Legal and regulatory update

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This section is intended to be a synopsis of recent legal developments and is not intended to be exhaustive. If any issue referred to in this section is to be relied on, specific advice should be sought. Please contact:

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Legal and regulatory update

NOTES FROM THE EU

France rejects ratification of the London Agreement

The London Agreement,[1] which was concluded in London on 17th October, 2000, was aimed at creating a less costly post-grant translation regime for European patents by enabling an applicant to obtain an enforceable European patent without the need to provide translations into the language of each of the designated states upon grant.

The Agreement first of all requires countries that use an official European Patent Office (EPO) language (English, French or German) to dispense with the requirement for a translation into their language under Article 65.1 EPC. More significantly, countries that do not use an official EPO language shall dispense with the translation requirement under Article 65.1 if the patent is granted in one of the official EPO languages prescribed by that state or if it has been translated into that official EPO language; but such states may nevertheless keep the right to require a translation into one of their official languages.

The Agreement has been signed by 11 states (Denmark, France, Germany, Lichtenstein, Luxembourg, Monaco, the Netherlands, Sweden, Slovenia, Switzerland and the UK), but will only enter into force when 8 signatories including France, Germany and the UK have ratified.

Of these compulsory signatories, only France is yet to ratify and on 7th March, 2006, the French National Assembly voted against ratification of the Agreement, perceiving it as a threat to the use of their national language. As a result, the Agreement will not come into force in the foreseeable future.

OFT to continue study into drug pricing scheme

On 13th September, 2005, a study was launched by the UK Office of Fair Trading (OFT) into the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is a voluntary scheme negotiated every five years between the Department of Health and the Association of the British Pharmaceutical Industry. It is used by the Department of Health to control the prices of branded drugs prescribed by the NHS by setting a cap on the profits that a pharmaceutical company may achieve through sales of branded medicines to the NHS. The NHS spends approximately £8bn every year on branded medicines. The decision to launch the study followed concern at the OFT about the impact of public procurement policy in the pharamaceutical sector on competition.

The OFT study is aimed at assessing whether the PPRS is the most effective means of securing medicines for the NHS at reasonable prices, while also promoting a profitable pharmaceutical industry capable of sustained research and development expenditure and encouraging the efficient and competitive development of medicines.

Thus far, the study has focused on collecting data from markets that are influenced by the PPRS. The study will then consider the effects that the PPRS has caused as well as possible alternatives to the PPRS. As a result of the cooperation and access to information received from the Government and industry throughout the study to date, the OFT has decided to allow the study to continue rather than make a reference to the Competition Commission at this stage. Such a course of action does, however, remain open to the OFT.

Report on intellectual property rights, innovation and public health

On 3rd April, 2006, the Commission on Intellectual Property Rights, Innovation & Public Health (CIPIH) published an independent report[2]

analysing the relationship between intellectual property rights, innovation and public health in developing countries based on evidence collected from a variety of stakeholders. The report was mandated by WHO.

Its remit was, *inter alia,* to collect evidence on the prevalence of diseases affecting poor people and their social and economic impact; to review the research and development efforts currently aimed at such diseases; and to consider the effectiveness of intellectual property and funding regimes in developing countries.

The report sets out recommendations to improve innovation in developing countries, thereby ensuring the accessibility of existing and new healthcare products to diagnose, treat and prevent diseases. These recommendations are principally aimed at actions that can be taken through governments, industry, science, international law and finance instruments to improve healthcare in developing countries.

The World Health Assembly will examine the findings of the Report during its annual meeting from 22nd to 29th May, 2006, and ultimately decide how these findings will be applied by WHO.

Commission publishes a working document based on experience gained from the EU orphan drug legislation

Orphan drugs are intended for the diagnosis, prevention or treatment of rare life-threatening or serious conditions. For a medicinal product to be designated as an orphan drug, it must be intended to diagnose, prevent or treat a life-threatening or chronically debilitating condition and the sponsor must establish that either the condition affects not more than 5 in 10 thousand persons in the Community at the time the application is made (known as the 'prevalence criterion') or that, without incentives, it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment (known as the 'insufficient return on investment criterion').

