Legal and regulatory update

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Legal and regulatory update

Pharmaceutical patent claims

In *Pharmacia v Merck* the English Court of Appeal on 14th December, 2001, upheld the Judgment of Pumfrey J in the Patents Court, in finding Pharmacia's European Patent (UK) 0 679 157 invalid, but reversed his judgment in so far as he had found the patent (had it been valid) not infringed by Merck's COX II inhibitor rofecoxib (VIOXX). The decision is important not only for the approach to construction and infringement, as to which the Court of Appeal differed from the trial judge, but also for its approach to insufficiency and inventive step, where it agreed with the trial judge, but as to which the consequences for pharmaceutical patenting are considerable.

Rofecoxib is a furanone, which in aqueous solution undergoes a well-known type of molecular rearrangement called tautomerism between it (the enol form) and its hydroxyfuran (keto) form. The Court of Appeal agreed with Pumfrey J that as the Pharmacia patent claimed hydroxy substitution (the enol form) and was silent about the corresponding keto form there was no literal infringement. However, because one tautomer would transform into the other, the Court of Appeal, differing from Pumfrey J, held that the skilled reader would have regarded the keto form as an obvious variant of the claimed enol one. Thus, to give effect to the Protocol on the interpretation of Article 69 of the European Patent Convention (which required, according to Aldous LJ, 'the middle way . . . in particular, ascertaining what would be fair to the patentee and whether that would unfairly impinge upon the required certainty for the public'), the reference in the claims only to the enol form did not preclude a finding of infringement in relation to the corresponding keto form. Arden LJ considered that 'the word ''hydroxy'' is descriptive and covers both the enol form of that name and the keto form into which the enol form is constantly and ineluctably interconverting when in solution.'

Pumfrey J had held that the Pharmacia patent was invalid for lack of novelty, obviousness, insufficiency and added subject matter. He had also found that amendments proposed by the patentee would not validate the patent. The Court of Appeal, upholding these findings, stressed that, under the now current law, the appellate court was not entitled to overturn a finding of fact by the judge at first instance unless it could be shown that his decision was based on an error of principle. However, in supporting Pumfrey J's approach the Court of Appeal findings on insufficiency and inventive step are of particular relevance to pharmaceutical patent practice.

On novelty, the Court of Appeal agreed with Pumfrey J's construction of an earlier published patent, on which basis there was a significant overlap between the class of compounds claimed in at least one claim of the Pharmacia patent and that described in the earlier published patent. A proposed amendment to specify the presence of a particular type of substituent had been refused by Pumfrey J as it was not reflected in the priority document or in the application as filed. This was because the proposed amendment was in effect to make a new selection of compounds, and so would have added subject matter, and the Court of Appeal agreed with this.

Pumfrey J's decision as to the Pharmacia patent not being entitled to claim priority (as it did not 'hint at [the] materiality' of certain types of substitution that featured in the application as filed) was also upheld, Aldous LJ holding that he had been 'right that the invention (technical contribution) of the priority document is not the same as that disclosed in the application'. Put another way, the priority document did not contain

sufficient material to constitute an enabling disclosure for the broadest claim of the Pharmacia patent. Aldous LJ observed that the strict view as to support that this reflected and that had been the English law since *Biogen v Medeva* had been only recently unequivocally established also to be European Patent Office (EPO) law by the decision of the EPO Enlarged Board of Appeal in Case G 2/98. The consequential loss of priority was fatal to several claims of the Pharmacia patent, including those that covered rofecoxib, because Merck's own application for this compound had an earlier priority date than the application for the Pharmacia patent.

