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McDermott Will & Emery

EDITOR
Andrea Hamilton
Partner
Brussels
+32 2 282 35 15
ahamilton@mwe.com

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Alongside the usual challenges of rising and falling values inherent in any family-owned asset, cryptocurrency, which is kept in key-protected digital wallets, is prone to getting lost or disappearing with the death of its owner. The intangibility of cryptocurrency is not the only challenge to ensuring the successful inheritance of family wealth. Trustees can make mistakes, and assets held overseas can often be difficult to access. Practical steps can, and should, be taken to prevent the loss of an inheritance, including a digital one. Of course, even if all the safeguards are in place, disputes can still arise, and there are a number of ways in which these can be tackled.

The investment landscape is always changing, but parallel developments in the United States and China are particularly noteworthy. China is simplifying opportunities for investment in its pharmaceutical sector, while the United States is applying additional regulatory hurdles to foreign investments into US biotech in line with a global trend of protectionism.

Please contact me if you have any comments on our articles or would like to discuss any of the issues raised.

PUBLICATION EDITORS
Aileen Devlin
Kate Hinze

CREATIVE SERVICES
Jane Hanlon
Christine Abrego

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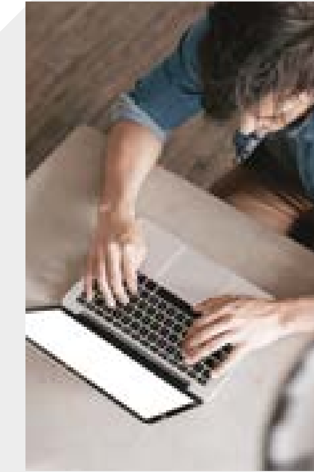

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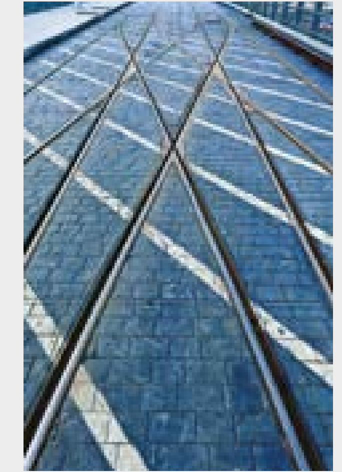

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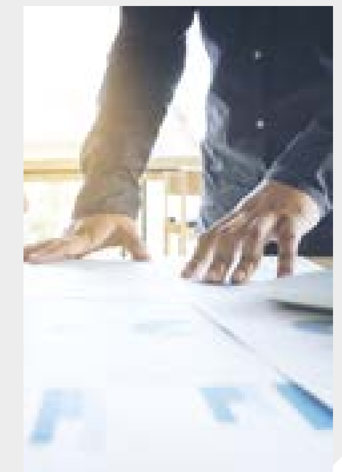

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"THEY DID WHAT?!?" TRUSTEE MISTAKES AND HOW TO FIX THEM

Ziva Robertson and Jennifer Ronz

Complex trust structures are usually administered by experienced and conscientious professionals at the top of their game. But mistakes can happen, and fixing them can be hard, time consuming and expensive.

High net worth families in the 21st century are internationally mobile, and this mobility often requires complex structures spanning a number of jurisdictions. This complexity can occasionally lead to mistakes being made by trustees.

To alleviate the hardship experienced by beneficiaries owing to mistakes made by their trustees, English law developed a doctrine, known as the Hastings-Bass principle (after a case bearing that name), which enables the court to reverse the actions of trustees taken in circumstances where the trustees' decision was made on the basis of irrelevant considerations, or through their failure to consider relevant factors.

Most, if not all, offshore, common law jurisdictions followed suit and, in a line of authorities in the early 2000s, trustee mistakes were regularly set aside. The most common examples were where the trustees' failure to consider the tax consequences of a transaction resulted in an otherwise avoidable charge to tax.

This changed in 2013 when the Privy Council held, in *Futter v Futter*, that Hastings-Bass had gone too far. In a landmark decision, the Court stated that trustees' decisions would only be reversed if the action resulted from a breach of trust, which can be difficult to show where the trustees have acted on (erroneous) legal advice; and the mistake was sufficiently serious to merit judicial intervention.

In circumstances where the trustees had taken legal advice that proved to be erroneous, said the Court, the remedy was to sue the lawyers. But this is not always possible: first, wrong advice is not necessarily negligent to the point where an action in negligence can be pursued; and second, the trustee may be reluctant to sue the lawyers.