The European Union (EU) orphan drug legislation provides incentives for the pharmaceutical industry to develop orphan drugs that they would otherwise be unwilling to develop under normal market conditions. Incentives available for the development and approval of orphan drugs include free protocol assistance, access to the centralised Community procedure for marketing authorisation with 50 per cent fee reduction and ten years of post-approval market exclusivity. Other Community-wide incentives are available by way of research funding, grants and possible tax incentives at the individual member state level.

Regulation (EC) No 141/2000 of the European Parliament and of the Council and Commission Regulation (EC) No 847/2000 came into force in January 2000 and April 2000 respectively and set out the key regulatory framework for orphan drug provisions in the EU. In addition, Regulation (EC) No 726/2004 makes the centralised procedure compulsory for orphan medicinal products.

Article 10 of Regulation (EC) No 141/2000 obliges the Commission to report on its experience of the application of the Regulation, together with an account of the public health benefits that have been obtained. On 8th February, 2006, in accordance with Article 10, the Commission published such a report (the 'Consultation Document').

The Consultation Document reports that there have been 458 applications for orphan drug medicines between April 2000 and April 2005 and, from these applications, 268 products have so far been designated. Of all the applications, only two were based on the 'insufficient return on investment criterion'. Of the 268 designated orphan medicinal products, 49 (19 per cent) have gone on to apply for a marketing authorisation.

The Consultation Document reports that, with the objective of ensuring full harmonisation of the internal market and in the interest of patients with rare conditions in the EU, making the centralised procedure compulsory by way of Regulation (EC) No. 726/2004 has been widely welcomed.

Of the incentives given to companies for the development of orphan drugs, the Consultation Document reports that the availability of a ten year market exclusivity period is considered to be the most valuable. Regulation (EC) No. 141/2000 provides for the possibility of a member state reviewing drugs at the end of the fifth year of the marketing authorisation. If maintenance is no longer justified, the period of marketing authorisation can be reduced to six years.

Another incentive which is reported as being particularly valuable is the availability of protocol assistance from the European Agency for the Evaluation of Medicinal Products (EMEA). Uptake of protocol assistance has been extensive and is increasing markedly over time.

The Consultation Document does highlight the fact that European patients' organisations have reported very different levels of access to treatment across the EU. Varying national policies regarding pricing, reimbursement and distribution help explain the differences in access to treatment for patients.

In conclusion, the orphan drug legislation in the EU has far exceeded initial expectations. It has delivered on its fundamental objective of improving public health in the EU. As a consequence, more than a million patients suffering from rare diseases may benefit from the availability of new treatments. However, the Consultation Document does highlight problems with availability of orphan drugs within the EU and this will need addressing at both Community and member state level.

European Commission guidelines on extended marketing protection on approval of new therapeutic indications

Introduction

Article 14(11) of EC Regulation No 726/2004 provides that:

> (. . .) medicinal products for human use which have been authorised in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection in which connection the latter period shall be extended to a maximum 11 years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation are held to bring a significant clinical benefit in comparison with existing therapies.

This entitlement to an extra year of marketing protection in the prescribed circumstances mirrors Article 10(1) of Directive 2001/83/EC (the 'Medicines Directive') as amended by Directive 2004/27.

For an in-depth analysis of the regulatory data and marketing exclusivity protection afforded to innovative medicinal products as against generic products authorised under the abridged procedures (the so-called '8 + 2 + 1' rule), please see pp. 157–166 of *Journal of Commercial Biotechnology*, Vol. 12, No. 2.

In December 2005, draft guidelines were published by the European Commission, setting out the elements that the marketing authorisation holder (MAH) will be required to demonstrate in order to support a claim that its medicinal product provides a significant clinical benefit in respect of a new therapeutic indication in comparison with existing therapies, and thereby obtain the extended marketing protection period.

The following provides a summary of the key points of these guidelines.

