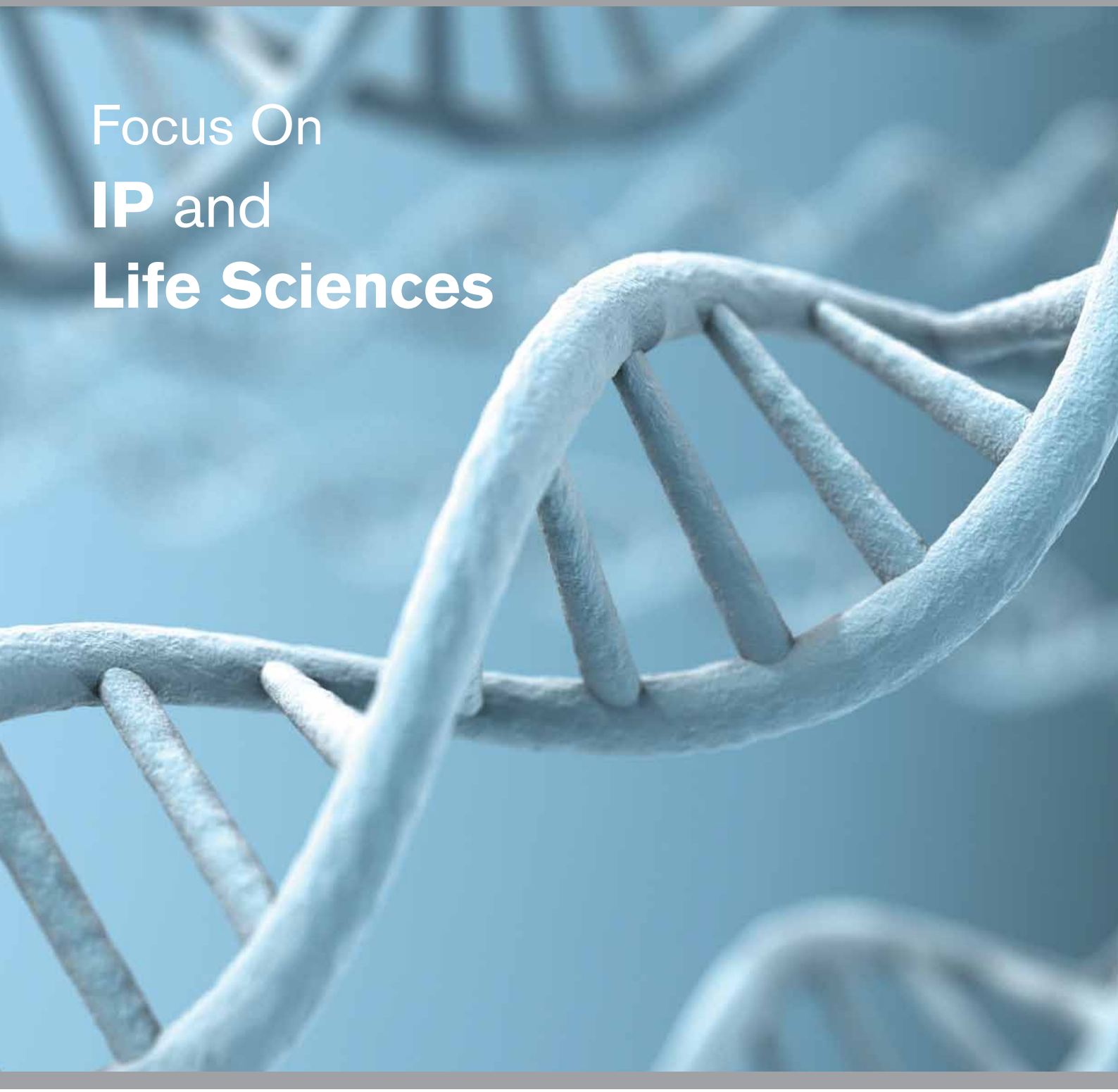
McDermott Will & Emery

International News

ISSUE 3 2010



Focus On **IP** and **Life Sciences**

Editor
Hugh Nineham
+44 20 7570 1425
hnineham@mwe.com

Managing Editor
Rohan Massey
+44 20 7575 0329
rmassey@mwe.com

Publication Editors
Kate Hinze

Ellen McDonald

Contributing Authors
David Adler, Paul Melot de Beauregard, Mélanie Bruneau, Henry Chen, Patrice Corbiau, William (Bill) Gaede, B. Ted Howes, Edwin (Ted) Laurenson, Robert Lundie Smith, Rohan Massey, Peter Nias, Eileen O'Connor, Stephan Rau, Hiroshi Sheraton, Heather Egan Sussman, Andrew Stone, Alison Wetherfield

To learn more about *International News* or our international practice, visit www.mwe.com/international/. To be added to our mailing list or report a change of address, please e-mail mcdermottnews@mwe.com. To sign up to receive substantive communications from McDermott, visit www.mwe.com/subscribe/.

McDermott Will & Emery

International News

CONTENTS

In This Issue

Welcome to the last issue of *International News* for 2010.

The focus for this issue is intellectual property and life sciences.

We start with a look at how it is possible, with careful portfolio management and creative commercial structuring, to realise greater value from intellectual property assets. In some cases, this can attract the additional benefit of increased tax efficiency, the holy grail of commerciality.

We move then to an examination of a recent US case which asks whether or not a gene can be patented. The court found that Myriad Genetics' patent claims directed to certain isolated DNA sequences were unpatentable. The case is currently on appeal and where the courts ultimately draw the line may have broader ramifications for the life sciences sector.

Staying with the subject of patents but moving to the European Union, we review the increasing complexity of the Supplementary Protection Certificates (SPC) regime. Given their commercial significance, SPC application procedures and policies have attracted the attention of EU competition authorities. The Court of Justice of the European Union has also recently restated the application of rules of privilege in investigations of alleged breaches of competition law. These factors suggest that now may be a good time for life science companies to reassess their strategies and procedures relating to SPCs.

We stay in the European Union with a look at the issues involved in the control and processing of data in clinical trials. Under the Clinical Trials Directive, every EU clinical trial that involves a pharmaceutical form or placebo being given to individual subjects must now have a "sponsor". Human subject clinical trials must also comply with the European data protection regime and the legislation of individual Member States.

Finally, Germany has long been the only country in Europe that allows pharmaceutical producers to determine their own prices for new, supposedly innovative products. This self-determination is coming to an end under a new law, which will come into effect on 1 January 2011.

Our Features section begins in China. In 1986 the People's Republic of China ratified the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the New York Convention), which requires the courts of signatory states to enforce foreign arbitral awards. For many, however, the question remains whether Chinese courts are faithful to the New York Convention in enforcing foreign arbitration awards against Chinese companies.

We move to the United States to review new guidance on the Foreign Account Tax Compliance Act (the FATCA provisions). As non-US financial institutions, trusts and other entities prepare for the new FATCA reporting and withholding regime that becomes effective as of 1 January 2013, it is important that they are aware of the scope of diligence that will be required of them.

Remaining in the United States, we look at a recent Massachusetts law that requires employers to give an employee notice whenever negative information is placed in their personnel file. This resembles EU employee privacy principles more closely than anything enacted previously in the United States and we ask if European privacy concepts are making their way across the Atlantic.

We then review the effect the US Dodd-Frank Wall Street Reform and Consumer Protection Act, effective with regard to investment advisory registration matters as of 21 July 2011, will have on non-US investment advisers.

Moving to France, we examine the implications of new Law 2010-476 of 12 May 2010, which is designed to open up to competition and regulate online gambling and gaming in France. The French Competition Authority's opinion, which will provide guidelines to authorised operators, is expected by the end of 2010.

Finally, we take a look at how to avoid an internal problem becoming a very public crisis. As one of the United States' first inventors, Benjamin Franklin, famously said, "An ounce of prevention is worth a pound of cure."

If you have any comments on this issue or would like to contribute to *International News*, please contact me at hnineham@mwe.com.

Hugh Nineham
Partner & London Office Head

Intellectual Property Planning and the Creation of Value

By **Rohan Massey** and **Peter Nias**

It is possible, with careful portfolio management and creative commercial structuring, to realise greater value from intellectual property (IP) assets. In some cases, this can attract the additional benefit of increased tax efficiency.

Intellectual Property Rights

IP rights are flexible; they can be assigned permanently or temporarily and they can be licensed in whole, or in part, on a territorial or field of use basis. Licences can be granted exclusively, non-exclusively or solely. This flexibility and the ease with which IP can be transferred internationally means it is relatively easy to restructure and relocate IP assets.

Intellectual Property Structuring

IP ownership can become fragmented. Acquired entities may begin using a group trade mark, or they may even apply for local trade mark registration, thereby fragmenting IP ownership by jurisdiction. Operating entities may continue to develop know-how and register patents and trade marks for their own products, thereby fragmenting know-how and creating tension in competing markets as different parties own similar rights.

IP ownership fragmented across a group suppresses value, as no single party has the power to exploit the IP globally. Without global rights there is always the risk of another party asserting rights against operating companies.

Maximising Value

There are two simple ways to maximise the value of IP assets. The first is to create IP centrally; the second is to consolidate existing IP in a single entity. There are a number of factors, however, that should be considered carefully in relation to any IP structuring: the commercial rationale for the project, specific IP issues and fiscal efficiency.

“IP ownership fragmented across a group supresses value, as no single party has the right to exploit it globally.”