Imagine, for example, that a trustee took a step that resulted in an otherwise avoidable charge to tax in the United States, not knowing that one of the beneficiaries became tax resident there earlier in the year. The failure by the trustee to appreciate the risk may not amount to a breach of trust, and the legal advice, which similarly ignored US tax considerations, may be erroneous but not negligent. Under English law, this would leave the beneficiaries without a remedy.

A number of offshore jurisdictions responded to the Privy Council decision by introducing legislation that reinstated the Hastings-Bass doctrine. Others—including the British Virgin Islands (BVI)—did not, and left the question open for future consideration. One such consideration took place recently in *Gany Holdings (PTC) SA and Asif Rangoonwalla v Zorin Khan v Others,* which is a Privy Council decision on appeal from the BVI.

GANY HOLDINGS

In *Gany Holdings*, the head of the family and father of the main protagonists settled a discretionary family trust known as the ZVM Trust. Following his death in 1998, his daughter Zorin, her husband, and her daughter made repeated requests for information about the trust from the trustee, Gany Holdings; her brother Asif, who controlled it; and a number of other persons, including lawyers and family members, who had knowledge about the trust.

Zorin's efforts were unsuccessful over a number of years, and she and her family ultimately issued proceedings against Gany Holdings and Asif for disclosure of information about the trust and an account of the trustee's dealings with the trust assets.

During the proceedings, Asif and Gany Holdings gave conflicting evidence about the assets received by the trustee. The explanations ranged from statements that the trust had never held any assets at all; to statements that it had, in fact, held shares in a Hong Kong company that had very little value; to statements that those shares had been appointed to Asif in December 1998, following which the Trust had come to an end. At first instance, the court accepted Asif's version of events, and held that Zorin had failed to disprove his evidence. Zorin's appeal reached the Privy Council in 2018.

The Privy Council found that the trust had, in fact, held valuable assets in the form of company shares, and that the contradictory evidence given by Asif and Gany Holdings showed that the trustee had failed to appreciate the extent of the assets in the trust fund, such that any appointment or distribution of those assets to Asif was founded on a fundamental mistake. The mistake was serious enough to affect the legality of the transaction, which was therefore reversed.

> "Regular communications between trustees and beneficiaries are key."

The Privy Council also helped Zorin (and other beneficiaries who may follow in her footsteps) in one other, significant way.

Up until this case, a trustee who failed to take into account the interests of beneficiaries such as Zorin, may have been able to say: "But so what? Even if I had taken her interests into account, I, or another trustee acting reasonably on an informed basis, would have acted in the same way. The result would have been the same."

Unless the trustee's decision was fraudulent, or so capricious as to be completely bizarre, it would be almost impossible for a beneficiary to show that a reasonable trustee would have acted differently. Showing that a reasonable trustee might have acted differently was only marginally easier. In *Gany Holdings*, the Privy Council said this was not part of the legal test, but rather one factor among others that the court would take into account.

The Court also held that there was no legal presumption that a transfer of assets to a person acting as trustee was intended as a settlement of the assets. If there is a dispute as to whether or not assets are held in trust, a court would look first to any written or oral declaration made by the settlor and/or the trustee. If no such declaration was made, the court would look

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at the factual circumstances surrounding the transfer to try and ascertain the intention from the conduct of the parties. If no such intention could be inferred from their conduct, the legal presumption of a "resulting trust" would arise, meaning that the assets would be seen as having remained in the ownership of the transferor.

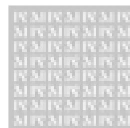
> "The jurisdiction of the court to reverse trustee mistakes can be an important safeguard."

IMPLICATIONS

There are a number of important lessons to be learned from the doctrine of Hastings-Bass and *Gany Holdings*. Prevention is better than cure and, while it is not always possible to avoid mistakes, there are steps that can minimise the risk of them happening.