Definitions

For the purposes of the guidelines, a 'new therapeutic indication' means a new target disease for the medicinal product in question. A change from treatment to prevention or diagnosis of a disease would also be considered a new indication.

Whether or not a medicinal product shows a significant clinical benefit as compared with existing therapies will be assessed by reference to one or more of the following measures: (1) efficacy and pharmacokinetic properties; (2) safety; or (3) any other major contribution to diagnosis or patient care that is clinically demonstrable.

Application for extended protection

In order to successfully claim the extended protection period, the authorisation of the new indication must have been completed with eight years from the date of the original marketing authorisation. Normally, a Type II variation application will be required for authorisation of the new indication. Where the new indication introduces the need for a new pharmaceutical form, route of administration or any other criteria set out in Annex II to Regulation (EC) No. 1085/2003, an Annex II application will be required.

Based on the timetables for processing such applications (published on the EMEA website), the MAH would be well advised to submit the necessary applications at least two years prior to the eight year anniversary of the original marketing authorisation.

It should be noted that it is the responsibility of the MAH itself to make the application within the deadlines set out.

Upon receipt of the appropriate application, the Committee for Medicinal Products for Human Use (CHMP) or competent national authority shall assess the novelty of the indication and the suggested significant clinical benefit of the medicinal product in terms of safety, efficacy and quality.

The MAH must submit a report demonstrating the following elements in respect of the medicinal product:

- **New indication**. The report must show that the proposed indication for the medicinal product in question is in fact new. This must be supported by scientific evidence which should include reference to the International Classification of Diseases (ICD), or where the proposed indication has not yet been classified by the ICD, that it is a 'medical entity distinct from the previous indication'. *Prima facie*, the development from treatment of a disease to prevention or diagnosis could be considered a new indication. However, the following will not be considered as new indications for the purposes of Article 14(11) or Article 10(1): different stages of severity of a disease; an extended target population; or switches between first and second line treatment or combination therapy and monotherapy.

- **Details of existing therapies**. In order to establish that the medicinal product shows significant clinical benefit in comparison with existing therapies (if any exist), the MAH must also provide details of those existing therapies in the Community. This can be achieved by supplying details of any relevant marketing authorisations and medical literature. Details must include all relevant medicinal products authorised by the Community centrally or by any member state nationally. Furthermore, the MAH must also report on non-pharmacological methods such as psychotherapy, physical methods, diet and surgery, where these methods are considered to be state-of-the-art treatment for the indication in question.

- **Significant clinical benefit**. Finally, the MAH must demonstrate that their medicinal product provides significant clinical benefit over and above that derived from the reported existing therapies. The MAH may typically rely on comparative clinical studies to achieve this. The existing therapy used in any such comparative study must be carefully chosen by reference to the relevant guidelines and advice from both the CHMP and competent national authorities. Significant clinical benefit requires a proven clinically relevant advantage, such as the improved safety or efficacy profile of the medicinal product, or a major contribution to patient care, such as a new mode of administration where, for example, ease of self-administration is critical.

The UK Patent Office's consultation on the 'inventive step'

In a consultation[3] launched in early February, the UK Patent Office has invited innovators, businesses and legal professionals to comment on whether the 'inventive step' that is required to make an invention patentable works in the best way for innovators and the economy in general in the UK.

The review comes following similar projects in the USA in response to a perceived drop in quality of patents, especially in emerging markets such as biotechnology. While the Patent Office recognises the importance of inventive step in the patent system, it wishes to determine whether innovation is being impeded because the bar for qualification is being set too high or whether the legitimate interests of third parties are being restricted by the granting of trivial patents.

The consultation is designed to ascertain whether the parameters of inventive step are set appropriately with respect to the objectives of the legislation; the impact on the role of the patents system in the economy; the effect on third parties; and patent quality.

The Patent Office acknowledges that there is a general international consensus that the objective test for the presence of an inventive step is the appropriate basic requirement. However, the consultation aims to discover whether any change to the more specific provisions contained in the regulatory framework is required, such as making alterations to the Patent Rules.