The Court of Appeal decision as to insufficiency, also based on the principles set out in *Biogen v Medeva*, is significant. As is traditional with pharmaceutical patents to new chemical entities, most of the claims defined chemicals by means of general structural formulae with no functional limitation in their wording. Aldous LJ held that there was 'no technical contribution in a list of compounds which a skilled man would know how to make' and that the '20 year monopoly was granted because of the disclosure in the specification that the class of compounds claimed had the quality disclosed in the specification. The invention or technical contribution justifying the monopoly claimed can only be that quality'. Aldous LJ agreed with Pumfrey J that the specification of the Pharmacia patent 'would be read by the skilled person as disclosing that the claimed class of compounds had anti-inflammatory and/or analgesic effect with fewer and less drastic side effects, the reduction in side effects being due to Cox II selectivity' and that it was 'that disclosure which is the technical contribution and invention'. The Court of Appeal, like Pumfrey J, was satisfied that Merck's experimentation had proved many instances of compounds falling within the general structural formulae set out in the broadest claims which did not inhibit the Cox II enzyme and, indeed, many such compounds (including some of those described in the patent examples) which did not even have anti-inflammatory or analgesic properties. Seeing its task as 'to ascertain whether the technical contribution in the specification applies to the class of the compounds claimed' the Court of Appeal held that such claims went beyond the technical contribution provided by the inventors and so were invalid for insufficiency. The proposed amendments would not have altered this position. Aldous LJ said: 'I do not consider that the work [the patentee] had done by the priority date nor the later work which they did justify any suggestion that it was a reasonable prediction that the class of [one of the broadest claims] either as granted or as amended would possess anti-inflammatory properties.'

Even more important for pharmaceutical patent practice is the decision of the Court of Appeal on inventive step, as they supported Pumfrey J in holding, in the light of a prior art disclosure of an anti-inflammatory compound with a 2,3-substitution pattern on a thiophene ring, that similar compounds, but with a 3,4-substitution pattern, were obvious. In addition to challenging Pumfrey J's assessment of the expert evidence on the point, the patentees had argued that it was necessary that there be a reason to take the step from the prior art, and for the step to serve a useful purpose, and that the failure of the developer of the 2,3-substituted compound to take such step was evidence that it was not obvious to do so. Aldous LJ observed that 'whether or not there is a reason for taking the step from the prior art may well be an important consideration, but that does not mean that it is an essential requirement of a conclusion of obviousness'. He also observed that it was unnecessary for the skilled person to have a reason for taking the step from the prior art, saying: 'whether or not a useful purpose would be served may be relevant, but that cannot in all cases be a requirement before a finding of obviousness results.'

Given the nature of much activity in the field of medicinal chemistry, in which novel compounds, albeit similar in structure to known ones, have previously been regarded as prima facie inventive, and in which

broadly drawn chemical claims have been regarded as necessary against 'me-too' compounds, these findings as to insufficiency and inventive step, supported by the Court of Appeal, are worrying.

Regulatory

Stem cell research

The English Court of Appeal on 18th January, 2002, allowed the Government's appeal against a first instance decision on 15th November, 2001, that had threatened to undermine its use of regulations (the Human Fertilisation and Embryology (Research Purposes) Regulations 2001) made under the Human Fertilisation and Embryology Act 1990, to control human cloning to, for example, facilitate stem cell research. A declaration had been granted at first instance that the definition of 'embryo' in the 1990 Act (which referred to fertilisation) was insufficiently wide to cover embryos produced by the cell nuclear replacement (CNR) cloning technique. In the light of the first instance decision the UK Government had rapidly enacted the Human Reproductive Cloning Act 2001 to fill the legislative lacuna. The Court of Appeal held that it had clearly been Parliament's intention that the 1990 Act should cover all human embryos, and that it was legitimate to construe the statute to give effect to such intention.

Consolidation and amendment of the regulatory framework for medicinal products

The long-awaited consolidation of 35 years of Community legislation in the field of medicinal products has taken place with the publication in the *OJEC* on 28th November, 2001, of

- Directive 2001/82/EC of the European Parliament and of the Council of 6th November, 2001, on the Community Code relating to veterinary medicinal products and
- Directive 2001/83/EC of the European Parliament and of the Council of 6th November, 2001, on the Community Code relating to medicinal products for human use.

This entails the repeal of Directives 65/65/EC, 75/318/EC, 75/319/EEC, 81/851//EEC, 81/852/EEC, 89/342/EEC, 89/343/EEC, 89/381/EEC, 90/677/EEC, 92/25/EEC, 92/27/EEC, 92/28/EEC, 92/73/EEC and 92/74/EEC, but preserves their effect, with references to them being construed as references to the new Directives. Regulation (EC) No. 2309/93, under which the European Medicines Evaluation Agency (EMEA) and the centralised procedure were established, is unaffected. Meanwhile the Commission's proposals for amending these three measures, which were outlined in the last *Pharmaceutical and Medical Review*, continue to be the subject of analysis and discussion.