- Regular communications between trustees and beneficiaries are key.
  - Trustees should take the initiative to truly know and understand the circumstances of the family for whom they hold assets, and keep themselves up to date on changes and developments in their beneficiaries' life choices.
  - Family members should ensure they share their news with their trustees and tell the trustees if they, for example, plan to educate a child abroad; if their leisure or business travel takes them regularly to other jurisdictions where they may become inadvertently tax resident; or if they plan to buy assets or property for their use and benefit in another country, as this may also have unintended tax consequences.
- Different jurisdictions offer different advantages or disadvantages in terms of their trust legislation. The needs of beneficiaries vary from family to family, and even within the same family they can vary over time or at the point of generational change. Understanding those needs and having a good knowledge of the relevant legislation across the common law world may contribute to wealth preservation and the ultimate benefit of the families.
- The jurisdiction of the court to reverse trustee mistakes can be an important safeguard for beneficiaries. Both trustees and beneficiaries should be aware of what is available, and act quickly if it appears that a mistake has occurred in the administration of the trust. There may be ways to fix the problem without engaging in lengthy and expensive litigation.

ZIVA ROBERTSON
Partner
London
zrobertson@mwe.com



JENNIFER RONZ
Associate
London
jronz@mwe.com

ALTERNATIVE DISPUTE RESOLUTION METHODS TO RESOLVE TRUST DISPUTES

Nicholas Holland and Lynsey McIntyre

The lack of privacy in court proceedings, and the fact that they will always carry a degree of uncertainty, is prompting high net worth individuals to seek alternative ways of resolving disputes over high value trusts.

Traditionally, trusts disputes tend to be resolved through court proceedings. This is because administration of trusts is subject to supervision by the court, generally by the court where the trust is administered, or the court whose law governs the trust.

Provided a beneficiary can demonstrate a genuine potential of them benefiting from the trust, they will likely be able to invoke the court's supervisory jurisdiction to obtain information about the administration of the trust or hold the trustees to account for decisions taken. Trustees can invoke the court's supervisory jurisdiction to obtain directions for major decisions concerning the trust, or where they face litigation with a third party.

There are certain weakness to court proceedings, not least because court judgments are often tricky to enforce. This is particularly an issue given the frequent need for non-monetary relief in trust disputes. Common law courts, except for those in Canada, do not generally enforce the non-monetary judgments of foreign courts, and many civil jurisdictions simply do not enforce foreign court judgments at all.

Whilst the courts of some jurisdictions have developed strong expertise in applications and disputes involving trusts (which can often be a factor supporting the establishment of a trust structure in one jurisdiction over another), many courts do not have this expertise, or may view trusts with suspicion.

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In addition, court proceedings tend to be public and, for numerous reasons, trustees and beneficiaries may not want the fact nor details of a dispute to be in the public domain. Most jurisdictions are committed to the notion of open justice and there has been a growing trend towards transparency in court proceedings concerning trusts.

> "Expert determination is flexible, informal and speedier than court."

For example, In *V. v T, A* in 2014 the English High Court ruled that a variation of trust application should not be heard in private, despite the application disclosing sensitive commercial information relating to an operating company owned by the trust. The Court did impose an anonymity order to shield the young beneficiaries from the knowledge of the family's extensive wealth.

Whilst it remains the case that in jurisdictions like England and Wales certain trust applications will be held in private, this will not be the case where trustees are involved in third party disputes.

What, then, are the alternatives to court proceedings for the resolution of trust disputes?

ARBITRATION

Arbitration awards are often easier to enforce cross-border (under the New York Convention) than court judgments, but arbitration tends to be very little utilised in trusts.

In the United States, trusts are viewed as contracts, so it is likely that an arbitration clause will be binding on trustee and beneficiaries in the United States. Outside the United States, however, trusts are not treated, nor viewed, as contracts. This makes it less likely that an arbitration clause in a non-US trust will be upheld and binding on the beneficiaries, as they are not technically parties to the trust deed.

Arbitration awards are much easier to enforce cross-border than court orders are. However, because of the unreliability of an arbitration clause in a trust being upheld, there are problems commencing arbitration proceedings in the first place.

Many trusts are discretionary and dynastic, and the representation of minors and unborns in arbitration proceedings, though not impossible, is therefore problematic.

MEDIATION

Mediation is a formal negotiation facilitated by an independent negotiator. In many jurisdictions, mediation cannot be imposed on parties without their consent. There are exceptions: parties in England and Wales may be penalised in costs post-trial if they unreasonably refuse to mediate; and in some Canadian provinces the court routinely appoints a mediator whose report on mediation efforts is a mandatory step in the court process.

The strongest benefit of mediation is that it is confidential: neither party can refer to discussions or documents used in the mediation process.

