Legal and regulatory update

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Legal and regulatory update

NOTES FROM THE EU

Human Tissue Act 2004

The Human Tissue Act received royal assent on 15th November, 2004, but its provisions will not come into force until the Secretary of State makes relevant orders by statutory instrument, which is expected to happen after 1st April, 2006. The Act will repeal and replace the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989. Pressure to introduce new measures arose following the public scandal surrounding the retention and use of organs and tissues from children at the Bristol Royal Infirmary and the Royal Liverpool Children's Hospital, without proper consent. The purpose of the Act is to set up a framework that makes consent the foundation of all lawful activities involving whole body donation and the removal, storage and use of human organs and tissues for transplantation, anatomical examination, education, training and research. The Act does not cover gametes or embryos outside the human body, activities in relation to which are governed by the Human Fertilisation and Embryology Authority. Nor does the Act cover the removal of material from living persons, although it does cover the storage and use of such material. The current law relating to removal of material from living persons without their consent will continue to apply.

The Act is divided into three parts. Part 1 relates to consent and sets out the requirement to obtain 'appropriate consent' to carry out activities regulated by the Act, including: (i) the storage and use of whole bodies; (ii) the removal, storage and use of organs, tissues and cells from the bodies of deceased persons; and (iii) the storage and use of organs, tissues and cells from living persons for the purposes set out in schedule 1 of the Act. Schedule 1 lists the activities of anatomical examination, determination of the cause of death, establishing the efficacy of a drug or treatment after a person's death, obtaining information about a living or deceased person which may be relevant to another person, public display, research in connection with disorders or the functioning of the human body, transplantation, clinical audit, education or training relating to human health, performance assessment, public health monitoring and quality assurance. Certain exemptions apply whereby appropriate consent is not required. There is a research exemption that permits the storage and use of human organs, tissues or cells for research purposes provided that the research has been ethically approved and the samples are anonymised so that the researcher cannot identify the persons from whom the samples were taken. Samples from living persons may also be used without appropriate consent for the purposes of clinical audit, education or training relating to human health, performance assessment, public health monitoring and quality assurance.

Appropriate consent is defined by reference to who may give it and covers adults, children, deceased persons and incapacitated adults. The type of information that the person giving consent must be made aware of in order for their consent to constitute 'appropriate consent' will be set out in a code of practice to be issued by the Human Tissue Authority. The Human Tissue Authority will also have the power to dispense with the requirement to obtain consent from a donor in certain, specified situations where the donor cannot be traced or is undecided about giving consent. The penalties for failing to comply with the Act are also set out in part 1.

Part 2 of the Act deals with the

regulation of activities covered by the Act. As a preparatory step to the Act coming into force, the Human Tissue Authority was established on 1st April, 2005, and the members of its board appointed by the NHS Appointments Commission. The Human Tissue Authority will be the regulating authority not only for activities covered by the Act, but also for activities governed by the EU Tissues and Cells Directive, which must be transposed into national law by 7th April, 2006. The Human Tissue Authority will issue codes of practice covering matters such as consent, the definition of death, anatomical examination, post-mortems, existing holdings, removal, storage and disposal of human tissues and the import and export of human organs and tissues. It will also be responsible for licensing 'designated individuals' under whose supervision the activities covered by the Act must be carried out. The duties of the designated individual and the penalties for breaching the licence requirement are also set out in this part of the Act.

Part 3 of the Act contains miscellaneous matters that include 'excepted purposes' relating to the use of human cells for DNA analysis. The excepted purposes permit the use of human cells for DNA analysis without consent where the results of that analysis are for specific, listed purposes, which include the diagnosis or treatment of the person whose body manufactured the DNA and the prevention or detection of crime. The Human Tissue Authority will also have the power to inspect records, enter, search and inspect premises and seize property in connection with the exercise of its regulatory functions.

It is proposed that the Human Fertilisation and Embryology Authority will merge with the Human Tissue Authority in 2008 to form a new authority which will also regulate activities involving the use of human gametes, embryos and blood (excluding for transfusion purposes).

Tissues and Cells Directive adopted

The Tissues and Cells Directive 2004/23/EC, was adopted on 31st March, 2004. Its aim is to create a unified framework across the European Union of comparable quality and safety standards for human tissues and cells.