Competition law and free movement of goods

IMS Health

The Court of First Instance (CFI) of the European Court of Justice (ECJ) on 10th August, 2001, suspended, on an interim basis pending a full hearing of the matter, a decision made by the European Commission on 3rd July, 2001, ordering IMS Health (IMS), the world's leading supplier of pharmaceutical sales information, to license competitors under the copyright in its so-called '1860 brick structure' for collecting pharmaceutical sales data. Competitor companies in Germany had previously been refused licences by IMS to use the system for gathering regional sales information after IMS had secured injunctions against them. The Commission concluded that IMS's refusal to grant licences constituted abuse of a dominant market position, and thus in what it considered to be the exceptional circumstances of this case, imposed interim measures forcing IMS to provide licences on non-discriminatory, commercially reasonable terms. However, the President of

the CFI considered there to be a number of potentially important differences between the facts of this case and those of the *Magill* case in the ECJ on which the Commission had largely based its decision, that the interim measures ordered by the Commission may have exceeded its powers under settled ECJ case law in not preserving the status quo, and that there was a prima facie challenge to the Commission's findings had become an industry standard. Accordingly he suspended the Commission decision.

Technology transfer block exemption

The European Commission has published an Evaluation Report on the Technology Transfer Block Exemption. The Report examines how the Block Exemption has operated in its five years in operation, and outlines the results of study on the block exemption undertaken among interested parties. It also compares its approach to licensing agreements with that under US anti-trust law and in particular under the Antitrust Guidelines for the Licensing of Intellectual Property. The Report notes that the block exemption is 'generally considered overly formalistic and too complex and in addition too narrow in scope', and floats the possibility of replacing the Technology Transfer Block Exemption with a wide, umbrella-type block exemption regulation in combination with a set of guidelines, but which will distinguish between licensing between non-competitors and licensing between competitors.

New Competition Act Guidelines on Intellectual Property Rights in the UK

The Office of Fair Trading published in November 2001 a draft Competition Act 1998 Guideline on Intellectual Property Rights. Most of it is concerned with intellectual property licensing, which potentially falls within the Chapter I prohibition under the Act (paralleling Article 81 EC Treaty) but which, in relation to patent and know-how licences, is automatically excepted under the 1998 Act by virtue of the parallel exemption provisions of the 1998 Act by which agreements falling within the scope of European Commission block exemptions such as the Technology Transfer Block Exemption (or which would do so if they were not subject to Article 81 because they did not affect trade between member states) are exempted under the 1998 Act. The Guidelines also briefly address the application of the Chapter II prohibition (paralleling Article 82 EC Treaty) to intellectual property, including matters such as refusal to licence, and base the analysis here on ECJ case law.

UK Competition Commission Appeals Tribunal in the Napp Pharmaceutical appeal

The Competition Commission Appeals Tribunal gave judgment on 15th January, 2002, in the appeal by Napp Pharmaceutical against the decision of the Director General of Fair Trading of 30th March, 2001, imposing a fine of £3.21m for breach of the Chapter II Prohibition under the Competition Act 1998 by abusing a dominant position in a particular drug in its pricing policies – the first fine to be levied under the Act. The appeal Judgment broadly upheld the Director's adjudication, but reduced the fine to £2.2m. The decision, based on ECJ case law under Article 82 EC Treaty, extensively discusses the law as to predatory pricing by companies with a dominant position in the relevant market, Napp having been found, by the degree to which it had cut prices in the hospital sector, to practise exclusionary conduct. The decision is less concerned with the concomitant allegation of overpricing in the community sector, although it does observe that once the finding of exclusionary conduct had been made in relation to the hospital sector, the fact that Napp complied with the Pharmaceutical Price Regulation Scheme (PPRS) in setting its prices for the community sector was of no assistance to it.

Parallel imports

As to the use of intellectual property rights (in this case trade marks) against parallel imports, judgment is still awaited from the ECJ in Case C-443/99 *Merck, Sharpe & Dohme v Paranova* and Case C-143/00 *Glaxo & ors v Dowelhurst & anr*, and in which the opinion of the Advocate General was outlined in the last *Pharmaceutical and Medical Review*. Judgment was however given on 20th November, 2001, in Case C-414/99 *Davidoff* concerning international exhaustion of trade marks. Previous ECJ case law had established that the Trade Mark Directive precluded national courts applying international exhaustion to trade marks. However one can clearly not infringe where the rights owner has consented to the import of his goods into the EEA. *Davidoff* analysed to what degree such consent could be inferred in various cases, and a permissive approach to implying consent would have reintroduced, through the back door, the scope for national courts to apply international exhaustion doctrines. The ECJ did not adopt this approach and listed a number of instances in which implied consent could not be inferred, as a result of which the scope for parallel imports of trade marked goods from outside the European Economic Area (EEA) remains limited. In view of the regulatory constraints on parallel imports of medicinal products and plant protection products from outside the EEA, the effect of the *Davidoff* decision on the biosciences sector in Europe is limited. However there have been two recent judgments concerning alleged regulatory constraints on parallel import regimes in the fields of pharmaceuticals and plant protection products.