Although the legal principles behind inventive step in the UK are similar to those in Europe, the consultation also seeks respondents' opinions on how these provisions have been interpreted differently in other European jurisdictions. For example, European patent examiners will often adopt an analysis of the 'problem and solution' underlying the invention. Respondents are therefore asked to advise whether the current parameters are sufficient to ensure consistency and harmonisation with other countries.

As well as examining the regulatory framework, the Patent Office has also asked for respondents' views on how its examiners are interpreting the requirements. For example, it is asked if the examiner should continue to give applicants the benefit of the doubt in situations where the examiner has a lack of technical expertise and feels unable to give proper consideration to the technical argument. Respondents are also asked to comment on how well examiners explain any objections they may raise to patent applications, and to what degree fair consideration of the applicant's observations is taken into account.

The closing date for views on the system is 31st May, 2006.

Recent implementation of the Biotech Directive in Italy

Directive no. 98/44/CE setting out the legal protection of biotechnological inventions was finally implemented in Italy with the Decree dated 10th January, 2006, no. 3. The provisions of the Decree

were converted into law on 14th February, 2006, and came into force on 11th March, 2006, after publication in the *Official Journal*.

The Decree is aimed at clarifying how the principles of patent law should apply to biotechnological inventions while ensuring that strict ethical rules are respected. However, the provisions of the Decree have not been inserted into the recent IP Code, which contains the substantive and procedural rules applicable to IP rights (including patents).

Most notably, the Decree states that, in order to obtain a patent either (1) on 'an invention concerning an element isolated from the human body or produced in a different way, by means of a technical process, even if the structure of that element is identical to that of a natural element'; or (2) on 'a simple DNA sequence or a partial sequence of a gene used to produce an entire or a partial protein', the applicant must not only indicate the industrial application of the invention, but must also describe and expressly claim the function of that invention. In contrast, the Directive merely requires that the patent application contains the indication of the industrial application.

The main provisions of the Decree can be summarised as follows.

Article 2 provides definitions for 'biological material' (ie a material containing genetic information), 'microbiological process' and 'process for the production of plants or animals'. Article 2 directly transposes Article 2 of the Directive.

Article 3 sets out what will be considered a patentable biological or biotechnological invention (provided that in each case, the invention is novel and capable of industrial application):

- Biological material that is isolated from its natural environment or produced by means of a technical process, even if it occurs in nature.

- A technical process by means of which the biological material is produced, manufactured or used, even if it occurs in nature.

- Any new application of a biological material or of a technical process already patented.

- An invention concerning an element isolated from the human body or produced by means of a technical process even if the structure of that element is identical to that which occurs in nature, provided that its function and its industrial application are clearly indicated, described and specifically claimed. 'Technical process' means a process that is implemented by human beings and not present in nature.

- An invention concerning plants, animals or a plant variety, characterised by the expression of a specific gene and not by its entire genome, provided that its application is not limited to obtaining a specific plant or animal variety and that it is not obtained by using only biological processes.

Article 4 clarifies which inventions cannot be patented. In particular, it confirms that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, is not patentable (see Article 5 of the Directive). This Article also confirms that procedures for treatment of humans or animals by surgery or therapy, as well as diagnostic methods, are excluded from patentability. In addition, processes for modification (in any form, including techniques for embryo splitting) of germ line genetic identity of humans and processes for cloning humans are excluded from patentability.

Article 4 of the Decree, however, allows for the patentability of a simple DNA sequence or a partial sequence of a

gene used to produce an entire or a partial protein, provided that the sequence performs a specific function that is capable of industrial application and that specific claims are made as to this function upon filing of the patent application. Furthermore, the Decree provides that any procedure for modifying the genetic identity of animals is not patentable if it causes unnecessary pain to animals without any substantial benefits for humans or animals.

Article 5 sets out detailed rules regarding the administrative procedure for the granting of biotechnological patents. In particular, when evaluating the patentability of biotech inventions, the Italian Patent and Trademark Office (ITPO) may seek the opinion of the National Committee for Bio-security and Biotechnologies.