On the negative side, the outcome is not binding unless the parties sign a written settlement agreement. It can be expensive, and timing is everything: mediate too soon and the parties may not fully understand their position; leave it too late and positions may be so entrenched, or so much money may have been expended, that a resolution by mediation is impossible.

EXPERT DETERMINATION

This is a binding process that is often used to determine disputes of a specialist or technical nature. The parties appoint one or more experts in a particular field to determine the dispute, based on agreed terms of reference (TOR).

In a commercial situation, the parties will often include a clause in contracts that provides for certain disputes to be resolved by expert determination, where the scope for dispute about the law or facts is likely to be limited.

In a trusts context, disputes over the valuation of assets, such as shares, would be suitable for expert determination. It does however, have broader application, such as the resolution of a third party trust dispute requiring determination of matters of law and quantum.

> "There are obvious advantages for trustees to use expert determination."

The key advantages of expert determination are as follows:

- The process is flexible, informal and speedier than court, as the parties can effectively control the process and the timetable for resolution.
- The parties can choose the expert, rather than find out who the presiding judge is hours before the trial.
- The time frame for the process can be agreed by the parties and expert.
- Provided the expert agrees, the determination can be dealt with by reference to the papers and written submissions where appropriate, avoiding the need for a hearing and oral evidence from witnesses.
- The parties' submissions and the outcome are confidential.

Expert determination is a viable and cost effective alternative to court proceedings, but there are some dangers that require careful navigation.

The determination is final and binding on the parties. There is no right of appeal unless the TOR provide for it, although this is usually confined to cases of "manifest error". It is imperative to ensure that the issues which need to be determined have been framed properly, and to thoroughly vet the proposed expert, before committing to their appointment.

Like mediation, one party cannot force the other to agree to expert determination: all parties must agree to be bound. This can have complications for trustees who want to engage in expert determination with a third party but owe obligations to the beneficiaries.

In order for expert determination to work effectively, the following steps should be taken:

- The beneficiaries must agree that the matter be resolved by expert determination.
- Alternatively, the court must authorise the trustees to proceed down this route, particularly if the beneficial class includes minors and unborns.
- Provisions should be made in the TOR to
  - Permit the trustees to disclose the determination to its beneficiaries, and
  - Enforce the expert determination at court in the event of non-compliance.

McDermott has recently been involved in a trust dispute (concerning matters of trust law and quantum) where the parties agreed to refer the dispute to expert determination. Whilst we cannot disclose the result of the determination, we and our offshore trustee clients found that the flexibility and confidential nature of the process provided advantages over the traditional court route.

There are obvious advantages for trustees to use expert determination in appropriate cases, and it should certainly be considered as an option.

NICHOLAS HOLLAND
Partner
London
nholland@mwe.com

LYNSEY McINTYRE
Partner
London
lmcintyre@mwe.com

CRYPTOCURRENCY – CURRENT INVESTMENT, FUTURE INHERITANCE?

Claire Murray and Elysa Jacobs

The growth in popularity of cryptocurrencies gives rise to real world questions, not least of which, can digital assets be inherited?

Investment in cryptocurrencies has been growing apace and, despite a few noticeable dips in the market, including the fall in Bitcoin value during 2018, it shows no sign of slowing down. Even institutional investors have joined the race, with Bloomberg reporting large private buyers, such as hedge funds and endowment trusts, purchasing millions of dollars' worth of digital coins in online transactions. This development confers a greater credibility and sense of legitimacy to crypto-exchanges and to currencies, such as VeChain, Ethereum and Bitcoin.

WHAT ARE CRYPTOCURRENCIES?

As a relatively new type of asset class, cryptocurrency has gained considerable attention and increased in popularity over recent years, especially amongst individual investors who hope their 'tokens' will appreciate over time, much like stocks and shares. It is no small task to keep informed about the various forms and uses of cryptocurrency, as it is constantly changing and evolving.

How are cryptocurrencies defined? It is generally accept that they are a virtual currency using cryptography for security, relying on blockchain technology to exist. In their simplest form, cryptocurrencies are digital representations, the values of which are determined by supply and demand. Due to their intangibility, cryptocurrencies are stored and traded electronically.

The attraction of these 'currencies' is their security. They are not issued by any central authority and, therefore, are theoretically immune to outside interference or interception. This feature explains their growing popularity and wider use. The term "cryptocurrency" quite literally means 'a secret form of payment' and privacy is one of the central benefits of this platform.