The Directive covers the donation, procurement, testing, processing, preservation, storage, distribution and use of human tissues and cells that are intended for human application, including those contained in manufactured products such as medicines and tissue engineered products. The use of human tissues and cells for *in vitro* research is not covered, as this Directive concerns only tissues and cells applied to the human body.

The Directive requires each member state to set up a competent authority to oversee, inspect and accredit those tissue establishments where testing, processing, preservation, storage or distribution of human tissues and cells may be carried out. In the UK, this will be the Human Tissue Authority. The penalties for failure to comply with the Directive must be effective, proportionate and dissuasive. The competent authority must ensure that all activities involving tissues or cells are carried out only by appropriately trained, experienced persons at accredited tissue establishments. Importing and exporting of tissues and cells may be undertaken only by accredited tissue establishments and all exported tissues and cells must comply with the standards set out in the Directive. Each tissue establishment must put in place a quality system based on the principles of good practice and appoint an appropriately qualified 'responsible person' who will be responsible for ensuring that the requirements of the Directive are complied with and provide information to the competent authority including keeping a record of activities and submitting an annual report to the competent authority. Each member state must also have a system for reporting serious adverse events and reactions.

Each member state must ensure that all tissues and cells procured, processed, stored or distributed in their territory can be traced between donor and recipient and that the data are stored for at least 30 years. All such data, including genetic data, must be stored securely so as to respect the confidentiality of the patients. Any data to which third parties have access must be anonymised so that the donors and recipients remain unidentifiable, but would still be capable of being traced if necessary.

All necessary consents must have been obtained from the donor before the procurement of tissue or cells. As a matter of principle, the Directive also requires member states to endeavour to ensure that donations of tissues and cells are voluntary and unpaid and that their procurement is carried out on a not-for-profit basis.

Tissue establishments will also have to ensure that their relationships with third parties comply with the requirements of the Directive. Where an external activity takes place that could influence the quality or safety of tissue or cells (for example, a third party performs a stage of tissue or cell processing for the tissue establishment), the tissue establishment must ensure that the third party is able to meet the standards laid down in the Directive. Having made this assessment, the tissue establishment must enter into a written agreement with the third party that specifies detailed procedures and the responsibilities of the third party. Copies of such agreements must be provided to the competent authority upon request.

Where an industrially manufactured product, such as a medical device, incorporates human tissues or cells, other relevant legislation will continue to apply (for example, the Community code relating to medicinal products for human use and legislation that regulates the processing, preservation, storage and distribution of tissues or cells). The new Directive will apply only in relation to donation, procurement and testing.

Blood, blood products, human organs and tissues and cells used as autologous grafts (tissues removed and transplanted back into the same patient) performed within the same surgical procedure without being subject to any banking process are excluded from the new Directive.

Each EU member state has until 7th April, 2006, to implement the Directive into national law, except in the case of tissue establishments bound by national provisions, in which case there is a derogation which extends the deadline by a year. The UK would therefore be able to defer applying the new regime to fertility clinics licensed by the Human Fertilisation and Embryology Authority until 7th April, 2007.

The European Commission in conjunction with the member states will produce two draft technical directives later this year containing the detailed requirements of the Tissues and Cells Directive.

European Medicines Agency road map to 2010: Preparing the ground for the future

At the beginning of March the European Medicines Agency (EMEA) published its strategy to protect and promote public health and animal health, improve the regulatory environment and promote innovation and R&D in the EU over the next five years. The enlargement of the EU and the introduction of new pharmaceutical legislation will have an impact on the operation of the EMEA. However, the EMEA's vision remains to provide a regulatory framework which permits rapid access to safe, effective medicines and to coordinate the input of all the National Competent Authorities (NCAs) and to apply good administrative practice which includes operating in a transparent fashion. In order to continue to pursue these goals the EMEA has set itself a number of key objectives to be achieved by 2010. These are as follows: top quality scientific assessment; timely access to safe and effective innovative medicines; continuous monitoring of medicinal products; access to information;

and specific needs for veterinary medicines.

In order to meet these objectives, the EMEA has produced a draft implementation plan containing a number of specific actions. The intention is to pursue the actions through the EMEA's planning process. Some of the actions are already part of the 2005 planning process and others will be included in the programmes for subsequent years. The actions are set out in the executive summary of the road map and include the following:

- Reinforcement of the partnership between all EU Regulatory Authorities in the different fields of medicines regulation, leading to the establishment of a network of excellence at EU level; renew efforts to acquire the best personnel for the scientific activities of the EMEA and NCAs, taking pains to reinforce the network in areas where expertise is insufficient.