Article 6 sets out provisions regarding the grant of the compulsory cross-licences as provided for by Article 12 of the Directive. The ITPO is responsible for granting of such licences, for which a fee is payable.

Article 7 provides for the invalidity of any act or transaction carried out in breach of the provisions of the Decree.

Article 8 (which reproduces Articles 8 and 9 of the Directive) specifies the scope of protection offered by the patent to a given biological material or process enabling a biological material to be produced.

Article 9 limits the scope of Article 8 by providing that:

> The protection referred to in Article 8 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation shall necessarily arise from the purpose for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 10 sets forth the procedural steps required to obtain a patent where an invention involves the use of, or concerns, biological material that is not available to the public and that cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art. In such a case, the deposit of the biological material in question at an institute recognised pursuant to the Budapest Treaty of 1997 is required.

The scope of protection of DNA sequences following the implementation of the Biotechnology Directive into German patent law

Following the amendment of the German Patent Act in February 2005, a new Sec. 1a was introduced into the Act. This provision implements Article 5 of the Biotechnology Directive 98/44/EC (the 'Directive') into German law. However, there is a significant discrepancy between Article 5 Para. 3, Recital 22 of the Directive and Section 1a of the Act. Section 1a Para. 4 of the Act provides that:

> In case the subject of the invention is a sequence or partial sequence of a gene, the structure of which complies with that of a natural sequence or partial sequence of a human gene, its use, the industrial application of which is disclosed according to paragraph 3, has to be included in the patent claim.

Article 5 Para. 3, Recital 22 of the Directive merely provides that the industrial application of a gene sequence must be disclosed in the *patent application* as filed. Thus, according to the Directive, it would be sufficient that the use of the DNA sequence is described anywhere in the patent application, not necessarily in the *claims*.

According to Section 14 of the Act (corresponding to Article 69 EPC), the scope of patent protection shall be determined primarily by the claims.

Therefore, a DNA-fragment patent filed in compliance with Section 1a para. 4 of the Act can provide protection only to the extent that the purpose of that DNA fragment is specified in the claims. In other words, this 'purpose-bound protection' provides only for prohibition against the *specific* use of the DNA fragment disclosed in the claims. 'Absolute substance protection' on the other hand, as envisaged by the Directive enables the patentee to prohibit *any* use of the identified sequence, regardless of what has been specified within the patent claims. Thus, under German law, the need to identify the use of the DNA sequence in the patent claims significantly limits the scope of protection afforded.

The German legislator considered that the grant of absolute substance protection might impede further research into the other unspecified (and perhaps unknown) properties/uses of a patented DNA fragment. It was therefore decided that this would not be in the public interest. For this reason as well, the European Commission found that the extent of patent protection for gene sequences could be a matter for review.[4]

For the time being, however, the Commission does not appear to be planning any amendments to the Directive as a consequence of the German provision. In its latest report about the 'Development and implications of patent law in the field of biotechnology and genetic engineering', the Commission states that it will not presently consider the choice between classical and limited scope of protection for gene sequences. In this context, it refers to the fact that when a specific field of technology becomes sufficiently advanced, the application of the normal patent criteria means that future patents become increasingly limited in scope as the invention claimed would have to be distinguished from the vast array of previously known inventions in the field.[5] Accordingly, the Commission appears to be relying on the patent system as it currently stands with regards to DNA fragment inventions.

The current patent system does provide incentives for further research with patented inventions. This includes the 'experimental use' exemption recently extended to the studies and trials necessary to obtain a marketing authorisation for drugs in Section 11 No. 2b of the Patent Act (so-called 'Bolar exemption') as well as the concept of dependent patents. Patent law also offers the possibility of using a technical teaching before the patent's expiration if the invention is the subject of public interest. In such a case, a compulsory licence may be obtained.

In summary, the German implementation is not in full compliance with the Directive since it is more restrictive on the patentee. Furthermore, it conflicts with Article 27 para. 1 of TRIPs, which provides that patents shall be available and patent rights enjoyable without discrimination as to the field of technology.

