICENSE COPYRIGHT

Its decision in *IMS Health v NDC Health* (Case C-418/01 29th April, 2004) has allowed the ECJ to refine the guidance provided by its decision in *Magill* (Case C-241/91 *Radio Telefis Eireann v Commission*; Case 242/91 *Independent Television Publications Ltd v Commission* [1995] ECR I-473, [1995] 4 CMLR 718; [1995] FSR 550) as to those 'exceptional circumstances' where refusal to licence copyright can constitute a breach of Article 82 of the EC Treaty, which outlaws the abuse of a dominant position. In *Magill*, on an appeal from a Commission Decision via the Court of First Instance, it had held such 'exceptional circumstances' to exist where television broadcasters, who published television listings magazines for their own channels, had refused to license their copyrights in television programme listing schedules to the publishers of a television listings magazine which provided programme information for a week ahead for all channels. Thus it had upheld the Commission Decision finding such refusal to licence to be a breach of Article 82 of the Treaty.

In *IMS* the ECJ ruled that the refusal by an undertaking holding a dominant position to grant a copyright licence that is indispensable for the provision of a product or service only constitutes an abuse that breaches Article 82. The refusal not only prevents the emergence of a new such product or service not offered by the rights owner and for which there is a potential consumer demand, but is also without objective justification and is such as to eliminate all competition on the relevant market. This emphasises how rare it will be in practice that all such conditions for such exceptional circumstances to exist are met.

The ECJ judgment in *IMS* was given in response to a request for a preliminary ruling from a German court. Both parties provided data on sales of pharmaceutical products in Germany. IMS Health was the established provider of regional sales data on pharmaceuticals, formatted according to a structure of 1860 'bricks', where each 'brick' corresponds to a designated geographical area. The IMS data structure, in which copyright subsists, had in practice become the industry standard. The dispute concerned IMS's refusal to grant a licence of such copyright to NDC, who had in vain tried to enter the market with alternative data structures. The same dispute had previously given rise to a complaint by NDC to the Commission, where the interim decision of the Commission, ordering IMS to license NDC, was reversed by an interim order of the Court of First Instance (CFI) (Case T-184/01-R *IMS Health Inc v Commission*), the President of which observed that the Commission had been in error in assuming that 'the prevention of the emergence of a new product for which there is potential consumer demand is not an indispensable condition of the "exceptional circumstances" developed in *Magill*'. The Commission subsequently abandoned its investigation and the defence of its decision in view of this pending reference to the ECJ.

The ECJ observed, first of all, that it

was for the national court to determine whether the product or service at issue is indispensable to an undertaking in order to carry on business in the relevant market. In that context, the national court must consider whether there are products or services that constitute alternative solutions. It then went on to hold that, in the present case, the national court could take into consideration the fact that a high degree of participation by the local pharmaceutical industry in the improvement of the brick structure may have created a technical dependency on that structure by users. In such circumstances, it observed that it was probable that the local pharmaceutical industry would have to make very significant technical and financial efforts to be able to acquire data presented on the basis of an alternative structure.

Next, the ECJ noted the settled case law, that although the exclusive right of reproduction formed part of the copyright holder's rights, so that the refusal of a licence could not, in itself, constitute an abuse of a dominant position, nonetheless, the exercise of an exclusive right might, in exceptional circumstances, give rise to abusive conduct prohibited by Article 82 of the EC Treaty. It then analysed the exceptional circumstances which had applied in *Magill*, as further explained in *Bronner* (Case C-7/97 [1998] ECR I-7791), and from this distilled the principle that the refusal by a copyright holder to give access to a product or service indispensable to carry on a particular business would be regarded as an abuse only if, expressing this by reference to the market in pharmaceutical data in issue in this case, the three following conditions were all fulfilled:

- 'The undertaking which requested the licence intends to offer, on the market for the supply of the data in question, new products or services not offered by the copyright owner and for which there is a potential consumer demand.'
- 'The refusal is not justified by

objective considerations.’