- Revise the current procedural framework to establish the best possible environment for the provision of scientific advice; increase the level of scientific support provided by the EMEA secretariat to the scientific committees to improve the quality and regulatory and scientific consistency of their scientific assessment work.

- Implement procedures foreseen by the new legislation which allow for more rapid access to medicines without compromising the safety of patients; implement special measures for innovative medicines, technologies and therapies, veterinary medicines, generic/non-prescription medicines and herbal medicines.

- Explore options to enhance the continuous monitoring of medicinal products on the EU market, especially by applying a more proactive approach to pharmacovigilance.

- Stimulate research and innovation in the EU's pharmaceutical, biotechnology and healthcare industries, leading to the development of an adequate product development toolkit, able to address the bottlenecks during the development of innovative medicines.

- Provide incentives for small and medium sized enterprises (SMEs).

- Strengthen the coordination of good manufacturing and clinical practices across the EU.

- Follow-up on initiatives to improve the EMEA's transparency and communication, with special emphasis on the provision of useful, clear and comprehensive information to patients/users of medicines and healthcare professionals.

- Engage more fully in dialogue with health organisations, academia, learned societies and other stakeholders.

- Continue the roll-out and development of EU-wide telematics systems.

- Strengthen the EMEA's international collaboration with non-EU regulatory authorities.

The road map does not simply contain a vision but goes further than that by setting out an implementation plan with specific actions to be undertaken by the EMEA. These are to be elaborated upon further over the course of 2006 to enable the development of a detailed plan for action to be taken in the period 2007–2010.

Clarification of Directive on Enforcement of Intellectual Property Rights

On 13th April, 2005, the European Commission published a list of the intellectual property rights it intends shall be covered by the scope of the Directive

on the Enforcement of Intellectual Property Rights (2004/48) (Directive). The Directive, dated 29th April, 2004, is due to be implemented by all member states on or before 30th April, 2006. It has caused uncertainty because of the perception that the Directive lacks clarity as to the intellectual property rights that will be affected. The relevant provisions are set out in Article 2 of the Directive which provides that the Directive shall apply 'to any infringement of intellectual property rights as provided for by Community law and/or by the national law of the Member State concerned.' Now that the Commission has helpfully explained that certain rights will be covered by the Directive, implementation by member states could be more straightforward. The following intellectual property rights are intended to fall within the scope of the Directive: copyright and any related rights; rights of database makers; rights of the creator of the topographies of semiconductors; trade marks; design rights; patents (including rights derived from supplementary protection certificates); geographical indications; utility model rights; plant variety rights; and trade names, providing always that the rights are protected as exclusive property rights in the national law of the member state concerned.

Publication of final decision of the Technical Board of Appeal of the European Patent Office in the Harvard oncomouse opposition case T 0315/03

The full reasoning for the decision of the Technical Board of Appeal (TBA) of 6th July, 2004, upholding the patent on amended claims to 'transgenic mice' has now been published, and is of especial interest as it reflects the current European Patent Office (EPO) thinking on many of the issues addressed by the biotechnology directive (EU Directive 98/44) and also the application of the EPO rules formulated in response to this directive to applications, such as this, which predated the directive.

The TBA expressed the view that it is clear that the new rules of the European Patent Convention (EPC) do not create a change in regime with respect to animal patents by allowing them to be patented where previously this was not permitted. The TBA did not hesitate in its finding that the new rules applied in this case. The TBA found that the rules created a balancing test in which the suffering to animals must be weighed against the medical benefit to human or animal. If there is no such benefit then no patent protection will be available (Article 53(a) EPC, Rule 23(d) EPC)). The TBA went on to say that a mere likelihood of suffering is enough to trigger the operation of rule 23(d). This is the first question in a three-part test set out by the TBA: (1) whether animal suffering is likely; (2) whether likely medical benefit has been established; and (3) whether the suffering and the medical benefit both exist in relation to the use of the same animals. Or, to put it another way, rule 23(d) should be used to ensure that any patent should only be granted in relation to those animals whose suffering is balanced by a medical benefit and will not be extended to animals in relation to which there is no such balancing with a benefit. It is for this reason that the TBA limited the extension of the patent to the mouse and would not allow the patent to be extended to other animals.