The practical consequences of this German implementation in respect of patents directed to human DNA sequences are, however, limited. Section 1a paragraph 4 of the Act is only applicable to German national patents. Thus, it will have no effect on applications for European patents, which are more commonly used in the field of biotechnology anyway. Rule 23e of the Implementing Regulations to the EPC (corresponding to Art. 5 of the Biotechnology Directive) does not contain any limitation corresponding to Section 1a paragraph 4 of the Act. Accordingly, European patent protection will be available for DNA sequences where the use of that DNA sequence has not been expressly indicated in the patent claims. Even if the validity of the German element of a European patent is challenged in a German nullity suit, the non-compliance with Section 1a paragraph 4 of the Act will not be an issue. The grounds for the invalidity of a European patent's national element are exclusively listed in Article 138 of the EPC.

Consequently, the specific requirement

of Section 1a paragraph 4 of the Act is only critical when applying for a German national patent for human DNA sequences where scope of protection of such a DNA fragment patent would be limited to the specific use of the DNA-sequence indicated in the claims. It should be noted that this restriction does not apply to human amino acid sequences encoded by a DNA sequence, which still attract absolute substance protection under German law.

An update on the implementation of the Bolar provision in Belgium and overview of the modified 'experimental use' exception

Implementation of the Bolar provision

Directive 2004/27/EC dated 31st March, 2004, is currently being implemented in Belgium. A Bill was presented before Parliament on 23rd December, 2005, and was discussed and approved by the Public Health Commission during the course of February 2006. It is still unclear whether the Senate will review this Bill or not. Depending on the approval process, the publication of the final Act is expected in March or April 2006. Apart from implementing the Directive, this Bill is also intended to review Belgian pharmaceutical legislation in its entirety.

The Bill amends the Law on Medicinal Products of 25th March, 1964, and, *inter alia*, transposes Article 10 of the Directive (the 'Bolar exemption') into Belgian law almost word for word.

It is worth noting that the exemption in the Directive is intended only for studies and trials accomplished in order to obtain market authorisations for generic products. Neither the Bill nor the preparatory works give more details about the specific activities that should fall within the exemption.

The 'experimental use' exception in Belgium

The Act of 28th April, 2005, modifying the Belgian Patent Act of 28th March, 1984, relates to the patentability of biotechnological inventions. Apart from literally transposing the Directive's provisions about patentability of living organisms in new legal provisions, it broadens the former provisions regarding the experimental use exception that have a general scope of application.

Under the old Patent Act of 1984, only acts accomplished in an experimental capacity *on* the subject matter of the patented invention would fall under this exception. From May 2005, acts accomplished for *scientific purposes on and/or with* the object of the patented invention now also fall within the statutory exemption.

This new wording '*on and/or with*' must, according to the discussions in Parliament, be interpreted as follows: '*on*' refers to acts accomplished in order to verify whether the invention can be implemented, ie investigations on the quality, function, etc. of the patented invention itself. '*With*' refers to acts where the patented invention is used in order to investigate something else, ie the patented invention is used as an *instrument*.

'*Scientific purposes*' refers to activities which have as their purpose the gathering of information. These terms could be interpreted broadly and encompass both pure scientific purposes and 'mixed' scientific and commercial purposes. Mixed purposes may include development of new applications; improvement of therapeutic effect; more efficient production means; new administration form; and new indications. The 'mixed' research should have a predominant scientific purpose in order to fall within the exception. Acts accomplished solely in order to obtain a marketing authorisation will, however, be considered as commercial only, and therefore not fall within the exception.