The covert nature of cryptocurrencies is a double-edged sword and it is arguable that the lack of regulation brings with it certain difficulties. Investing in cryptocurrencies does not come without risk and the Bank of England identifies the primary danger to be the lack of central management, *i.e.,* by a bank or government, to assist in the event of any trouble, such as fraud or theft. The cryptocurrency market has also proven itself quite volatile and unpredictable.

PITFALLS AND PRACTICALITIES

To keep up with the growing use of crypto assets (including cryptocurrencies), HM Revenue & Customs (HMRC) is striving to establish their position and recently issued guidance for individuals who possess crypto assets. It is clear that HMRC and the Cryptoassets Taskforce do not class crypto assets as 'money' or even as 'currency' and, as noted above, the buying and selling of such assets are likened to investments, as opposed to gambling. This means that, in general, Capital Gains Tax will be relevant on the disposal of a crypto asset and there may be Income Tax implications on the receipt of certain types of crypto assets.

If one does invest in crypto assets, and specifically cryptocurrency, consideration should be given to what will happen on death – who will have access to the virtual wallet and how will it be accessed? The intangible nature of these assets and the complexity, exchange and transfer of these assets within the digital space can make it extremely difficult to ascertain the true value of the asset on death, to access the assets in question and even to identify the owner.

One example that crystallises the complications of inheriting cryptocurrency occurred in 2013, whereby Bitcoin miner Matthew Moody died in a plane crash in Chico, California. At the time of his death, Matthew had an unspecified number of bitcoins in his online wallet, which were each worth just under US$100. Today, the same coin is worth over US$8,000.

> "Cryptocurrencies are digital representations Digital assets...liable for Inheritance Tax?"

Matthew's relatives were unable to access his online wallet, lacking the "private key", *i.e.,* the identifying information required for access to the assets. Without this, the family were unable to recover any of the Bitcoins in question.

More recently, Gerald Cotton, the young founder of Canadian cryptocurrency exchange Quadriga CX, died suddenly whilst travelling abroad. As the only person with knowledge of the key unlocking the investments, it is estimated that approximately 115,000 individuals are owed between CA$180 million and CA$190 million in cryptocurrency, which may now be lost forever. To make matters worse, it is understood that Mr Cotton held the key securely on his laptop; however, attempts to recover the funds have shown the digital wallets to be empty, leaving Quadriga CX's auditors Ernst & Young with the task of investigating the missing funds.

According to research by the *Financial Times*, between 2.3 million and 3.7 million bitcoins have been lost for a variety of reasons, including the death of the asset holder, which accounts for roughly 30% of the bitcoin market. The losses can be significant and ultimately claiming rights to cryptocurrency may prove to be a real issue.

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PRACTICAL STEPS

How can we guard against this loss?

The best advice lies in the old adage, prevention is better than cure. It may be that a specific gift of the digital asset is contained within the Will itself or a Letter of Wishes is prepared, to sit alongside the Will, detailing instructions on how to access the funds or the private key itself.

Smart contracts or "blockchain contracts" may also offer an innovative solution to the problem. In contrast to traditional contracts, these are self-executing contracts with terms directly written into the blockchain code and are particularly suited to cryptocurrency because of their global enforceability and their protection of the contacting parties' identities.

Various platforms have also made use of blockchain technology to help users set up systems through which keys to digital assets can be shared with beneficiaries after death, by distributing private keys or passphrases providing access.

Inactivity can be a significant indicator of a change in circumstance. Certain platforms have made use of Application Programming Interface (API) integrations, which measure activity signals. Users are able to pre-define a period of inactivity, *e.g.*, three years, which on elapsing will trigger the transfer of digital assets to select beneficiaries.

> "Smart contracts or 'blockchain contracts' may also offer an innovative solution to the problem."

Another possible solution lies in the token exchanges themselves. These exchanges, such as Coinbase and Kraken, are platforms that allow the purchase, sale and storage of virtual assets. Some of these exchanges have policies in place to allow the transfer of the deceased's wallet to intended beneficiaries, after appropriate documents, such as a death certificate have been produced. This process may, however, prove just as cumbersome as attempting to access the wallet directly.

Inheritance Tax

Naturally, once assets, including digital assets, have been inherited by a beneficiary, the next question is whether they will be liable for Inheritance Tax? Thankfully, the answer to this is clear. The recently published HMRC guidance, "Cryptoassets for Individuals", states that "cryptoassets will be property for the purposes of Inheritance Tax" And therefore chargeable to Inheritance Tax.