There is also a discussion as to the nature of evidence that would be relied on and it was emphasised that this must be relevant to the likelihood of suffering and the likelihood of substantial medical benefit and the links between the two as at the date of the application (and any evidence becoming available after that date must be directed to the position at that date).

Roche's PCR patents expire

It has been reported that Roche's polymerase chain reaction (PCR) patents have expired. It is true that some of the

core process patents for amplifying, detecting and cloning nucleic acid sequences expired at the end of March. This will reduce costs for many companies who will no longer have to pay royalties in relation to those patents. It does not, however, mean that licences from Roche are no longer required. There are other patents that remain in force and so it will be important to keep under review any technology being used under licence to ensure that intellectual property rights are not infringed and that royalties are properly paid.

New Committee on Safety of Medicines

On 5th April, 2005, the Department of Health announced that the Medicines Commission is to be abolished and replaced with the new Committee on Safety of Medicines, as a result of amendments to the Medicines Act 1968. It is expected that the NHS Appointments Commission will advertise positions on the Committee from April; however, the changes mean that industry will no longer have the right to be represented. Instead more lay members will be sought. Technical input will come from a number of expert advisory committees that will advise the Committee. These new committees are designed to increase the amount of technical expertise available to the Committee. Still under review are proposals to establish a Herbal Medicines Advisory Committee.

Medicinal product liability in France

As biotechnology based products are coming on the market, there is no doubt that they will face product liability issues. The French pharmaceuticals liability regime seeks to find a fair balance between consumers' protection and the need to encourage innovation and pharmaceutical research. It seems the more active the medicinal product, the more likely it is to have side effects and to be subject to product liability litigation. A decision from the '*Cour de cassation*' (the French supreme civil court) dated 5th April, 2005, emphasised the key points which are necessary to assess liability in this field.

Until recently, French case law almost systematically held manufacturers of medicinal products liable. This was chiefly due to the fact that French judges would find causation between the harm sustained by the victim and the medicinal product at issue merely on the basis of presumptions. The *Cour de cassation* has now rejected this interpretation and stated that the proof of causation must clearly be established by the person questioning the safety of the medicinal product. In its decision of 5th April, 2005, the *Cour de cassation* upheld this position and furthermore provided information on the assessment of the defectiveness of a medicinal product.

In this case, a patient who had developed a serious skin necrosis also known as Lyell syndrome estimated that this syndrome had stemmed from the absorption of two medicinal products which had been prescribed to him for the treatment of a severe gout attack. He consequently decided to sue the manufacturers of these two medicinal products for injuries caused by them. After a long-running legal battle before the court in the first instance, then appeal judges, the *Cour de cassation* decided to reverse the appeal decision and to discharge one of the defendants of its liability.

The following three key points were specified by the *Cour de cassation*. Firstly, the *Cour de cassation* confirmed that the claimant must afford sufficient evidence to prove the causal link between the harm he sustained and the medicinal product and set out several criteria for this purpose.

Second, the *Cour de cassation* made it clear that dangerous does not mean defective. The judges of the *Cour de cassation* specified that the judges in the earlier decision should not have considered that one of the medicinal

products was defective and did not provide the safety which a person is entitled to expect merely because 'some of its active principles are dangerous, even if the danger's appearance is exceptional'. The *Cour de cassation* specified that it was necessary in order to assess the defectiveness of the product to take all circumstances into account and in particular 'the presentation of the product, the use that the public could have expected from it, the time when the product was put into circulation and the seriousness of its harmful effects'. This position is in line with the provisions of the EC directive of 25th July, 1985, and notably because it is based on the use of the word 'public' in order to assess the objective nature of the product's defectiveness: it is necessary to take into account the use of the medicinal product that could have been expected collectively by the public and not only by the patient.

Lastly, this decision highlights that information supplied with or in relation to the medicinal product is of paramount importance, eg the patient information leaflet. Before commercialising a medicinal product, the pharmaceutical manufacturers first have to assess the medicinal product's dangers and possible side effects and then to ensure that the public is well informed of the possible risks. A medicinal product having potentially dangerous active ingredients can be considered as reasonably safe if accompanied by proper and detailed warnings. In this respect, the information should be drafted very carefully. Furthermore, it is noteworthy that a medicinal product's approval by the AFSSAPS (French Agency for Sanitary Safety of Health Products) is not a guarantee of its safety and will not shelter a manufacturer from liability (as results from Article 25 of the EC directive 2001/83 of 6th November, 2001, on the Community code relating to medicinal products for human use).