Proposal for a EC regulation clarifying food supplement labelling

Sometimes making a clear-cut distinction between food supplements and medicines

is not that easy. Manufacturers were reminded of this by a recent decision in the criminal branch of the French highest court (*Chambre criminelle de la Cour de cassation*) on 18th October, 2005. In this case, several manufacturers were found guilty by judges of having marketed products as food supplements when in fact they were medicinal products. For instance, one manufacturer had marketed a product in a capsule form as having anti-eyestrain effects. The presentation of that product contained a reference to studies conducted in an ophthalmology unit and a warning advising consumers to see an ophthalmologist in the event that their symptoms persisted. The product was described as having the ability to relieve headaches, increase blood circulation and relieve eye strain caused by age and work. The Court underlined that such claims were 'at the borderline with therapeutic indications'. As a result, the Court held that the product was a 'medicinal product by presentation' and that the manufacturer was therefore guilty of the illegal practice of pharmacy and for having marketed such product without a marketing authorisation.

Decisions such as this are not uncommon. In France, manufacturers are increasingly placing food supplements on the market that could later qualify to be medicinal products. This highlights the fact that the legislation in this area is not sufficiently clear for manufacturers or indeed consumers.

As consumers become increasingly health-conscious, nutritional and health claims made by products play a more influential role in their purchases. As such, the law must evolve to keep up.

At the European Community level, the Commission has undertaken to propose rules governing such claims so as to ensure that all claims placed on products are unambiguous, truthful and reliable. These rules were set out in the Proposal for a Regulation of the European Parliament and of the Council dated 16th July, 2003, 'on nutrition and health claims made on foods'. This proposal sets out rules governing whether claims will be prohibited or considered misleading.

For instance, Article 11 prohibits 'implied health claims' which make reference to (a) 'general, non-specific benefits of the nutrient or food for overall good health, well-being'; (b) to 'psychological and behavioural functions'; (c) to 'slimming or weight control, or to the rate or amount of weight loss which may result from their use or to a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy diet'; or (d) 'to the advice of healthcare professionals'. However, this provision has been the subject of significant lobbying.

A Common Position was reached by the Council on 15th December, 2005, in which the treatment of 'implied health claims' has been changed. The above-mentioned list of Article 11 prohibited claims was reduced to (a) claims suggesting that not consuming a food could affect health; (b) claims making a reference to the rate or amount of weight loss; and (c) recommendations from individual doctors, health professionals or some specific association. All general and non-specific claims (such as those on well-being) could be used if accompanied by a specific health claim from an authorised list of health claims.

On 13th January, 2006, a Communication of the Commission to the European Parliament specified that the Commission had welcomed the Common Position adopted unanimously by the Council.

For the time being, the European Parliament and the Council still disagree on two significant points. The Parliament voted to reject the principle that the use of claims is conditional on respecting the 'overall nutrient profile' of the food and favoured a notification system rather than pre-approval of certain health claims by the European Food Safety Authority (EFSA). However, the Council opposed such a position. The future of this text therefore remains uncertain.

Finally, the original proposal does not make reference to food supplements. Even though some amendments proposed make reference to them in the core of the text to 'avoid any uncertainty on whether food supplements are included in the scope of this Regulation', they are not currently clearly covered by the scope of the text.

In light of the above, it seems uncertain whether the finalised Regulation will end the confusion surrounding the labelling of food supplements. At present, a balance between the interests of food supplement manufacturers and those of the consumer has proved hard to achieve in practice.

NOTES FROM THE USA
US Supreme Court agrees to hear MedImmune/Genentech dispute

The US Supreme Court has agreed to hear a case[6] later this year to decide whether MedImmune has the right to challenge the validity of one of Genentech's Cabilly patents even though it is a licensee in good standing under that patent. The patent in question is the well-known US patent number 6,331,415, which describes a method of producing monoclonal antibodies using recombinant DNA technology. Under the terms of the licence agreement, MedImmune agreed to pay a royalty to Genentech on sales on sales of SYNAGIS (palivizumab) for respiratory syncytial virus (RSV). However, MedImmune is reported to have to have agreed to enter into the licence agreement under protest and reserved its right to challenge the validity of the Cabilly patent.

MedImmune subsequently commenced proceedings seeking a declaratory judgment to the effect that Cabilly was invalid and unenforceable and in any event not infringed by the manufacture, marketing and sale of palivizumab. Article III of the US Constitution gives jurisdiction to the federal courts in 'all cases in law and equity arising under the laws of the United States'. However the Declaratory Judgement Act[7] permits a court to make a declaratory judgment only where there is an 'actual controversy' between the parties.