Structure

The commercial rationale must be set out clearly and be well documented. This may include auditing the IP, hosting workshops with the management of the operating companies to discuss legal considerations surrounding the exploitation of IP, and educating management on the benefits of the proposal. Often operations management sees a proposed licence fee for the use of new group IP as a wasteful expense, but this expense may be looked on more favourably once the advantages of the proposal are explained. These may include the leveraging of services and skills across business units, group-level procurement savings, reduced human capital costs and better attraction and retention rates, and cross-branding opportunities.

Once the commercial rationale has been established, the new structure can take shape. This will usually involve the following basic steps:

1. Conducting an audit to identify the group's IP assets. A group-wide audit of the IP will give an overview of the rights held and their current ownership. Performing the audit has a number of additional advantages, such as presenting an opportunity to consolidate the progress of research and development companies in different jurisdictions. The audit may also reveal further gaps in ownership or protection.
2. Consolidating ownership. Having established the current ownership structure, IP rights can be transferred to new group company (IPHoldCo) from other group entities. Rights applied for after this transfer should be applied for in the name of IPHoldCo.
3. Licensing by IPHoldCo of the IP to operating companies (OPCos). The licence should be a non-exclusive, royalty-bearing licence (calculated on an arm's length basis) with a fixed-term agreement, enabling the OPCo to use the consolidated IP for the operation of their business. By having a limited, fixed term, IPHoldCo can refresh the IP periodically or link the licence to the term of the IP protection.

A significant factor in any structuring will be the location of IPHoldCo. Apart from the commercial considerations already discussed, fiscal efficiencies can

legitimately play a part in planning, producing savings that can assist a group in managing its effective tax rate. Tax authorities and international organisations such as the Organisation for Economic Co-operation and Development (OECD) recognise tax planning can play a part in any business decision-making process, provided the arrangements have the requisite commercial substance.

The UK Government (through HM Treasury and HM Revenue and Customs) is reforming the controlled foreign company (CFC) anti-avoidance legislation to include an exemption for offshore IP companies that undertake genuine and effective management activity with the aim of maintaining and/or increasing the value of their IP. In its Restructuring Paper, the OECD accepts that a restructuring can be carried out to obtain tax savings if functions, assets and/or risks are actually transferred. In other words, it can be tax motivated provided there is a commercial, non-tax purpose present.

Any transfer of IP between jurisdictions is likely to be a taxable event. The United Kingdom (as in other jurisdictions) is keen to avoid the artificial diversion of profits that could result from such a transfer, and the new CFC legislation, which will likely be effective in 2012, is expected to include some measures to protect that potential exchequer loss.

IP-Specific Issues

There are a number of IP-specific issues that need to be considered in any relocation that could adversely impact the value of the IP.

> There are two simple ways to maximise the value of IP assets.

For example, where the benefit of a structure results in the creation of a patent-holding company generating revenue streams from licensing the patents in its portfolio to others, this may affect the value of the patents when asserted. In the United States, only a patent owner has "legal standing" to prosecute an infringement claim in court. Whereas an exclusive licensee has the right to be joined as a co-plaintiff to such an action, a non-exclusive licensee has no such right, regardless of the level of economic harm it suffers. Even if the parent may have a claim of equitable ownership of the patent, this is generally not sufficient for the purpose of establishing legal standing in the United States, and the parent will be unlikely to succeed in claims to either injunctive relief or monetary damages.

If applied to the example structure, IPHoldCo will not be able to seek a recovery of OPCo's profits due to the infringement. Instead, as a non-manufacturing licensor, IPHoldCo's damage recovery will be limited to a reasonable royalty, which may be relatively small (20 to 25 per cent of a lost-profits calculation). Additionally, attempts to circumvent such restrictions by re-assigning the patent to the party actually using it prior to bringing suit will have limited success, as the period for any claim for loss of profits will be calculated from the date of the assignment. Such legal limitations can have a serious impact on the value of the patent.

Summary

Depending on the investment made in IP consolidation and its ongoing implementation, in our experience, the royalty may range from 0.5 per cent to 10 per cent of turnover.

Structures are flexible and, as such, can accommodate different attitudes to risk from an aggressive stance (in which rights are disposed of at an arm's length value and then licensed) to more conservative structures (in which any existing rights are licensed to the consolidating company, avoiding a taxable event on disposal, in return for an offset of the royalty paid by the owning company to use the IP globally).

Finally, it is critical that the commercial justification behind the proposed consolidation of the currently fragmented IP rights is well documented with contemporary evidence. That evidence will be needed to satisfy any tax authority that the structure has the requisite substance and meets any "genuine economic activity" test.

Rohan Massey is a partner based in the Firm's London office, focusing on IP. His client base is international in scope, as he works extensively across Europe and has been based in our Los Angeles office. Rohan can be contacted on **+44 20 7575 0329** or at **rmassey@mwe.com**.

Peter Nias is based in the Firm's London office and is head of the London Tax Department, where his practice focuses on direct and indirect tax advice on a broad range of corporate and commercial business activities for multi-national organisations. He can be contacted on **+44 20 7577 6920** or at **pnias@mwe.com**.

Court Ruling Strikes Down Gene Patents on Appeal

By **William (Bill) Gaede**

May a gene be patented? Or does a gene belong to all of humanity? It has long been held in the United States that inventions reflecting the "hand of man" can be patented. It has also long been established there that products of nature, abstract principles or natural phenomena may not be patented, but the applications of abstract principles or natural phenomena may. Since the early 1980s the United States Patent and Trademark Office (PTO) has issued patents on isolated DNA sequences, but the issue of whether such patents were patentable subject matter had never been challenged in court.

In May 2009 that changed when various individuals, medical researchers and organisations represented by the American Civil Liberties Union (ACLU) filed suit in New York challenging gene patents held by Myriad Genetics (Myriad). The patents cover two genes—BRCA1 and BRCA2—and methods for correlating mutations in those gene sequences. Mutations in the genes are detected through a Myriad-developed diagnostic test used to determine whether a woman is predisposed to breast and ovarian cancers. The cost of the test is approximately US$3,000 and, according to plaintiffs, Myriad is its sole supplier. Further, according to plaintiffs, Myriad has threatened to sue any entity that provides the diagnostic test or entities that perform research on BRCA1 and 2 mutations.

The ACLU suit sought effectively to overturn a long-standing policy of the PTO that isolated gene sequences are patentable subject matter. Under this policy the PTO has issued thousands of patent claims directed to isolated DNA sequences. Plaintiffs stylised the suit as one of control over one's personal genome, which is the very definition of a natural product that the patent laws do not cover. Plaintiffs further argued that patenting basic genetic sequence information impedes medical progress.

Myriad, with support from the life sciences industry, argued that patented gene sequences isolated from an individual through a series of chemical manipulations were no longer a product of nature and did not preempt all uses of the sequence. Myriad

and other life science companies further argued that a broad ruling striking down these types of patent claims would have a deleterious effect on the US biotechnology industry, retarding the development of new diagnostics and therapeutics tailored to an individual's genomic make-up. The US Congress on several occasions in the past has considered, but not passed, legislation addressing whether there should be restrictions on the ability to patent genes.

> Products isolated from nature must possess 'markedly different characteristics' from the product in nature.

On 29 March 2010 Judge Sweet of the US District Court for the Southern District of New York answered the question by granting the plaintiffs' motion for summary judgment in *Association for Molecular Pathology et al v USPTO and Myriad et al* 09-CV-4515. The highly significant ruling found that Myriad's patent claims directed to isolated DNA sequences, methods of detecting BRCA mutations and methods of using cells transformed with BRCA to screen for potential drugs are unpatentable subject matter under 35 U.S.C. Section 101.

Specifically, for the claims directed to just isolated DNA encoding the BRCA1 or 2 proteins (or fragments thereof), Judge Sweet held these claims were unpatentable subject matter because they claimed a product of nature. In doing so, Judge Sweet held that products isolated from nature must possess "markedly different characteristics" from the product in nature to constitute patentable subject matter. Notably, the Court rejected the application of the isolated DNA in gene therapy or for use in recombinant protein expression as evidence of a marked difference. In rejecting this evidence, the Court focused on the similar properties of the claimed isolated DNA and DNA in nature (*i.e.*, the genetic information encoded in its sequence). Further, Judge Sweet said DNA is "distinct in its essential characteristics from any other chemical found in nature [and its] existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes".

Myriad's method patents claimed methods of detecting BRCA mutations in a patient. Judge Sweet held these claims invalid because the claimed methods constituted unpatentable abstract mental processes of comparing or analysing two gene sequences, and the claimed steps of analysing and comparing failed to recite the specific transformative steps that are a hallmark of patentable subject matter. Judge Sweet further noted that even if the analysing or comparing steps were interpreted to include the steps of isolating DNA from a patient and sequencing that DNA, these transformative steps would be nothing more than data gathering, which is insufficient to meet the transformation requirement.

Myriad's cell-screening patent claimed methods of identifying compounds useful in treating BRCA-associated cancer by screening compounds against cells transformed with BRCA. Again Judge Sweet held these method claims failed the transformation test because the transformative steps were mere data gathering. In a footnote, Judge Sweet rejected the argument that drugs that affect the BRCA cell impart a patentable transformation for the claim because compounds that fail in the screen would have no such transformative effect.