- ‘The refusal is such as to reserve to the copyright owner the market for the supply of the data on sales of pharmaceutical products in the member state concerned, by eliminating all competition on that market.’

The ECJ stressed that it was for the national court to determine whether each of those conditions were fulfilled.

TRADE MARKS IN TABLET SHAPES – REFUSAL FOR REGISTRATION OF A 3D TRADE MARK

Summary

Henkel KgaA, a company that manufactures chemical derivatives, lost its appeal to annul the decisions made by the CFI. The CFI refused to annul the decisions of the Office for Harmonisation in the Internal Market’s (OHIM) Board of Appeal not to register the shape and colour of dishwasher tablets as community trade marks on the grounds that they were devoid of distinctive character.

Background

Henkel filed two applications for a community trade mark. Registration was sought for the three-dimensional marks, which both consisted of rectangular tablets. Each was composed of two layers, in one case (C-456/01 P) white and red, and in the other (C-457/01 P) white and green.

OHIM rejected the 3D marks according to Article 7(1)(b), which states that a trade mark cannot be registered if it is devoid of any distinctive character. Henkel unsuccessfully appealed against this decision to the OHIM Board of Appeal. Henkel then appealed for an annulment of the decision made by the Board of Appeal to the CFI. This was dismissed. The present appeal, which has

also been dismissed, was for the annulment of the CFI’s judgment.

Reasons for decision

The appeal was rejected as it was held that the decision of the CFI had correctly taken into account the relevant case law of the Court for the interpretation of Article 7(1)(b).

The Board of Appeal accepted the Examiner’s decision and pointed out that a trade mark had to enable the products to be distinguished by their origin and not by reference to their nature. In the case of a 3D mark, as was being considered here, this means that the shape of the product had to be sufficiently unique to imprint itself easily on the mind of a consumer. A rectangular tablet was neither particularly special nor unusual and was typical of the relevant market. The Board of Appeal did not accept that the arrangement of the different colours added any kind of distinctive character to the shape.

The CFI held that a rectangle is a basic geometric shape and was an obvious choice for a dishwasher tablet. It also held that the consumer was used to seeing coloured speckles in washing powder. It also pointed out that this may be misleading, as the coloured particles may indicate the presence of an active ingredient, and in terms of Article 7(1)(c) suggests the product has certain qualities rather than being indicative of its origin. The CFI concluded that the distinctive character of the mark should be considered from the point of view of an average consumer who was ‘reasonably well informed and reasonably observant and circumspect’. The court held that since dishwasher tablets were everyday goods the average consumer would not pay very much attention to the shapes and colours of the tablets. It was also held that the product’s origin was not affected by the number of similar tablets already on the market.

On 13th October, 1998, Procter & Gamble made a similar appeal against the Court when they applied for several registered trade marks for 3D objects

which consisted of (i) square tablets with slightly rounded edges, and (ii) rectangular tablets with chamfered edges. The Examiner refused the application for a registered trade mark on the grounds that the sign was devoid of any distinctive character, and held that the different types of edges, suggested colour variations and indentations in the tablet were 'mundane variations' on the normal get-up of the products.

In both the Proctor & Gamble and Henkel cases it was held that the tablets would not be registered as community trade marks as leading competitors in the field must also be allowed to make products using the simplest geometric shapes, such as a square or rectangle.

Counterclaims

Both appellants counterclaimed that at the time when they tried to register the tablets as trade marks, tablets for dishwashers and washing machines were not as familiar to consumers and so they were not devoid of distinguishable character at the time. The distinctive character of a sign must be assessed in the light of the circumstances prevailing at the time when the application is filed. The response to this was that a trade mark must still be distinguishable at time of registration, and means that registration can be refused even if the trade mark was distinguishable at the time of filing, but has since become indistinguishable at the time of registration.

Proctor & Gamble also counterclaimed that the CFI was wrong to hold that the number of similar-looking tablets being sold at the time had no effect on the judgment. Proctor & Gamble argued that the shapes for which registration was being sought would have been different from the point of view of the consumer, and could thus not be said to be devoid of distinctive character. The court disputed this and held that what was important was not the number of similar products being sold, but the way in which the consumer perceived them.