The first was a decision of the English Court of Appeal on 9th December, 2001, in Secretary of State for Department for the Environment, Food and Rural Affairs, acting by the *Pesticides Safety Directorate v Crop Protection Association*. The Court sought to reconcile the apparently conflicting decisions of the ECJ in Case C-100/96, *R v Ministry of Agriculture Fisheries and Food, ex parte British Agrochemicals Association* and Case C-94/98, *R v Medicines Control Agency, ex parte Rhone Poulenc Rorer*, as to the extent to which excipients (in pharmaceutical formulations) and co-formulants (in pesticide formulations) had to be identical for two formulations to be regarded as sufficiently the same for parallel imports to be allowed of a formulation that was authorised in one EEA country into another EEA country where the other was authorised. They decided that to require literally the same formulation for parallel imports would be wholly disproportionate to the needs of safety and thus an unjustified restrictions on trade contrary to Articles 28 and 30 of the EC Treaty.

The second was the decision by the English Court of Appeal of 18th December, 2001, rejecting an appeal by the UK association of parallel importers, the British Association of European Pharmaceutical Distributors (formerly the Association of Parallel Importers), against the rejection of its challenge to the modulation provisions of the revised Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is a voluntary, non-statutory scheme, which indirectly controls the prices of branded prescription medicines to the NHS in the UK by regulating the profits that companies can make on these sales. The modulation provisions give companies flexibility as to how they apply price cuts across their product range to achieve the negotiated one-off across-the-board price reduction of 4.5 per cent. In a judgment given on 14th March, 2001, in *R v Secretary of State for Health, ex parte (1) British Association of European Pharmaceutical Distributors (2) Dowelhurst Ltd & Association of the British Pharmaceutical Industry (Affected Party)* the Divisional Court had held that such provisions were not contrary to Articles 28 or 81 of the EC Treaty by reason of their effect on parallel imports, which the applicants had alleged allowed discriminatory targeting against parallel importers. The Court of Appeal considered that the modulation provisions could not be separated from the rest of the PPRS scheme and dealt with in isolation, and that in any event there had been modulation provisions

of one sort or another in the previous versions of the scheme. If the operation of the scheme as a whole over all this period was to be examined, it was inappropriate to do this in court on such an application, but was the sort of investigation which the European Commission could undertake.

Meanwhile, GlaxoSmithKline, which has appealed the European Commission's rejection of its sales conditions regarding pharmaceuticals supplied to Spanish wholesalers, continues to explore the extent to which various trading practices can be used legally to control parallel imports. Its most recent action has been to notify the European Commission that it would set sales quotas on pharmaceuticals to limit the quantities that wholesalers in Europe can buy.

Convention for Protection of Human Rights and Biomedicine

The Council of Europe has approved an additional protocol to the Convention for Protection of Human Rights and Biomedicine, which applies to the transplantation of organs and tissues of human origin.

The additional protocol contains general provisions restricting transplantation services to those on an official waiting list run on transparent, objective rules according to medical criteria, medical, health and safety standards, the prohibition of organ trafficking and of financial gain by donors and provisions requiring donors, recipients, health professionals and the public to be properly informed. There are specific provisions establishing when organs may be removed from living and deceased persons and how organs and tissues so removed can be used. Information relating to donors and recipients is to be kept confidential in accordance with professional standards and rules of data protection. However, such information may be collected and used so far as is required for medical purposes, including traceability. The protocol also provides for sanctions and compensation.

The protocol is to be opened for signature on 24th January, 2002, to member states that have ratified the original convention. The United Kingdom has not ratified the convention. It has, however, been ratified by the Czech Republic, Denmark, Georgia, Greece, Portugal, Romania, San Marino, Slovakia, Slovenia and Spain.