This decision, which is in line with the French Administrative Supreme Court (*Conseil d'Etat*) Report for 2005 advising in essence adopting a reasonable approach to the precautionary principle, will definitely have a positive impact on the pharmaceutical sector.

Belgian law amending 1984 Patents Act

On 28th April, 2005, royal assent was given to new law, the principal objective of which is to implement Directive 98/44 on the legal protection of biotechnological inventions ('Biotech Directive') into Belgian law. In contrast with a previous draft law of 2000, the new law transposes the Biotech Directive in a very literal manner. This approach has generally been welcomed in Belgium and does not in this respect raise any novel issues of particular significance.

The legislative initiative is, however, notable not only for its belated implementation of the Biotech Directive, but also for two, rather controversial, moves to extend the experimental use exemption and to introduce a specific compulsory licensing regime 'in the interests of public health'. Both these initiatives go beyond those mandated by the Biotech Directive.

The wording of the current experimental use exemption under Belgian law, in common with other European jurisdictions, provides that acts carried out for experimental purposes relating to the subject matter of a patented invention shall not be considered to be patent infringement. The Belgian patent law now extends this experimental use exemption to acts done on or with the subject matter of the patented invention. In other words, acts exempted from patent infringement would not only be those experiments relating to the subject matter of the invention (eg experiments related to an improved version of a patented product) but also acts with a patented invention (eg the use of a technology platforms used in drug or diagnostic research and development). In addition, the acts must be done for 'scientific' purposes rather than, as at

present, 'experimental' purposes. It is not clear whether this would restrict the benefit of the exemption to academic institutions, but this could be how the new law will be interpreted.

The other controversial provision is that relating to compulsory licensing 'in the interest of public health'. Article 31bis introduces the possibility for the government to issue a compulsory licence 'in the interest of public health' for any patented invention in the field of medicinal products, medical devices, diagnostic products, combination therapeutic products, including methods or products necessary for the production of any of these products as well as methods of diagnostics applied outside the body of humans or animals. The concept of 'interest of public health' is not defined in the law.

The procedure under Article 31bis differs significantly from that applicable to patents relevant to other industrial sectors. Two examples from the text illustrate the disadvantage to which medical patent holders may be put. First, any infringement action shall be automatically stayed if an application for a compulsory licence in the interest of public health is filed with the competent authority, which is not the case for other patents. Secondly, although the law provides that the Council of Ministers should determine the remuneration for the patent holder in the case of a compulsory licence granted in the interest of public health, the extent of such remuneration is not defined (contrary to other types of compulsory licences, where the remuneration should be adequate and take the economic value of the licence into consideration).

These original proposals resulted in concerted lobbying efforts by stakeholder representatives in Belgium with the Flemish Inter-University Institute for Biotechnology, the Belgian Bioindustries Association, Belgo-Biotech, pharma.be and FlandersBio taking a common position on the draft law.

In essence, the position advocated the deferral of any amendment to the experimental use exemption pending a detailed evaluation of the implications of the change and indeed the reasons behind the proposed change. It is indeed remarkable that the Belgian government chose to take action in respect of the experimental use exemption given that it is not on the political agenda anywhere else in Europe other than as regards the new 'Bolar' exemption introduced in conjunction with the amendments to the Community Code on medicinal products for human use. Interestingly, no draft legislation has yet been introduced to implement this provision in Belgium. It could even be thought that the amendment would make Belgium the jurisdiction of choice for undertaking experimental work that would in other jurisdictions require a licence, thereby creating distortions in the research-based environment in Europe.

As far as the compulsory licensing extension is concerned, the justification for this seems to the industry bodies to be the fear of patents such as that granted to Myriad Genetics in respect of the diagnostic tests for the *BRCA1* gene, which may have the effect of blocking all testing and not just the use of methods offered by the patent holder. Stakeholders therefore proposed limiting the new regime to this specific situation. It was also suggested that the procedure can only be invoked by the Minister of Public Health rather than on the initiative of a private party, so that it would not be possible for an application for a compulsory licence to be used solely for commercial benefit or even as a delaying tactic in patent litigation.