Henkel counterclaimed against the

CFI's judgment regarding an average consumer's response to such 'everyday' goods. Henkel argued that the consumer has a particular interest, not only in knowing about the category of the product, but also in the product itself. Proctor & Gamble further argued that since they were everyday goods, consumer attention is even less likely to be low, but in fact produces a high degree of attention. However, the definition of the person from whose point of view distinctive character is assessed is a matter of fact, and may not be reviewed on appeal.

TRADE MARK INFRINGEMENT

In *Bayer Cropscience SA v Agropharm Ltd* the claimant Bayer accused the defendant Agropharm of infringement of its registered trade mark, PATRIOT, and applied for summary judgment. The application was refused. Bayer had used its trademark PATRIOT widely for preparations for killing weeds and destroying vermin. Bayer accused the defendant Agropharm of infringement of its trade mark under the Trade Marks Act 1994 s. 10(1) and s. 10(2). Agropharm produced products similar to Bayer's, such as insecticides, and Bayer claimed Agropharm had used websites to sell its products using an identical mark to that of Bayer's. Agropharm counterclaimed that it had sold a public health insecticide with the name 'Patriot Flying and Crawling Insect Killer' and two other products called 'Patriot C' and 'Patriot P', and argued its goods were public health insecticides whereas Bayer's were agricultural insecticides.

The court refused Bayer's application for a summary judgment. It held that although both Bayer and Agropharm's marks both contained the word 'PATRIOT', the addition of the letters in Agropharm's marks meant they were not identical marks. The court could not determine whether or not this small difference would allow the marks to be

distinguished. The court held it could not make assumptions on behalf of what the average consumer would consider was or was not a distinguishing factor. Such questions could only be determined at a full trial.

DIRECTORS' FIDUCIARY DUTY

Summary

The High Court has held in *Item Software (UK) Ltd v Fassihi* [2003] IRLR 769 and *Item Software (UK) Ltd v Fassihi* [2002] EWHC 3116(Ch) that a company director who sabotaged his company's distribution contract with one of its clients in order to secure the contract for his own business was in breach of his fiduciary duty. This was because the defendant did owe a duty of disclosure to that client by virtue of his position as director.

Following previous cases, the court held that an employee did not have the duty to disclose his own misconduct to his employer (*Bell v Lever Bros Ltd* [1932] AC 161). In contrast, an employee has a duty to reveal the misconducts of his fellow employees to his employer, even if this means he will be revealing his own misconduct as a consequence (*Sybron Corporation v Rochem Ltd* [1983] IRLR 253).

Background

The first defendant, F, was employed as the sales and marketing director of the claimant, Item Software (UK), until he was summarily dismissed. Under a distribution agreement between the claimant and the fourth defendant, Isograph, Item acted as distributor for Isograph. The agreement was terminated following the failure to renegotiate the amount of royalties to be paid by Item on Isograph's products. During the notice period, the second defendant L (who previously worked for Item Software UK) was employed by the third defendant, RAMS International, a company that the claimant believed was owned or

controlled by F. A distribution agreement was set up between RAMS and Isograph, although it was terminated as a result of these proceedings.

Item Software (UK) claimed that F had been in breach of his duties as a director and employee in that firstly he sabotaged the negotiations for the distribution agreement with Isograph and sought to gain the contract for F's own 'new company', causing Isograph to give 12 months' notice of termination. Secondly, during or after the notice period, F assisted the third defendant in the negotiations for the Isograph agreement. Thirdly, during and after the notice period, F persuaded staff to leave Item Software and join RAMS; and lastly F used confidential customer databases belonging to the claimant in order to divert customers to RAMS International.

F counterclaimed against Item Software for wrongful dismissal, arrears of salary and holiday pay and a share of the money from the sale of a Mercedes, for which he had contributed £5,000 when it was first purchased. While still a director of Item Software, F had written a letter to Isograph suggesting that they work together through a new company to be set up by F to take over the distribution agreement and the claimant's staff.