Myriad has appealed this broad ruling and the appeal is now pending before the US Court of Appeals for the Federal Circuit. Briefing by the parties is ongoing and, on 29 October 2010, several friends of the court, or "*amicus*", briefs were filed. Surprisingly, the US Department of Justice (DOJ) filed an *amicus* brief opposing the patenting of genes *per se*, acknowledging that its position was at odds with the PTO policy, as well as various governmental agencies obtaining patents on such isolated DNA sequences. However, the brief acknowledged that chemical manipulations that result in, for example, cDNA, or genetically engineered crops or microorganisms, would constitute patentable subject matter, as these patent claims reflect more than the mere isolation and purification of a product from nature.

In contrast, a separate coalition of personalised medicine companies and organisations argued that Myriad's method claims comparing alterations in gene sequences from patient tissue samples for screening should be upheld under US Supreme Court precedent. The *amicus* brief further argued that a broad view of patentable subject matter was necessary to maintain the incentives to invest in personalised medicine. Without a broad view of patentable subject matter, the *amici* argued, "diagnostic companies would struggle to attract the investment necessary to drive future research and development", thereby "negatively impacting the US economy and diminishing the rate of advance toward new treatments powered by molecular information".

Judge Sweet attempted to limit the reach of the case by holding that DNA is a unique chemical molecule. Ultimately, however, many life science inventions intersect with nature. Powerful natural agents, such as taxol, have been isolated from nature and used as new chemotherapeutic agents. Proteins and antibodies based on natural products are used as therapeutic agents. In short, the life sciences draw on nature and where the courts ultimately draw the line may have broader ramifications.

The Federal Circuit Court will likely issue its decision by the middle of 2011. Any predictions on how the Court will rule are speculative, with a number of possible options. Ultimately, however, it is likely the US Supreme Court will answer definitively the question of whether isolated DNA sequences and methods for correlating sequence mutations may be patented.

William (Bill) Gaede is a partner based in the Firm's Silicon Valley office. He co-chairs the Firm's Life Sciences & Medical Devices group and focuses his practice on intellectual property litigation in the life sciences and medical device industries, as well as risk management for companies addressing freedom to operate issues. He serves as lead counsel for a wide range of companies and research institutes and has experience with genomics, proteomics, small molecule and protein therapeutics, antibodies, diagnostics, formulations and devices. Bill can be contacted on **+1 650 815 7435** or at **wgaede@mwe.com**.

SPCs: Is a Simplistic System Becoming Too Complicated?

By **Hiroshi Sheraton** and **Robert Lundie Smith**

Obtaining and enforcing Supplementary Protection Certificates (SPCs) for medicinal products in the European Union is a fertile ground for challenge and the law is still unclear in a number of key areas. Given their commercial significance, the application procedures and policies with respect to SPCs have attracted the attention of EU competition authorities. The Court of Justice of the European Union (ECJ) has also recently restated the application of rules of privilege in investigations of alleged breaches of competition law. These various factors suggest that now may be a good time for life science companies to reassess their strategies and procedures relating to SPCs.

The European SPC System

Delays caused by the need for lengthy and rigorous clinical testing of medicinal products have prompted many legislative systems around the world to operate a regime of patent term extension. The European Union introduced its solution in the form of the SPC in 1990 by way of Regulation 1768/92/EEC (the Regulation). Unfortunately, the simplicity of the legislation on its face has led to widespread uncertainty in its practical application.

At the core of the Regulation are the concepts of: i) a medicinal "product", ii) a "first marketing authorisation" (to place the product on the market in the European Community), and iii) a patent that "protects the product" that has not previously been granted an SPC. Unfortunately, each of these concepts have been beset by uncertainty in the case law.

What is a "product"?

Although a "product" is defined as the active ingredient or combination of active ingredients of a medicine, numerous cases have highlighted areas of uncertainty. For example, can a "product" be limited to a single active ingredient (that is protected by a patent) in a medicine that includes several other active ingredients?

Another uncertainty arises in that the particular use to which a product is intended to be put does not form part of the concept of the "product" itself, so raising questions about the viability of certain SPCs based on second medical uses.

> "Now may be a good time for life science companies to reassess their strategies and procedures relating to SPCs."

What is the "first marketing authorisation" for the product?

This question has arisen when considering medicines made up of several components, *e.g.*, when an earlier marketing authorisation

includes a combination of active ingredients and an SPC is granted in relation to a later authorisation for one of the components on its own. As discussed below, the practical meaning of the term has also come under scrutiny.

In addition, the geographic scope of this provision has led to uncertainty, *e.g.*, how the rules apply to marketing authorisations in Switzerland/Liechtenstein and new accession states of the European Union.

> This … presents particular challenges, given the state of the law as a whole.

When does a patent "protect a product"?
Perhaps most fundamentally, the meaning of this apparently simple phrase is open to debate. It is thus not clear if it is sufficient that an authorised product would infringe a patent or whether the claim (or specification) of the patent must disclose the particular product/combination in question and, if so, to what extent. Different courts in Europe have repeatedly reached conflicting decisions on this question.

A duty of candour for SPC and other applications?
How applicants address this legal ambiguity in their dealings with patent offices can have significant implications from a competition law perspective. A widely reported breach of competition law arising from alleged abuse of the SPC system has recently been confirmed by the Advocate General of the Court of Justice. At the time of the SPC application in question, it was unclear as a matter of law whether a "first marketing authorisation" referred to the actual grant of a marketing authorisation or to the practical ability to place the medicine on the market, which could be delayed several years. The applicant adopted the most favourable position. By doing so, it was alleged that it unlawfully abused its dominant position and materially misled patent offices, resulting in an extended monopoly to which the company ultimately was not entitled.

Importantly, the Court indicated that, insofar as a company is wrongfully granted an exclusive right, it has a "special responsibility" not to impair genuine undistorted competition that requires it "at the very least" to inform the patent office of any errors made in its communications.

In the field of SPCs, this potential duty to highlight to patent offices alternative interpretations of the law presents particular challenges, given the state of the law as a whole.

Restrictions on Privilege

Of course, in order to assess the prospects of whether an alternative interpretation should be presented, applicants will normally take advice from specialist legal counsel and/or patent attorneys, both internal and external. Another recent case from the ECJ underlines the fact that, in stark contrast to the position in the United States, many such communications will not attract privilege from disclosure in European investigations under competition laws.

That case focused on whether communications with in-house legal counsel admitted to the relevant national bar were immune from disclosure on the grounds of legal professional privilege. The debate centred on whether in-house lawyers are sufficiently independent to justify their communications being protected by privileged. The Court held that, since an in-house lawyer is bound economically to his or her employer and is more closely linked to its commercial policy, mere membership of a bar does not ensure sufficient independence to give rise to privilege.

It was noted in the course of the decision that this differs from the position under the national laws of certain Member States where privilege *does* extend to communications with in-house counsel. The ECJ nevertheless held there is no requirement for EU law and national law to apply the same standards.

> The European Patent Convention does not form part of the legal structure of the European Community.

Although not binding, the Advocate General's opinion in this case took a clear position that privilege does not apply to communications with individuals who are not admitted to the bar of an EU Member State. Significantly, this rationale would also appear to apply to communications with external US counsel and to external European patent attorneys. The reason is that the privilege is said to attach only to communications that affect the right of defence of the client to the investigation in question. Whilst communications with European patent attorneys "in their capacity as such" are afforded privilege under recent amendments to the European Patent Convention, it is debatable whether that privilege will protect documents from disclosure in Commission investigations. First, it is not clear whether it is possible for a European patent lawyer's remit "as such" to extend to questions of European competition law. Further, it should be remembered that the European Patent Convention does not form part of the legal structure of the European Community or any EU Member State.

Conclusion

It is almost unprecedented that the law concerning SPCs, having such commercial significance, should create such uncertainty. Moreover, it is unfortunate that disputes uncovering such uncertainties should coincide with an increased scrutiny of patent protection from a European competition perspective and the apparent erosion of attorney-client privileges.

Nevertheless, any organisation considering taking advantage of the patent term extension provided by SPCs should take careful note of these developments, and take steps to ensure appropriate strategies are adopted and suitable processes for their execution are implemented.

Hiroshi Sheraton is a partner based in the Firm's London office. He originally trained as a medicinal chemist in industry and has a degree in biochemistry and molecular biology. Hiroshi focuses his practice on all aspects of intellectual property law, with a particular emphasis on the life sciences sector. He can be contacted on **+44 20 7575 0324** or at **hsheraton@mwe.com**.

Robert Lundie Smith is an associate based in the Firm's London office, and is qualified as a Barrister of England and Wales. He originally trained as a chemical physicist and has a degree in chemistry and Ph.D. in chemical physics. He can be contacted on **+44 20 7575 0371** or at **rlundie-smith@mwe.com**.

Controlling and Processing Data in EU Clinical Trials

By **Rohan Massey** and **Paul Melot de Beauregard**

The legal regime for the conduct of clinical trials of medicinal products for human use in the European Union is set out in Directive 2001/20/EC (the Clinical Trials Directive). Pursuant to this, every EU clinical trial that involves a pharmaceutical form or placebo being given to individual subjects must now have a "sponsor" that is established, or has a legal representative, in the European Union.

The sponsor is an individual, company, institution or organisation that must take responsibility for the proper initiation, management and/or financing of the clinical trial. The sponsor is also legally responsible for applying for the authorisation for a trial, as well as for ensuring there is sufficient insurance or indemnity in place to cover the liability of the sponsor and its sub-contractors. The conduct of the trial will often be sub-contracted to a trial centre, more formally known as a Clinical Research Organisation (CRO). The CRO will in turn use investigators, usually doctors on site in hospitals, to collect data from trial participants. However, such sub-contracting does not shift the sponsor's potential legal exposure to penalties for breach under the Clinical Trials Directive.