Unfortunately for some, industry's lobbying efforts proved effective in the upper house.

Recent amendments to the German Patent Act 1981: The implementation of the Biotechnology Directive

On 28th February, 2005, the German act implementing the Biotech Directive (as defined above) into German patent law

came into force after a long-lasting controversial debate. The act implements the Biotech Directive almost verbatim into German patent law. However, there is a significant difference in that the Biotech Directive provides that the industrial application of a DNA-sequence must be disclosed in the patent application as filed (Art. 5, para 3; Recital 22). Thus, it is sufficient if one use of the sequence is described anywhere in the patent application, eg in the specification. As long as the use is solely included in the specification, but not mentioned in the patent claims, the scope of protection is not limited to this use. According to a provision in the amended German Patent Act (Sec. 1a, para 4), however, the use must be included in the patent claim. Thus, the scope of protection is limited to this very use. The consequence of this difference is that under the provision of the Directive the patentee can prohibit any use of the identified sequence, whereas under German law he or she may only prohibit the specific use as included in the patent claim.

One may argue that the German provision is more supportive of research because in Germany an independent patent would be granted to an inventor identifying another use of the sequence, whereas under the Biotech Directive he or she would only obtain a dependent patent, providing fewer incentives for further research. However, it seems to be clear that the German provision does not comply with the Biotech Directive as it stands, since it is more restrictive for the patentee.

The question arises as to whether the Biotech Directive may have direct effect in Germany because of this incorrect implementation, so that an applicant could demand to obtain a patent which includes the use of the sequence only in the specification. According to ECJ case-law a directive may have a direct effect when incorrectly implemented into national law, which is consistent with article 10 of the treaty establishing the European Community, which obliges all member states to take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations resulting from action taken by the institutions of the Community. Such direct effect requires that the provisions in the directive are unconditional as regards the contents and sufficiently precise. The Biotech Directive is unconditional and provides very detailed rules. It can be argued that it is clear from its wording that the inclusion of the use in the specification shall be sufficient. Thus, it is conceivable that in such a scenario the German Patent Office would have to apply the Biotech Directive and would have to grant the patent without any limitation to the use of the DNA-sequence within the claims.

It remains to be seen whether the Biotech Directive will be amended in the future with regard to the scope of DNA patents in a manner corresponding to the German provision. The European Commission has already announced that the extent of patent protection for genes or gene sequences could be a matter for review.

NOTES FROM THE USA

The CREATE Act

The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act), enacted on 10th December, 2004, amends the US Patent Act in a way intended to 'promote cooperative research involving universities, the public sector, and private enterprises.' By expanding upon an exemption under 35 USC Section 103(c), the CREATE Act allows parties to collaborate under a 'joint research agreement' without fear that the subject of the collaborations will be used as the basis for an obviousness rejection against a patent application covering an invention developed pursuant to the joint research agreement.

Prior to the enactment of the CREATE Act, parties in collaborative research efforts would try to negotiate the assignment of all resulting intellectual

property to one party, usually the party owning the prior art that is the subject of the collaboration. The parties would thereby preserve the exemption from a prior art challenge under the original Section 103(c). Although such assignments were common, negotiating them could prove difficult owing to one entity's reluctance to make an assignment to another entity prior to any research success. Consequently, the enactment of the CREATE Act was viewed as a way to minimise the obstacles and preserve the safe harbour of Section 103(c) without necessitating such negotiations.

Notwithstanding the CREATE Act's laudable goals to expand the original safe harbour, the United States Patent and Trademark Office (USPTO) enacted new rules on 11th January, 2005, that appear to limit the expanded exemption by introducing a new ground for a 'double patenting' rejection and by introducing a new terminal disclaimer requirement to overcome the double patenting rejection. As a result, parties must carefully consider whether the complications of the CREATE Act and the USPTO Rules militate towards relying on the Act or returning to operate under the old paradigm and to negotiate the assignment of all intellectual property to one entity.

Background

Historically, prior to initiating research, parties to collaborative research efforts would sometimes attempt to negotiate the assignment of any resulting intellectual property. The party owning the prior art that was the basis for the collaboration was typically deemed the proper assignee of such intellectual property. By doing this, the parties could safely rely on the original exemption provided under Section 103(c), which stated, in general terms, that subject matter owned by the same entity that owns the later-filed patent application or patent may not be used as prior art to reject such later-filed patent application or invalidate such later-filed patent.