Decision and reasons for decision

The High Court found that although F was in breach of his duty in seeking to persuade Isograph to terminate the distribution agreement, and continuing to encourage Item Software UK to negotiate reducing royalties on Isograph's products, there was no loss made on behalf of Item Software as a result of these breaches. Also, F was in further breach of his duties by failing to disclose his misconduct to Item Software. Had he done so, the claimant would not have continued to push negotiations for a reduction on royalties, and the contract would not have been terminated. Thus, Item Software was entitled to recover any losses from F

as a result of the termination of the distribution agreement.

The fact that F was connected with L's rival bid did not absolve him from his duty of disclosure to his employer. In addition, F was in breach of his fiduciary duty as a director by diverting the contract with Isograph to RAMS rather than to Item Software. A duty of disclosure and to account for profits arose in this capacity as a director.

F's employment contract included a part relating to confidentiality, and required F to reveal information to the company that was relevant to Isograph. Thus, F had a duty to reveal details of the rival bidder to Item Software because this was in Item Software's interests. Also, there was evidence provided that clearly showed that F had encouraged employees to leave Item Software and apply for jobs at RAMS International, under the false impression that the company would be closing.

F's counterclaim for wrongful dismissal was rejected in view of the above findings, and it was held that F was not entitled to arrears of salary although he was entitled to a proportion of the proceeds from the sale of the Mercedes.

CONSULTATION ON THE ROLE OF NON-EXECUTIVE DIRECTORS

The European Commission launched a consultation on non-executive directors and board committees on 5th May, 2004, as part of the action plan entitled 'Modernising Company Law and Enhancing Corporate Governance in the EU' (published in May 2003). This is designed to address a number of corporate governance issues including the role of non-executive directors. It is proposed that minimum standards are introduced at a European level to set minimum standards of qualifications for such appointees. Part of the consultation is also directed at the role of audit committees. The consultation closed on 4th June, 2004, but there is likely to be a report on

the consultation and recommendations from the Commission in autumn 2004.

NOTES FROM THE USA: BIOTECH-BIOTECH ACQUISITION HIGHLIGHTS UNIQUE LEGAL AND REGULATORY ISSUES

On 1st July, 2004, Molecular Devices Corporation (MDC) announced that it had completed the acquisition of Axon Instruments, Inc. The acquisition combined two developers of complex bioanalytical equipment that is used in drug discovery and life sciences research. MDC is a Delaware corporation based in Sunnyvale, California, and publicly traded in the USA. Prior to its acquisition, Axon was a California company based in Union City, California, which was publicly traded in Australia and operated a development facility in Melbourne, Australia. MDC markets equipment and reagents for a broad range of bioanalytical applications, including microplate readers, liquid handling systems, screening systems, microscopy and electrophysiology equipment. Axon, in contrast, offers a more focused selection of analytical systems for molecular screening, imaging and electrophysiology research.

This section summarises a few of the unique legal and regulatory aspects of this acquisition, which may become more common as merger and acquisition activity increases in the biotechnology and biopharmaceutical industries. First, the transaction employed the new 'double' merger structure, which may be useful to biotech companies that acquire, or are acquired by, US corporations. Second, this acquisition illustrates how biotech transactions can raise possible antitrust concerns, despite their modest size and limited market.

The MDC/Axon acquisition utilised a 'double' merger structure

The 'double' merger structure is both

unique and simple. First, a subsidiary of MDC merged with Axon, with Axon surviving. Then, a second MDC subsidiary was formed, and Axon merged into the subsidiary, with the subsidiary surviving. There are several advantages to splitting a single acquisition into two separate transactions, and recent US Internal Revenue Service (IRS) rulings have made this structure particularly beneficial. The MDC/Axon deal is instructional in how parties can take advantage of these IRS rulings to gain flexibility in deal structure and tax benefits without sacrifices in protection, speed or efficiency.