In parallel with the Clinical Trials Directive, any human subject clinical trials that require the collection, analysis, transfer, storage and eventual destruction of data taken from individuals must also comply with the European data protection regime, as set out in Directive 95/46/EC (the Data Protection Directive) and in the legislation of individual Member States.

The roles and responsibilities of the parties set out clearly in the Clinical Trials Directive may not be as easy to determine under the data protection regime. As such, a clinical trial may involve more than one controller, or indeed more than one processor. It is crucial to get a sense of the obligations under the respective data protection regime in the relevant jurisdiction(s) before starting a clinical trial in any European country.

The Data Protection Directive

It is important to identify clearly the roles of the parties in any clinical trial, as the roles will determine the following: who will be responsible for compliance with EU data protection rules, which Member State laws apply, which data protection authorities are competent to supervise data processing operations and how data subjects can exercise their rights.

> "The factual matrix is the key to determining roles within the data protection regime."

On 16 February 2010, the Article 29 Working Party, an independent EU advisory body for data protection matters, adopted Opinion 1/2010, which confirms that the current definitions of the terms "data controller" and "data processor," as set out in the Data Protection Directive, continue to be relevant and workable.

The Working Party, however, recognised the difficulty in applying these concepts to complex processing environments (such as clinical trials) and provided guidance intended to clarify the allocation of the two roles and their respective responsibilities. Although the opinion is not legally binding, it is likely that national authorities will take it into account when applying the national laws transposing the Data Protection Directive.

The Data Controller

The Working Party identifies and interprets the three main building blocks of the data controller definition:

1. "Natural or legal person"—the potential addressee
2. "Which alone or jointly with others"—allows pluralistic control
3. "Determines the purposes and means of processing"—the decisive competence of the data controller

When considering point 3 (*i.e.*, the why and how of processing activities), the Working Party highlighted the importance of the factual circumstances. Contracts stipulating who determines the purpose and who, thus, shall be the data controller, may only give an indication of the parties' intentions, and it will be the conduct of the parties that will be determinative. Even if a contract is silent on who is the data controller, it can still contain sufficient elements to assign the responsibility of data controller to a party that apparently exercises, at least in practice, a dominant function in that regard.

> "The risks of failure to understand and comply with the regime are now more serious than ever."

In determining the purposes and means, the Working Party focuses on the "purpose" of processing rather than the "means" of processing. Accordingly, whoever decides on the purposes of the data processing operation triggers the qualification to be the (*de facto*) data controller. Determination of the means of processing can be delegated by the data controller as far as technical or organisational measures are concerned. Substantial decisions that may affect the lawfulness of the data processing, however, may only be determined by the data controller. In a situation where both trial centres and sponsors make important determinations with regard to the way personal data relating to clinical trials is processed, they may be regarded as joint data controllers. For example, if the trial centre carries out trials autonomously—albeit in compliance with the sponsor's guidelines—and the centre is responsible for the safekeeping of documents, it would appear that responsibilities are vested in the individual parties.

> "Sub-contracting does not shift the sponsor's potential legal exposure to penalties."

The Data Processor

Because a data processor must be a legal person or entity separate to the data controller and must process personal data on the data controller's behalf, it is expected to execute and implement the data controller's instructions. A data processor may, however, at its own discretion, choose the most suitable technical and organisational means for processing without qualifying as (joint) data controller.

The lawfulness of the processing by the data processor depends on the specific mandate given by the data controller, but a data processor working beyond that mandate could be viewed as assuming the responsibilities of a (joint) data controller. There is, of course, a certain degree of flexibility in sharing and allocating data protection obligations and responsibilities provided all parties are compliant. Also, the relationship between the sponsor and the trial centres could be structured so that the sponsor determines the purposes and the essential elements of the means while the trial centre is left with a very narrow margin for manoeuvre and autonomy.

According to the Working Party, the Directive allows several entities to be designated as data processors or data sub-processors, as long as they comply with the instructions of the data controller(s).

Comment

Assuming personal data is collected, on the surface it would appear that the sponsor will be a data controller, because it is responsible for designing the study and consequently determines the purpose of the processing of the data. The CRO will be a data processor because it carries out the trials in compliance with the sponsor's guidelines. Although an individual investigator is likely to be a data processor, much will depend on how the data is being collected from participants and whether the trial data is being collected discretely from any other personal data.

What is clear from the opinion is that the factual matrix is the key to determining roles within the data protection regime. Although it is always a good starting point to set out in any commercial agreements and codes of practice the roles between parties, there must be periodic review to ensure that roles have not evolved or changed. A contractual agreement will not provide any defence for the data processor whose role has morphed into that of a data controller and who fails to comply with the increased burdens placed on the data controller. With data protection authorities in Europe focusing increasingly on enforcement, and sanctions for non-compliance reaching US$750,000, the risks of failure to understand and to comply with the regime are now more serious than ever.

Rohan Massey is a partner based in the Firm's London office. He focuses on data protection, IT and IP structuring and commercialisation. Rohan can be contacted on **+44 20 7575 0329** or at **rmassey@mwe.com**.

Paul Melot de Beauregard is a partner based in the Firm's Munich office. His practice covers data protection as well as labour and employment law. Paul can be contacted on **+49 89 12712 121** or at **pbeauregard@mwe.com**.

An End to Free Pricing in the German Pharmaceuticals Market

By **Stephan Rau**

Germany has long been the only country in Europe that allows pharmaceutical producers to determine freely their prices for new, supposedly innovative products. As a consequence, prices for these products are higher than in most other countries, except the United States, though there are some exceptions made for generic medicines and those used to treat specific diseases (*e.g.*, under the *Festbetragsregelung*).

This self-determination is coming to an end however. A new law, the *Arzneimittelmarktneuordnungsgesetz* (AMNOG), which will come into effect on 1 January 2011, obliges the regulatory authority, the *Gemeinsamer Bundesausschuss* (GBA), to publish within three months of a new drug entering the German market a report on the additional benefit of the new product as compared to other products already available. This report will be based on documents that pharmaceutical companies will have to submit to the GBA. Pharmaceutical companies will be obliged to submit and make available to the public all documents (such as clinical trial protocols and results, and any related documents) in connection with a new or altered product. This therefore includes not only the documents supporting the claimed benefits of the new product, but also study results or other documents that demonstrate a claimed additional benefit is dubious or even non-existent.

On the basis of these widely published documents, the public (including administrators of statutory health funds) will have the opportunity to comment on the GBA's preliminary decision within three months of that decision being published.

> The Association will have six months to negotiate the final price for the new product with the producer.

After the three months have expired, the GBA will publish a final decision on the additional benefit of the new product. If the product has not been found to have any additional benefit, the exception for firmly

determined caps for certain products under the *Festbetragsregelung* will apply. If the GBA finds that it does provide additional benefit, the Association of German Statutory Health Funds (the Association) will have six months to negotiate the final price for the new product with the producer. If the Association and the pharmaceutical company do not come to an agreement, they are obliged to go to arbitration, which will determine the final price.

> The public … will have the opportunity to comment on the GBA's preliminary decision.

Given that this new system of negotiation of prices, which is beyond European public procurement law and must take place within a fixed, short period of time, marks a change of paradigm for the German pharmaceuticals market, it can be assumed that shortly after AMNOG has entered into effect a large proportion of negotiations will have to be resolved by the arbitral body. Developing the jurisdiction of the arbitrators so that pharmaceutical companies and the Association of Statutory Health Funds will be able to rely on their decisions is likely to be a slow process.

It is still largely unclear how those new rules will be implemented in practice. In particular, the short time periods applicable are striking and it remains to be seen how the GBA, with its current limited staff capacities, will be able to cope with its new challenges. However, after some time, one should expect to see a real change in the German pharmaceutical market. This will likely be to the detriment of producers of items that are actually *not* innovative, but will benefit the producers of genuinely innovative products. That is, at least in comparison with the potential alternatives, such as pure price regulation by authorities.

While still limiting pharmaceutical companies' ability to determine prices of their new products freely, the AMNOG reinforces the application of German antitrust law and European Public Procurement Law for agreements between statutory health funds and pharmaceutical companies. Although for some time German antitrust law was considered inapplicable to such agreements, its applicability was reinforced in 2007 with the caveat that antitrust law—to the extent applicable—was largely to be applied by social security courts, which have a tendency to decide in favour of statutory health funds. Now, the AMNOG regulates that antitrust law shall again be applied by the antitrust chambers of ordinary courts. This will no doubt lead to a growing importance of antitrust law for agreements between large statutory health funds and smaller pharmaceutical companies.

What is also striking is that the price resulting from negotiations or an arbitrator's decision will also apply to the approximately 12 per cent of the country that is privately insured. This is a major new development, one that private insurers will no doubt welcome. It marks a fundamental step toward overcoming the immense price differences currently existing between prices applicable to statutory health funds on one side and private payers/insurers on the other. In this respect the AMNOG marks another milestone. However, this milestone was supposed to be linked to another reform, which would have led to payers of higher taxes (who are often privately insured) contributing disproportionately to the financing of the statutory health fund system. The reform of the financing structures of the statutory health fund system was, however, largely blocked by a regional party in the German Government, as well as by the representation of state governments in the Upper Chamber of German Parliament.