Notwithstanding the advisable practice of assigning intellectual property resulting from collaborations to a single party, in certain circumstances parties did not make such assignment. This was the situation in *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997), in which an OddzOn inventor received two confidential disclosures that 'inspired' him to design the contested matter. In that case the Court held that the exchange of confidential information by members of a research team, such team comprising researchers from more than one organisation, could render an invention 'obvious' within the meaning of 35 USC Section 103 and thereby unpatentable unless the researchers had an obligation to assign their rights to the invention to a single entity prior to the making of the invention. Because the OddzOn inventor had relied on subject matter contained in the disclosure that was not owned by OddzOn, the resulting invention was deemed obvious under Section 103(c). Concerned that the OddzOn decision would have a chilling effect on communications between collaborators and research teams, Congress developed the CREATE Act.

The Act

Prior to Congress's enactment of the CREATE Act, 35 USC Section 103(c) provided that subject matter only qualifying as prior art under one or more of 35 USC Sections 102(e), (f) or (g) would 'not preclude patentability' under Section 103 (ie obviousness), where actual common ownership or an obligation of common ownership existed for that subject matter and the claimed invention. This prior version of the statute, however, did not accommodate collaborations among different companies or institutions with separately owned information unless one party to the collaboration assigned its rights under the invention to the party who owned the prior art subject matter.

By way of the CREATE Act, Congress has expanded the scope of the exemption under Section 103(c) to permit the owner of a patent application for an invention

made pursuant to a joint research agreement to claim the benefit of Section 103(c) without requiring the potentially disqualifying subject matter and the invention to be owned by a single entity or subject to an obligation of common assignment. Specifically, under the CREATE Act, Section 103(c) is available to applications that meet the following three criteria:

- the claimed invention must be made by or on behalf of parties to a 'joint research agreement' in effect on or before the date the claimed invention was made;
- the claimed invention must be 'made as a result of activities undertaken within the scope of the joint research agreement;' and
- the application for the claimed invention must disclose or be amended to disclose the names of the parties to the joint research agreement.

Thus, it was hoped that under joint research agreements provided for by the CREATE Act, companies and organisations could more freely collaborate and share information, without assigning one party's rights to another and without fear that any information of one of the parties to a joint research agreement may become the basis for an obviousness rejection of a patent application for an invention developed pursuant to the joint research agreement.

Double patenting

In reaction to the CREATE Act, the USPTO proposed new rules ostensibly intended 'to implement the CREATE Act'. Those interim rules, however, also scale back the expanded exemption discussed above to some extent by providing a new ground of 'double patenting' rejection of a patent application for an invention developed pursuant to a joint research agreement.

The USPTO's interim rules have expanded the doctrine of double patenting to include patents or patent applications owned by different entities if the joint research agreement exemption of the CREATE Act applies, even though this doctrine historically has been used only when the basis of the rejection and the rejected patent application are commonly owned. Thus, information that qualifies under the expanded exemption of Section 103(c) under the CREATE Act can now form the basis of a double patenting rejection.

Overcoming such a rejection based on a patent or patent application previously filed by one of the parties to the joint research agreement could prove difficult because the USPTO's interim rules require a broad waiver from the owner of each patent or patent application forming the basis of the rejection and the owner of the rejected patent application. Specifically, each owner must sign a terminal disclaimer form that includes a provision waiving the right to separately enforce or license any patent or patent application involved in the double patenting rejection. Such a waiver may be difficult to negotiate among parties to such a joint research agreement since neither is likely to want to disclaim its rights to separately license and enforce its patent.

Conclusion

While the CREATE Act was intended to encourage and promote collaborative research efforts by expanding the safe harbour under Section 103(c), the possibility of a double patenting rejection seems to undermine this goal. As a consequence, parties to collaborative research efforts may decide that it in their better interests to operate under the old paradigm rather than relying on the CREATE Act and the proposed Rules of the USPTO. Under the old paradigm, parties to a collaborative research effort would try to negotiate the assignment of intellectual property resulting from the collaboration to one entity, thereby qualifying for the exemption under the prior Section

103(c). Under the CREATE Act, such assignment is unnecessary, but comes at the risk of a double patenting rejection. Until the interim USPTO rules are finalised, parties to a collaborative research effort in the USA may want to consider seeking counsel from a qualified lawyer.