Traditional triangular merger design – benefits and limitations

Most US biotech/biotech mergers utilise a traditional triangular merger structure. The main benefits of a traditional triangular merger are (i) the minimisation of third party consents and (ii) the isolation of the target's pre-existing liabilities. Both goals are realised because the target company survives. This common structure, however, is subject to certain limitations when the parties intend that the selling stockholders be able to defer tax on any stock component of the deal consideration. These limitations include a limitation on the use of non-stock consideration (which is usually cash), and a requirement that 'substantially all' of the assets of a target corporation be acquired. These requirements are often hurdles for a biotech–biotech merger, in that they limit the ability to construct a tax-deferred deal with different mixes of consideration, or when there are significant 'unwanted' target assets.

The double merger – overcoming the limitations of traditional mergers

Using the double merger structure liberalises many of the tax-related restrictions on the traditional triangular merger. For example, double mergers allow for substantially more non-stock consideration and for the disposition of unwanted target assets, while still

preserving the ability of target stockholders to defer tax on a portion of the deal consideration. The parties, however, retain the ability to close the transaction quickly and efficiently, while preserving the ability to isolate a target's pre-existing liabilities. The result is a much greater flexibility for the parties in structuring their deal.

Tax benefits of the double merger

The double merger structure presented no tax implications for Axon's Australian stockholders, but was favourable for both Axon and MDC, as well as Axon's US stockholders. The structure was favourable to Axon in that it protected Axon from corporate-level tax gain. It was favourable to MDC because it reduced the corporate-level tax liabilities Axon carried to the MDC corporate group. It was also favourable to Axon's US stockholders because it ultimately allowed the transaction to qualify as a 'reorganisation' for tax purposes. US tax law provides several alternative tests for reorganisation status, and it was not certain at the time of closing that the deal would, in fact, qualify. The double merger structure permitted the transaction to be evaluated under the most flexible of these tests. Ultimately, the transaction did qualify as a reorganisation, which enabled the US stockholders to defer a portion of the tax gain inherent in their stock.

Given the goals of the parties and specific facts of the MDC/Axon deal, no other merger variant could have provided the same benefits as the double merger structure. This structure will be applicable to a wide range of future biotech–biotech mergers and acquisitions because of the added flexibility it provides, particularly with respect to non-stock consideration and asset purchase requirements. Biotech companies involved or potentially involved with US mergers or acquisitions should be aware of both its existence and the benefits it provides.

Biotech–biotech transactions may raise unique antitrust concerns

Antitrust concerns are not often raised in the biotechnology industry, given the degree of competition between a wide range of small to moderately sized companies. Given the relatively small size of the industry, however, even a modest transaction can present potential antitrust implications, and the MDC/Axon transaction illustrates this point.

Both MDC and Axon develop and market products for cellular electrophysiology. More specifically, in their public statements, both companies had devoted significant attention to their respective patch clamp products. Those skilled in the biotechnology industry can recognise and appreciate the broad range of applications and variations inherent in commercial patch clamp systems, but these differences may not be apparent to the casual investor. Therefore, the companies' emphasis on these products could have created, at least facially, the appearance of antitrust concerns.

Notwithstanding this apparent overlap, the parties were able to accentuate the

clear differences in their products. Axon's products were 'low'–throughput devices, with greater seal resistance and the ability to dynamically interact with an experiment in progress. MDC's products were, on the other hand, significantly faster 'high'–throughput devices, but essentially static with regard to experiments in progress. Understanding these differences, and being able to address them clearly with the antitrust regulators, enabled the parties to proceed with the transaction without any antitrust delay.

MDC's acquisition of Axon demonstrates a new trend in biotech–biotech transactions. The acquisition highlights the advantages and versatility of the double merger structure as opposed to traditional structures more commonly used in biotech–biotech transactions. This transaction also exemplifies the unique nature of the biotechnology industry, where even relatively small transactions between small to medium-sized companies can raise potential antitrust concerns that are typically associated with major corporations.

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