> If the Association and the pharmaceutical company do not come to an agreement, they are obliged to go to arbitration.

Thus, while the new government has been fairly unsuccessful in reforming the financial basis of the statutory health fund system, it has successfully introduced landmark reforms to pharmaceutical pricing for statutory health funds and private insurances, as well as with respect to the importance of antitrust law. As a happy side effect, it appears to have achieved some of the reforms it was prevented from achieving earlier in the year.

Stephan Rau is a partner based in the Firm's Munich office. He is a member of the Firm's Health Industry Advisory Practice Group and focuses his practice on corporate law, M&A transactions and health care regulation (including academic organisations), licensing issues and related compliance. Stephan has worked for various private equity companies and strategic investors, speaks regularly at health care conferences and is the author of numerous publications on corporate law and licensing issues. He can be contacted on **+49 89 12712 322** or at **srau@mwe.com**.

"Public Policy" and the Enforcement of Foreign Arbitration Awards in China

By **Henry Chen** and **B. Ted Howes**

In 1986, the People's Republic of China ratified the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the New York Convention), the multinational treaty that requires the courts of signatory states to enforce foreign arbitral awards. For many, however, the question remains whether Chinese courts are faithful to the New York Convention in enforcing foreign arbitration awards against Chinese companies.

The New York Convention permits the courts of signatory states to refuse to enforce foreign arbitral awards that violate the "public policy" of the state. Western courts have generally interpreted this public policy exception very narrowly, only vacating awards that clearly violate the due process rights of the participants, *e.g.*, where there is evidence that one of the arbitrators was bribed.

Practitioners outside China tend to believe Chinese courts are far more willing to invoke public policy as a reason to reject the enforcement of foreign arbitral awards. This, however, is somewhat of a misconception. Because any Chinese court decision refusing to enforce a foreign arbitral award is subject to the *mandatory* review of the Supreme People's Court of China (SPC), the SPC has been able to monitor attempts by the Chinese lower courts to reject foreign arbitral awards. This mandatory review requirement, which was adopted by the SPC in 2000, has apparently had a positive effect. According to a 2008 speech by Deputy Chief Justice of the SPC, Wan E'xiang, between 2000 and 2008 the SPC did not uphold a single decision by the Chinese lower courts that refused to enforce a foreign arbitral award on public policy grounds.

Still, the fact that public policy is not defined by Chinese law is problematic for foreign companies that hope to enforce foreign arbitration awards in China. Under some Chinese protocols, public policy has been equated with "social public interests", but this term itself is vague and subject to manipulation. According to the Deputy Director of the Enforcement Bureau of the SPC, "'social public interests' is a concept that falls within the political domain rather than a term of law. … For a foreign-related or foreign arbitral award, social public interests are the same as the State's sovereign interests."

In order to better understand how Chinese courts apply the concept of public policy to foreign arbitration awards, it is instructive to consider three specific case studies.

Case Study 1: Morality

In this first case, dating from 1977, a US band contracted to perform a concert in China. This concert, however, was suspended when Chinese authorities asserted that the performance included heavy metal music that had not been approved by the Ministry of Culture of China, and was otherwise "not suitable" for China. After not being paid, the musical group commenced arbitration and the arbitration tribunal awarded damages to the performers.

Upon review of the arbitration award, the SPC concluded the performance did in fact violate China's social public interest and, as such, the performers had breached the contract. As a result, the SPC held that the arbitral award could not be enforced without damaging China's social public interests and refused to enforce the award.

Admittedly, this case took place over three decades ago, and the moral issue that the authorities had with the music would likely not be a public policy issue in China today. Nevertheless, morality is a relative concept, and this case demonstrates that morality does play a role in the Chinese concept of public policy.

Case Study 2: Mandatory Administrative Regulations

In this second case, dating from 1999, a Japanese company commenced an arbitration against a Chinese state-owned enterprise (SOE) under the Arbitration Rules of the Stockholm Chamber of Commerce. Specifically, the Japanese company alleged the SOE was contractually obligated to pay back certain debt owed to the Japanese company by a Hong Kong company, and that the SOE was delinquent in repaying this debt.

After the Stockholm tribunal ruled in favour of the Japanese company, the SOE challenged the award in a Chinese court, arguing the award violated Chinese public policy because the repayment of the foreign debt to the Japanese company had not been approved by the State Administration on Foreign Exchange and this approval was compulsory. The lower court agreed and refused to enforce the award.

Upon review, the SPC agreed with the lower court that the SOE had violated Chinese law regarding the approval of foreign debt, as well as China's policies on the foreign exchange administration. However, the SPC went on to explain that "violations of compulsory provisions in the administrative regulations and departmental regulations *will not naturally constitute a violation of the public policy of China*" (authors' emphasis). The SPC therefore reversed the lower court's decision, ruling that the award could not be vacated on public policy grounds.

Case Study 3: Sovereignty of the Chinese Courts

In this third case, dating from 2009, a Chinese company and three foreign companies executed a contract to form a joint venture. This contract provided that all disputes among the parties would be resolved by International Chamber of Commerce (ICC) arbitration. When a dispute subsequently arose between the Chinese company and the joint venture entity, the Chinese company commenced a lawsuit against the joint venture entity in the Chinese courts, which ruled in favour of the Chinese company and ordered the assets of the joint venture be impounded. The three foreign parties thereafter commenced an ICC arbitration against the Chinese party. The foreign tribunal held that the Chinese company had breached the joint venture contract by petitioning a Chinese court to impound the joint venture assets, and awarded damages to the foreign parties.

When the Chinese company did not pay these damages, the foreign parties brought suit in China, seeking enforcement of the arbitral award. The Chinese court, however, held that the arbitration clause in the joint venture contract only covered disputes between the contracting parties and, therefore, did not cover the dispute between the Chinese party and the joint venture entity (which was not a party to the contract). As a result, the Chinese court ruled that the ICC arbitration award, by purporting to resolve a dispute that was subject to the jurisdiction of the Chinese courts, violated China's judicial sovereignty and, with it, Chinese public policy. This decision was affirmed by the SPC, which ruled the arbitration award should not be enforced.

Conclusion: An Evolving Judiciary

The above three case studies provide some parameters about what constitutes public policy under Chinese law with respect to the enforcement of foreign arbitral awards. As appears from Case Study 2, the violation of administrative regulations, even mandatory regulations, does not constitute public policy. Rather, a violation of public policy seems to require proof of an affront to the higher social public interest of China, whether it relates to China's moral order (Case Study 1) or the sovereignty of its courts (Case Study 3).

While no one can ever guarantee a foreign arbitral award will be enforced in China, the climate is better than many think. Moreover, if China expects its economy to continue its global march, it seems clear that it will increasingly require a more sophisticated and "internationalist" judiciary to soothe foreign investors and importers. The Chinese concept of public policy, as applied to foreign arbitration awards, will also need to evolve.

Henry Chen is a partner of MWE China Law Offices based in Shanghai. He advises clients on international arbitration, domestic litigation, compliance with the Chinese Anti-Monopoly Law, antitrust filings, Foreign Corrupt Practices Act investigations and auditing, and other corporate services. Henry is a member of the New York State Bar Association and the Commissioner of the Economic Committee of All China Lawyers Association. Henry is also a member of the Swiss Arbitration Association. He can be contacted on **+86 21 6105 0586** or at **henrychen@mwechinalaw.com**.

B. Ted Howes is a partner based in the Firm's New York office and is the head of the Firm's International Arbitration practice. Ted also has significant experience handling Chinese arbitrations. He can be contacted on **+1 212 547 5354** or at **bhowes@mwe.com**.

Initial Guidance on the US Foreign Account Tax Compliance Act

By **Andrew Stone** and **David Adler**

The Hiring Incentives to Restore Employment (HIRE) Act of 2010, which became US law on 18 March, largely incorporates the legislation previously circulated as the Foreign Account Tax Compliance Act (the FATCA provisions). The FATCA provisions force non-US financial institutions to provide the US Department of the Treasury (the Treasury) with information sufficient to establish which accounts are held by US persons, or suffer 30 per cent withholding on US-source payments to those accounts.

Guidance on the FATCA provisions was released on 27 August 2010 in Notice 2010-60 (the Notice), which describes how non-US financial institutions are to comply with these new information reporting requirements and how US payors to non-US entities are to comply with the corresponding new withholding, documentation and reporting obligations.

The FATCA provisions will be effective for payments made after 31 December 2012, although payments on "obligations" that were outstanding as of 18 March 2012 will be exempted from the new regime. The Notice provides that the term "obligations", for this purpose, does not include any instrument treated as equity for US tax purposes or any legal agreement that lacks a definitive expiration or term (*i.e.*, savings deposits, demand deposits or brokerage or custodial accounts). The Treasury intends to issue regulations providing that any significant modifications to grandfathered obligations within the meaning of regulation Section 1.1001-3 will result in the obligation being treated as newly issued for purposes of the FATCA provisions.

> The Notice provides helpful preliminary guidance.