At first instance, the US District Court for the Central District of California dismissed the action in April 2004 relying on the March 2004 decision by the US Court of Appeals for the Federal Circuit in *Gen-Probe Inc.* v *Vysis Inc.*[8] That decision held that when a patent licensee has complied with its royalty obligations, there is no 'actual controversy'. The District Court in MedImmune therefore concluded that controversies over patent validity, enforcement and infringement would not be recognised while licence agreement protected the licensee from suit for infringement.

The first instance decision was affirmed on appeal by the Court of Appeals for the Federal Circuit,[9] relying largely on the *Gen-Probe* decision and rejecting MedImmune's argument that such a decision conflicted with prior Supreme Court case law, in particular *Lear Inc.* v *Adkins*.[10] In the *Lear* case, the Supreme Court held that the licensee was not required to continue making payments to the licensor while it was challenging the validity of the licensed patent on the basis that the federal interest in placing inventions protected by invalid patents in the public domain outweighed the requirements of state contract law.

As things currently stand, a patent licensee seeking to challenge the validity of a US licensed patent may do so only if it first places itself in breach, and therefore runs the risk of losing its licence entirely together with the risk of treble damages for patent infringement (where the patent is ultimately held valid and infringed) and further attorneys' fees.

The issue for the Supreme Court therefore is whether a patent licensee has to refuse to pay royalties and be in material breach of its licence agreement before it can sue to have a patent declared invalid, unenforceable or not infringed. The case is of practical interest to many

biotech companies because of the fairly common practice of taking a patent licence at an early stage of development not because the patent is believed to be valid, but in order to buy some breathing space for the licensee until the commercial potential for the product becomes clear. It should be noted finally that the Supreme Court will only be considering the preliminary issue of standing to sue and will not at this stage be reviewing the validity of the Cabilly patent.

FDA ordered to consider NDA for follow-on biological

In the previous update, we reported that the committee for medicinal products for human use (CHMP) of the EMEA had issued a positive opinion on OMNITROPE somatropin human growth hormone (hGH) made by Sandoz. The CHMP found that OMNITROPE has been shown by studies demonstrating comparable quality, safety and efficacy to be similar to a reference medicinal product already authorised in the EU, namely GENOTROPIN somatropin marketed by Pfizer and recommended approval of OMNITROPE for all indications on the GENOTROPIN label. This recommendation has now been accepted by the European Commission, making this the first product marketed under the new European biosimilar regulations.

Meanwhile in the USA, a federal court has ordered the Food and Drug Administration (FDA) to act on a new drug application (NDA) from Sandoz for OMNITROPE.[11] The NDA was first filed in July 2003 and, notwithstanding a statutory time limit of 180 days to review the application, the FDA had failed to issue a decision some two years later. Sandoz had been told in August 2004 that the review of the application had been completed, but that it was delaying the final decision while it prepared guidelines for approving generic versions or variations of biotechnological products. Sandoz argued in court that OMNITROPE was not a true generic and is therefore subject to the regulatory process used for variations of approved products, hence the draft guidelines cited by the FDA as the reason for the delay were not relevant.

In granting the motion for summary judgment, the District Court ruled that the FDA is legally required to act on NDAs within 180 days of submission and rejected the FDA's contention that language in the Food, Drug and Cosmetic Act instructing it to act on NDAs within 180 days was 'aspirational'. The judge commented that the 180 day time limit was at the very least a strong indication that the FDA's behaviour had been unreasonable. The court furthermore did not require the FDA to approve the NDA or even set an explicit deadline for FDA action, but the FDA did admit in its submissions that it 'in essence concedes that it has not yet found grounds for denying approval of OMNITROPE'. Nevertheless, this further hurdle on the route to approval for OMNITROPE in the USA demonstrates the lack of a clear regulatory pathways for biosimilars compared with the situation in Europe.

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