Company/commercial law

Statute: Financial Services and Markets Act 2001

Summary/facts

The Financial Service and Markets Act 2001 (FSMA) came into force on midnight, 30th November, 2001. The FSMA substantially replaces the regulatory framework that existed under the Financial Services Act 1986, Banking Act 1987 and the Insurance Companies Act 1982 and brings the regulation of the securities, banking and insurance industries under the supervision of the new single regulator, the Financial Services Authority. A number of important statutory instruments made under the FSMA, such as Financial Promotion and Regulated Activities Orders, are now in force.

Comment

The effects of FSMA on companies in general are far-reaching. As far as shares and other securities are concerned, FSMA broadly follows the previous law, though there are some changes. The provisions of the Act and the secondary legislation are extremely detailed, but, very broadly, section 19 of the Act prohibits persons from carrying on a 'regulated activity' unless they are authorised or exempt. This means that people who are involved in dealing with shares, other securities, or the operation of insurance companies or banks, need to familiarise themselves with the prohibition. In particular, people involved in raising finance for a company as a business, *may* find themselves involved in a regulated activity if they offer shares to the public or to certain classes of private investors. Some exemptions are available.

The Financial Promotion provisions also need to be carefully considered. FSMA section 21 prohibits anybody from making an unlawful 'financial promotion'. The definition of 'financial promotion' is extremely wide, and includes, for example, telephone conversations, presentations, letters, e-mails and advertising brochures concerning the sale of shares or other securities, or insurance and banking services. This means that people wishing to raise finance for a company may need to communicate with potential investors through an authorised person or through solicitors.

A breach of the prohibitions against regulated activities or financial promotion may result in any agreement made being potentially unenforceable, and may also constitute a criminal offence, punishable by imprisonment or a fine.

Electronic communications with shareholders

Summary

The Institute of Chartered Secretaries and Administrators (ICSA)[1] has published an update to its guide on electronic communications with shareholders, which clarifies certain points since the publication of the original guide in December 2000.

Background

The Companies Act 1985 (Electronic Communications) Order (*SI 2000/3373*) introduced the ability for companies to communicate with their shareholders by e-mail or notices posted on a web site or by any other electronic medium. The Order amended the Companies Act and Table A to allow for such electronic communication.

Facts

The guidance deals with practical issues regarding the interpretation of the new provision including when notices are deemed to have been 'sent', whether a consent to short notice can be sent electronically, the application of the electronic communications provisions to written resolutions, the retrospective effect of the amendment to Table A and the form of electronic proxy forms.

Directors' home addresses – DTI Direction

Summary

The Department of Trade and Industry (DTI) has set out detailed proposals to allow company directors at risk of violence or intimidation to apply to keep their home addresses off the public register.

Background

Attacks carried out against directors of companies, such as Huntingdon Life Sciences, have prompted changes to companies' legislation to allow directors to keep their home addresses secret.

The Criminal Justice and Police Act 2001 amended the Companies Act 1985 (1985 Act) to allow an individual who is or proposes to become a director, secretary or permanent representative of a relevant company to make an application for a 'confidentiality order' where that person believes that the availability of inspection by members of the public of the individual's usual address is likely to create a serious risk that the individual, or a person who lives with him or her will be subject to violence or intimidation.

If a confidentiality order is granted it will remove the requirement for the public record to show a director's residential address, showing a service address instead. The residential address will still need to be disclosed to Companies House, and this address will be available to certain prescribed categories of persons. The amendments to the Companies Act make provision for regulations to be introduced concerning the operation of confidentiality orders.

Facts

The DTI has issued a consultation document, which includes a set of draft regulations on the operation of confidentiality orders. The key issues for consultation are: (a) the fee that should accompany any application for a confidentiality order; (b) the Secretary of State of Trade and Industry's ability to refer to the police or other persons any question relating to the assessment of an application for a confidentiality order; (c) the appeal process to the High Court or the Court of Session on the grounds that the decision not to grant such an order is unlawful, is irrational or unreasonable, or has been made on the basis of a procedural impropriety or otherwise contravenes the rules of natural justice; (d) the term of the confidentiality order (proposed to be five years); (e) the confidentiality order being revocable prior to the expiry of the five year period if the applicant has provided false or misleading information or has failed to comply with the procedural requirements concerning the filing of information; (f) where a confidentiality order is granted, no person (other than a competent authority specified in the regulations) having the right to inspect, copy or otherwise have access.

Reference

1. ICSA website URL: http://www.icsa.org.uk