Definitions and Examples

The FATCA provisions define "foreign financial institution" as any non-US entity that: 1) accepts deposits in the ordinary course of a banking or similar business, 2) holds financial assets for the account of others as a substantial portion of its business, or 3) is engaged in the business of

investing or trading in securities, partnership interests or commodities, or interests in the same. The Notice provides that the Treasury intends to issue regulations on each of these three categories, and in the interim provides examples of each. Illustrative examples of entities described in each respective category are: 1) savings banks, commercial banks, savings and loan associations, thrifts, credit unions, building societies and other cooperative banking institutions; 2) broker-dealers, clearing organisations, trust companies, custodial banks, and entities acting as custodians with respect to the assets of employee benefit plans; and 3) mutual funds, funds of funds, exchange-traded funds, hedge funds, private equity and venture capital funds, other managed funds, commodity pools, and other investment vehicles. Importantly, the Notice states explicitly that a trust company will be considered a foreign financial institution. The Notice further states that "a small family trust settled and funded by a single person for the sole benefit of his or her children" could be categorised as a foreign financial institution, although goes on to provide that the Treasury is considering adopting a less burdensome reporting regime for such "small" foreign financial institutions.

> The FATCA provisions will be effective for payments made after 31 December 2012.

Foreign Financial Institution Compliance

The FATCA provisions require a foreign financial institution to enter into a Foreign Financial Institution (FFI) Agreement to avoid 30 per cent withholding on payments from US payors. The Treasury has yet to publish a draft, but under such an agreement the foreign financial institution would undertake to obtain and report information regarding each holder of each of its accounts in accordance with due diligence procedures prescribed by the Treasury. Further, it would agree to withhold on payments to non-participating foreign financial institutions and to account holders who fail to provide the information necessary to determine whether they are US persons. Pursuant to an FFI Agreement, the foreign financial institution would undertake to obtain and report: i) the name, address and taxpayer identification number of each US account holder that is not otherwise exempted from the FATCA provisions; ii) for accounts held by non-US entities, the name, address and taxpayer identification number of each US person that has a 10 per cent interest in such entity; iii) the account number; iv) the account balance and value; v) the gross receipts and gross withdrawals or payments from the account; and vi) such other account-related information as the Internal Revenue Service (IRS) may request.

The Notice describes the procedures to be applied by participating financial institutions to make the determinations required to comply with the FATCA provisions. The FATCA provisions only apply to accounts with an average month-end balance of US$50,000 or more. A foreign financial institution will be able to rely on any W-9s it has collected with respect to such accounts and so treat them as US accounts. For all other existing accounts, the foreign financial institution shall mine its "electronically searchable information" associated with the account for "indicia of potential US status", which the Notice describes as: a) identification of any account holder as a US resident or US citizen, b) a US address, c) a US place of birth for the account holder, d) an "in care of" or "hold mail" address, e) a power of attorney or signature authority granted to a person with a US address, or f) standing instructions to transfer funds to an account maintained in the United States, or directions received from a US address.

If the foreign financial institution finds any such indicia of potential US status, it is then to obtain either IRS Form W-9 from the account holder to establish US status or IRS Form W-8BEN to establish non-US status, as the case may be. Account holders who do not provide the information requested will be subject to 30 per cent withholding. The foreign financial institution will have one year from the effective date of its FFI Agreement to search its databases and make the requisite information requests of its account holders.

The Notice creates analytically distinct categories for accounts opened by individuals after the effective date of an FFI Agreement, but the procedures are essentially the same as for pre-existing accounts. The FFI will gather W-9s or otherwise examine the information collected in connection with opening the new account, and will likewise categorise the account as a US or non-US account based on the presence or absence of the same "indicia of potential US status" described above (however, without regard to whether the account information is held in "electronically searchable files"), unless the account holder provides documentary evidence to the contrary. Similarly, the procedures for accounts held by entities, opened before and after the effective date of an FFI Agreement, closely mirror the procedures for individual accounts.

As non-US financial institutions, trusts and other entities prepare for the new FATCA reporting and withholding regime that becomes effective as of 1 January 2013, the Notice provides helpful preliminary guidance as to the scope of diligence that will be required of non-US financial institutions in order to identify US accounts if withholding on payments of US source income is to be avoided. It will be interesting to see whether the FATCA provisions achieve their intended result of greater transparency and cross-border information sharing, or instead trigger a degree of capital flight from the United States and deepen the growing reluctance of certain non-US financial institutions to maintain accounts on behalf of US clients.

More information on the FATCA provisions is available at www.mwe.com/info/news/wp0410b.pdf.

Andrew Stone is a partner based in the Firm's Chicago office. He counsels individuals, families, fiduciaries and family offices on all aspects of estate planning, with an emphasis on international aspects of estate planning. Andrew can be contacted on **+1 312 984 7577** or at **astone@mwe.com**.

David Adler is an associate based in the Firm's New York office. He advises on personal income and transfer tax matters. David can be contacted on **+1 212 547 5896** or at **dadler@mwe.com**.

New Massachusetts Law: The Start of a US Trend toward EU Privacy Principles in the Workplace?

By **Heather Egan Sussman** and **Alison Wetherfield**

Multinational companies doing business in the United States, the European Union and beyond are all too familiar with how vastly laws can differ across jurisdictions.

A good example is the gulf between the privacy laws of the United States and the European Union. Under the EU's Data Protection Directive (95/46/EC), EU employers are required to inform employees of the types of personal data they expect to process and to follow a set of principles during that processing to ensure that it is lawful and fair, which may include seeking specific consent from the employee in certain circumstances. In the United States, by contrast, there are comparatively few statutory privacy protections in place when it comes to processing an employee's personal data. With limited exceptions, US employers are free to process all kinds of sensitive information about their employees—from racial and ethnic origin to sexual orientation and political opinions—without the employee ever being notified, let alone asked for consent.

These two worlds seem to be moving closer as a recent Massachusetts law now requires employers in that state to give an employee notice whenever negative information is placed in an employee's personnel file. This resembles EU employee privacy principles more closely than anything enacted previously in the United States. Are European privacy concepts making their way across the Atlantic? Is this a good thing?

The Massachusetts Law

The new amendment to the existing Massachusetts Personnel Record Law, M.G.L. c. 149, Section 52C, now requires Massachusetts employers to, among other things,

… notify an employee within 10 days of the employer placing in the employee's personnel record any information to the extent that the information is, has been used, or may be used, to negatively affect the employee's qualification for employment, promotion, transfer, additional compensation or the possibility that the employee will be subject to disciplinary action.

Apparently, two legislators pushed for the amendment after a local police officer lost a promotion based on information he never knew was in his personnel file.

Interestingly, the existing Personnel Record Law already gave the officer the statutory right to respond to information in his file. The amendment now purports to ensure that employees will know when negative information has been placed in their file, so they may assert this statutory right to respond. The law also gives the employee the right to review, inspect and be given a copy of his or her personnel record within five days of submitting a written request.

The newly amended law does not, however, create a private right of action for aggrieved employees. Only the Massachusetts Attorney General can enforce the Personnel Record Law and each violation is punishable by a fine of between US$500 and US$2,500. Thus, if an employee is dismissed based on information not shared previously, the employee must take his or her complaint to the Attorney General who then can elect whether to investigate and assess a penalty. In other words, the employee has no independent right to sue for reinstatement or back pay in such circumstances.

The European Approach

The EU Data Protection Directive sets baseline principles governing the rights of "data subjects": people who are identified or identifiable from information ("personal data") processed by "data controllers" who determine the purpose and means of that processing.

EU Member States are free to increase the protections for their residents when they write their own laws implementing the Directive's principles, but at a minimum the principles give European employees the right to be informed by their employer—who is the "controller" in this case—of the purposes for which the information about them is processed and of their right to access the information and rectify it if incorrect or inaccurate.

The access right is, at a minimum, access "without constraint at reasonable intervals and without excessive delay and expense" to the data in an intelligible form. Different EU Member States approach this in different ways. In the United Kingdom, for example, the employee/data subject has to ask in writing with some specificity as to what is sought, pay £10 and wait up to 40 days, but can then access not only a hard copy personnel file, but also e-mails about them (usually redacted for any contents identifying other data subjects).

Most EU employers deal with the "information" requirement by having a broad statement in their handbooks about what sort of data they expect to process about employees, including data relevant to appraisal, promotion, discipline, *etc.* There is no general content-based requirement to inform the employee about a specific, routine, but possibly negative piece of information generated by the employer.

When information comes to the employer from a third party (*i.e.*, not from the employee), information about the purposes of its processing should, according to the Directive, be provided "at the time of undertaking the recording". Again, most employers deal with this in a general data protection policy. Certain EU Member States do, however, take a strict approach to "non-standard" data. France, for example, takes a very strong legal stand against allowing whistle-blowing claims to be registered against employees by third parties unless they relate to serious risks to the company in the fields of accounting, financial audit, bribery and banking, or other serious risks to the vital interests of the company or its employees' physical or mental integrity. If a claim outside these areas is made, the French Data Protection Authority, CNIL, advises that the reported person should be informed unless the report is deleted rapidly, so that the employee can exercise his or her rights of access and rectification. This is a position that many US multinationals will recognise as having complicated the establishment of group-wide Sarbanes-Oxley compliance helplines in France.

A Cultural Shift in the United States?

While the amendments to the Massachusetts law may appear to be an isolated, state-based example with limited application, if the approach begins to take hold in other US states, it could signal the start of a broader cultural change in the US workplace from a privacy rights perspective. Texas was the first state to enact a law giving employees the right to be notified when an employer "processes" negative information about them by placing it in a personnel file, although it applies only to public sector employees in the Sheriff's Department. The Massachusetts law has now expanded the requirement beyond the public sector and into all Massachusetts workplaces. In addition, from a data protection and employment rights perspective, the Massachusetts law seems actually to go beyond existing European protections both in terms of process—placing far more onerous and frequent obligations upon employers—and by focusing on content (European data protection laws are generally content neutral).

Conclusion

It may be too early to tell whether the Massachusetts law signals a broader trend. In the meantime, there is no question that in-house privacy officers and persons responsible for data management at companies with employees in Massachusetts need to be aware of this new requirement and evaluate how it will affect their existing policies and procedures. In particular, companies with multi-jurisdictional reach will be wise to consider the broader implications of this new Massachusetts law and consider whether and how to accomplish its requirements while, at the same time, staying consistent with the culture of the existing workplace.

An expanded version of this article appeared in BNA's Privacy & Security Law Report, 9PVLR38, 09/27/2010. Portions of the article were reprinted here with permission from BNA. Please contact the authors for a copy of the full article as it appeared in the BNA's Privacy & Security Law Report, including an expanded analysis of how multinational companies can adapt their existing privacy policy frameworks to account for these legal developments.

Heather Egan Sussman is a partner in the Firm's Boston office. She brings a practical, business-sense approach to solving workplace issues that helps clients efficiently and effectively manage every kind of HR risk. Heather can be contacted on **+1 617 535 4177** or at **hsussman@mwe.com**.

Alison Wetherfield is head of the London office Employment Group, where her practice focuses on employment and labour law in the United Kingdom and the European Union. She can be contacted on **+44 20 7577 3489** or at **awetherfield@mwe.com**.

Dodd-Frank Act Effect on Non-US Investment Advisers

By **Edwin (Ted) Laurenson**

The Dodd-Frank Wall Street Reform and Consumer Protection Act (the Act), enacted on 21 July 2010 and effective with regard to investment advisory registration matters as of 21 July 2011, mandates significant changes to the regulation of offshore (from the United States) investment managers. The Act deletes the existing "private adviser" exemption from required registration with the US Securities and Exchange Commission (SEC). In its place, the Act adds a set of exemptions for investment advisers to "private funds" and "foreign private advisers".

Managers that advise only private investment funds will be exempt from SEC registration, but subject to SEC-specified record-keeping and reporting obligations, if they have "assets under management in the United States" of less than US$150 million. Virtually all hedge and private equity funds will be "private funds", which are investment funds that rely on either section 3(c)(1) of the Investment Company Act of 1940 (no more than 100 US person beneficial owners permitted in an offshore fund) or section 3(c)(7) of that Act (all US person beneficial owners in an offshore fund must be "qualified purchasers"). Advisers that solely advise venture capital funds (to be defined by the SEC) will be exempt from registration but also will be required to retain records and file reports with the SEC.

"Foreign private adviser" means an adviser that:

- Has no place of business in the United States
- Has fewer than 15 US direct account clients and investors in the private funds it advises
- Manages less than US$25 million (or an SEC-determined higher amount) of aggregate assets "attributable to clients in the United States" and to US investors in private funds it advises
- Does not hold itself out in the United States as an investment adviser
- Does not advise a US-registered investment company or business development company.

Matters Requiring SEC Clarification

What are "assets under management in the United States" for purposes of the private fund exemption as it will apply to offshore managers? The term will probably be defined to relate to assets attributable to US investors rather than the locus of the managed assets but could take into account management by an offshore adviser's US personnel (if any).

Will an offshore manager be considered to exclusively advise private funds for purposes of the private fund exemption so long as the manager has no US direct account management clients (as opposed to non-US direct account management clients)? Who will be considered a US client or investor? The SEC's current position is that if an offshore adviser's direct account client moves to the United States, that client becomes a US person for purposes of the expiring private adviser's 15-client exemption. However, if an investor in an offshore adviser's private fund moves to the United States or transfers his investment to a US resident, that relocation or transfer does not affect qualification for the expiring exemption because the fund, not its investors, is considered to be the client. The SEC may not continue to take the latter position with regard to fund investors, especially because the foreign private advisers exemption requires the joint counting of direct account management clients and fund investors in "counting to 15" and the aggregation of amounts under management in determining qualification for the US$25 million limit on assets under management.

If offshore advisers will be required to track the location of their fund investors and of secondary market transferees in order to avoid US investment adviser registration, significant issues will arise as to how that tracking can be accomplished and whether the adviser can require the redemption or transfer of fund interests in order to avoid US registration. The SEC might take a bifurcated position to the effect that tracking fund investments initially purchased by non-US persons offshore will be required only if an adviser has direct US person investment management clients (who may have moved to the United States) or manages funds that have made direct placements to investors in the United States.

Edwin (Ted) Laurenson is a partner based in the Firm's New York office. Ted focuses his practice on public and private investment funds and investment advisory matters. He can be contacted on **+1 212 547 5657** or at **elaurenson@mwe.com**.

Online Gambling Opened Up to Competition in France: Implications of Expected Reform

By **Patrice Corbiau** and **Mélanie Bruneau**

The new Law 2010-476 of 12 May 2010 (the Law) is designed to open up competition and regulate online gambling and gaming in France. The Law follows the reasoned opinion sent in 2007 by the European Commission requesting that France amend its legislation in order to put an end to obstacles to the free movement of sport betting services.

Reform Limited in Scope

Online gambling and betting are now authorised but are subject to strict rules. In short, online horse bets should be exclusively in their mutual form, while betting odds and live betting are also authorised for online sports bets. Authorised cash games are limited to online poker; other online casino games, such as slot machines, roulette and black jack, are still prohibited.

Necessary Authorisation

Online operators must obtain authorisation granted by ARJEL, the new regulatory authority. In the first five months, ARJEL has granted authorisations to 31 operators. The authorisation is valid for a renewable five-year period and is not transferable. Online operators should have the technical and financial capacity to comply with their obligations, which relate notably to the combating of fraud and money laundering, the prevention of gambling addictions and the implementation of measures to prevent minors from gambling. They should set up a dedicated website with a ".fr" domain name, be established in the European Union, Iceland or Norway, be sure of the identity, age and address of the player, and hold an account in a bank established in the European Union. All information must be submitted in French.

Controls and Sanctions

Operators offering online gambling activities without authorisation are subject to three years' imprisonment and a €90,000 fine, while companies may be fined up to €450,000 and can be prevented from requesting an authorisation for five years. Authorised operators in breach of their obligations can have their authorisation suspended, cancelled or reduced and can be fined.

ISP Obligations

The Law grants ARJEL the power to ask internet service providers (ISPs) to block access by French players to illegal gambling websites. Before implementing this procedure, a letter of formal notice is issued, demanding that the unauthorised online operator stops its activities within eight days. The Paris Court of First Instance has already applied this procedure by ordering ISPs to block French players from accessing stanjames.com, subjecting them to a €10,000 daily fine if the website was not blocked within two months.

Advertisement Obligations

The Law provides that broadcasting advertising in favour of approved operators shall be accompanied by a message warning against excessive or compulsive gaming. Advertising is prohibited in publications, audiovisual communication services and online services directed at minors, as well as in cinemas when it can be viewed by minors. Failure to comply with advertisement obligations can trigger a fine of €100,000, which can go up to four times the amount of the advertising expenses.

Competition Issues

The French Competition Authority has decided to analyse the competition questions likely to arise in this sector. The market access conditions (notably the agreements providing betting rights), the subsistence of monopoly activities, as well as the existence of vertically integrated operators and the pricing policies applied by operators, such as tied reductions or loyalty-building discounts, are under scrutiny. The French Competition Authority's opinion, which will provide guidelines to authorised operators, is expected by the end of 2010.

Patrice Corbiau is a partner based in the Firm's Brussels office. He is a member of the Firm's corporate practice and focuses primarily on Belgian and international corporate and commercial law. Patrice can be contacted on **+32 2 230 50 59** or at **pcorbiau@mwe.com**.

Mélanie Bruneau is an associate based in the Firm's Bussels office. She is a member of the Firm's corporate practice where her practice focuses on French contract law and commercial law and EU/ competition law. Mélanie can be contacted on **+32 2 282 35 18** or at **mbruneau@mwe.com**.

Avoiding Those "Oh Sh!#" Moments

By **Eileen O'Connor**

Do you ever worry about a potential call from a reporter telling you something about your business that you didn't know? Global companies are often caught in the spotlight, involved in catastrophic accidents, technological breakdowns, rogue traders, manufacturing malfunctions and product safety issues. What starts out as local can quickly affect global operations, especially if it is not addressed immediately.

The best way to manage a crisis is to avoid it. Proper planning goes a long way in avoiding crises and mitigating damage to reputation and legal liability when it occurs. Planning requires regular crisis audits and the development of a culture of risk identification and avoidance.

> What starts out as local can quickly affect global operations.

A thorough risk audit requires general counsel and/or outside lawyers, sometimes under attorney-client privilege, talking to each of the company's units and work teams, particularly middle managers who are closest to potential issues. Companies often make the mistake of surveying only top managers, but full inclusion not only helps identify issues that are just starting to become a problem, it also creates a culture of risk identification and avoidance. For example, middle managers are most likely to hear rumours that several female employees have complained of inappropriate comments or actions by an employee, which could blow up into a lawsuit, or know about a continuing problem with a certain manufacturing facility meeting product safety standards. Conducting regular audits empowers these units and work teams to think daily about possible issues and address them as they arise.

It is also critical to look beyond the organisation and talk to key customers and outside counsel. Customers will identify areas of their concern. Outside counsel can help explore developments in the law, including those relating to regulatory compliance, that could present peril in some key areas.

In military exercises there is always a "red" team that acts as the enemy. Management needs to task key people with being the red team and thinking outside past experience. After the fact, many managers often say while they planned for the "usual" crisis, they had not even envisioned the catastrophic event that wreaked havoc. Engaging in thinking outside the box could help you plan for the worst, unexpected occurrence.

This brings us to the bottom line: Some risks are just so unlikely they don't deserve a lot of time, attention or money. To calculate what a potential crisis is worth, put an expected value to the anticipated event by multiplying its dollar impact by the probability of it occurring. The most unlikely event, such as a bombing, with the same dollar impact as a more likely event, such as a gas explosion at a plant, would therefore be given a lower priority. Another determining factor is how much it may cost to avoid the risk. If extra security at each plant would not cost very much, but would help guard against terrorist infiltration, workplace violence or a fire, then the cost may be worth prioritising. Alternatively, assigning low priority to a low probability but extremely high impact event may be simply unacceptable if the event could mean complete disaster for the company.

Once you've identified those "Oh, sh!#" moments, the next step is avoiding them. This is where counsel can be extremely helpful by brainstorming new policies and procedures, and strengthening compliance to lower the risk of harm to a company's reputation and its legal exposure. As one of the United States' first inventors, Benjamin Franklin, famously said, "An ounce of prevention is worth a pound of cure."

> It's critical to look beyond the organisation and talk to key customers and outside counsel.

For more crisis management tips, please go to **www.mwe.com/info/news/blogs.html**.

Eileen O'Connor is counsel based in the Firm's Washington, DC, office, where she is head of the Legal Crisis Strategies practice. Eileen is a 24-year veteran journalist with experience working for ABC News and CNN in London, Moscow, Tokyo and Washington, DC. She can be contacted on **+1 202 756 8222** or at **emoconnor@mwe.com**.

Learn More

Stay up to date with current issues through McDermott's other publications and news alerts. Please visit our website, www.mwe.com, to read the full articles, or sign up to receive substantive communications from McDermott at www.mwe.com/subscribe/.

We provide a range of publications which include the following:

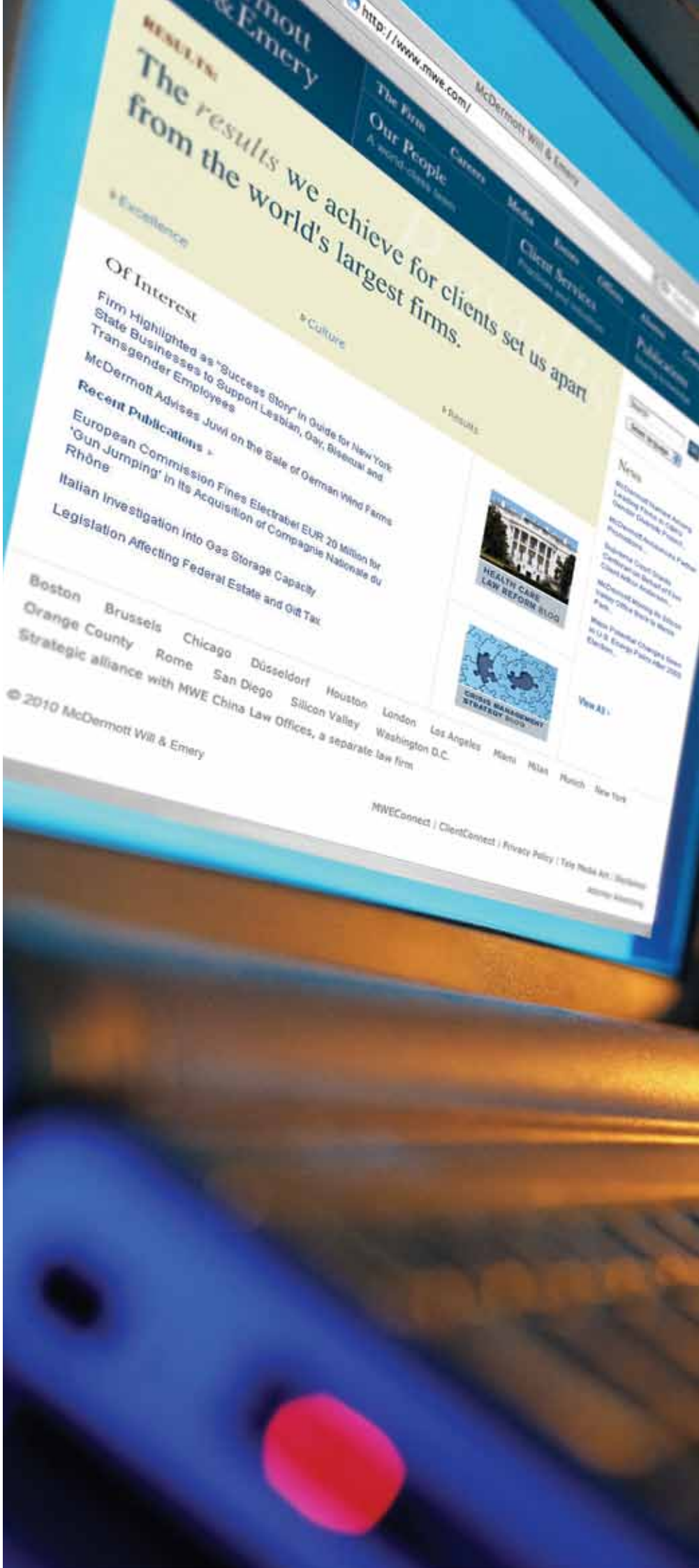
- *Brussels Brief*
- *China Law Alert (MWE China Law Offices)*
- *European Intellectual Property Bulletin*
- *Inside M&A*
- *IP Update*
- *On the Subjects*
- *UK Employment Alerts*
- *White Papers*

McDermott's blogs track key legal developments and industry news. Follow them at:

www.employeebenefitslawblog.com
www.energyandcommoditieslaw.com
www.healthcarereform.com
www.itc337update.com
www.legalcrisisstrategies.com

Our *On the Subjects* provide insight into key legal developments and the way in which those developments affect business. A recent selection includes the following:

- Puerto Rico Enacts New Excise Tax That Impacts U.S. Companies
- Top 5 Potential Pitfalls in Health Care M&A Transactions
- USTR Initiates Large Investigation of China's Renewable Energy Measures and Requests Public Comment
- EU Financial Reform
- Energy Tax Incentive Bill Introduced in Senate



McDermott
Will & Emery

www.mwe.com/international/

BOSTON
28 State Street
Boston, MA 02109
USA
Tel: +1 617 535 4000
Fax: +1 617 535 3800

BRUSSELS
Rue Père Eudore Devroye 245
1150 Brussels
Belgium
Tel: +32 2 230 50 59
Fax: +32 2 230 57 13

CHICAGO
227 West Monroe Street
Chicago, IL 60606
USA
Tel: +1 312 372 2000
Fax: +1 312 984 7700

DÜSSELDORF
Stadttor 1
40219 Düsseldorf
Germany
Tel: +49 211 30211 0
Fax: +49 211 30211 555

HOUSTON
1000 Louisiana Street
Suite 3900
Houston, TX 77002
USA
Tel: +1 713 653 1700
Fax: +1 713 739 7592

LONDON
7 Bishopsgate
London EC2N 3AR
United Kingdom
Tel: +44 20 7577 6900
Fax: +44 20 7577 6950

LOS ANGELES
2049 Century Park East
38th Floor
Los Angeles, CA 90067
USA
Tel: +1 310 277 4110
Fax: +1 310 277 4730

MIAMI
201 South Biscayne Blvd.
Miami, FL 33131
USA
Tel: +1 305 358 3500
Fax: +1 305 347 6500

MILAN
Via A. Albricci, 9
20122 Milan
Italy
Tel: +39 02 89096073
Fax: +39 02 72095111

MUNICH
Nymphenburger Str. 3
80335 Munich
Germany
Tel: +49 89 12712 0
Fax: +49 89 12712 111

NEW YORK
340 Madison Avenue
New York, NY 10173
USA
Tel: +1 212 547 5400
Fax: +1 212 547 5444

ORANGE COUNTY
18191 Von Karman Avenue
Suite 500
Irvine, CA 92612
USA
Tel: +1 949 851 0633
Fax: +1 949 851 9348

ROME
Via A. Ristori, 38
00197 Rome
Italy
Tel: +39 06 462024 1
Fax: +39 06 48906285

SAN DIEGO
11682 El Camino Real
Suite 400
San Diego, CA 92130
USA
Tel: +1 858 720 3300
Fax: +1 858 720 7800

SHANGHAI
MWE China Law Offices
Strategic alliance with
McDermott Will & Emery
28th Floor Jin Mao Building
88 Century Boulevard
Shanghai Pudong New Area
P.R. China 200121
Tel: +86 21 6105 0500
Fax: +86 21 6105 0501

SILICON VALLEY
275 Middlefield Road
Suite 100
Menlo Park, CA 94025
USA
Tel: +1 650 815 7400
Fax: +1 650 815 7401

WASHINGTON, D.C.
600 Thirteenth Street, N.W.
Washington, D.C. 20005
USA
Tel: +1 202 756 8000
Fax: +1 202 756 8087

McDermott's international legal professionals advise multinational entities on cross-border legal matters. Interdisciplinary practice groups, integrated by practice rather than geography, allow our lawyers to respond to challenges our clients face, day or night.