CONCLUSION

Unquestionably, cryptocurrency, and crypto assets more broadly, remain a very novel and unchartered area, from both practical and legal perspectives. The law has always been slow to adapt to the changing digital landscape, in particular as regards the definitions of assets and property held virtually.

It is important to take precautionary steps to avoid one's cryptocurrency being inaccessible at a time when it may be needed the most and including clauses relating to digital assets either within a Will itself or as part of an ancillary Letter of Wishes is becoming increasingly popular. Though digital currency exchanges are beginning to explore varying uses of the blockchain to prevent lost tokens and ensure greater certainty in matters of bequest, the best strategy is risk mitigation and for token owners to take action now to ensure their crypto assets are inherited by their intended beneficiaries.

CLAIRE MURRAY
Professional Advisor
London
cmurray@mwe.com

ELYSA JACOBS
Associate
London
ejacobs@mwe.com

RESEALING FOREIGN GRANTS

Simon Goldring and Laura Harper

A resealed grant enables the personal representatives of the deceased to administer an overseas estate in England and Wales, giving the original grant force and effect similar to what it would benefit from had it originally been issued in England.

The process of resealing a grant of probate or letters of administration in the English courts is likely to be required where a deceased individual was living in a jurisdiction other than England or Wales, but held assets within those countries.

This process is not, however, possible for all jurisdictions, and there are various pitfalls to watch out for, so care needs to be taken when considering how to start the application.

A definitive list of countries to which the option of resealing applies is available in The Colonial Probates Act Application Order 1965. Most of the countries are British Overseas Territories and have, at some stage, had links to the Commonwealth.

THE RESEALING PROCESS

A district judge or registrar can issue a resealed grant to the following applicants:

- The person, or up to four persons, entrusted with the administration of the estate by the court with jurisdiction in the place where the deceased died domiciled.
- The person beneficially entitled to the estate by the law of the place where the deceased died domiciled (the heir) or, if there is more than one, to as many heirs that would benefit under the laws of the jurisdiction where the deceased died domiciled
- The executor named in a valid will written in any language.

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"A grant in a foreign language will not be accepted for resealing."

A grant in a foreign language will not be accepted for resealing. A court certified translation will be needed if the will is written in any language other than English or Welsh.

It is also vitally important that all of the relevant documentation is to hand prior to making the application, to ensure the probate courts can be provided with all the evidence required.

Section 2 of the Colonial Probates Act 1892 authorises the resealing of one of the following:

- The original grant.
- A duplicate of the original grant, sealed with the issuing court's seal.
- A copy certified as correct by, or under, the authority of the issuing court.

If there is a will, it should ideally be physically annexed to the copy of the grant. If it is not, the probate registry may require some extra evidence that the two are linked.

Depending on the value of the UK-situated assets, it will also be necessary to file an estate tax return with Her Majesty's Revenue & Customs (HMRC) prior to making the application, even if only to declare that no tax is payable.

If the UK-situated assets are worth less than £325,000, the estate tax return is relatively simple to complete. If, however, the deceased was born in the United Kingdom, or was ever domiciled there, a longer, more complicated estate return form will need to be completed.

HMRC aims to provide the initial certificate required within two weeks of the date of submission, but the time required for processing the estate return varies, depending on the complexity of the estate.

Once the original documents and confirmation of the tax payable have been collated, an application can be made to the probate registry with the appropriate fee.

All being well, the application should be processed by the probate registry within 2-4 weeks of submission. The personal representatives can then proceed to administer the estate in the United Kingdom.

FOREIGN GRANTS

Grants issued in the "Crown Dependencies", such as the Channel Islands, will not be recognised in England and Wales and are not eligible for resealing. If the deceased had assets in a Dependency, it will be necessary to apply for a separate grant to deal with the assets in England and Wales.

The process of applying for a separate foreign grant is more complicated, and therefore more costly, than for a resealing. An oath with details of the deceased, their domicile, and the entitlement of the person making the application will need to be sworn. Advice should be sought at the outset to ensure that the oath is drafted to fit the particular circumstances.

SIMON GOLDRING
Partner
London
sgoldring@mwe.com

LAURA HARPER
Associate
London
lharper@mwe.com

"WHOLLY GROUNDLESS" EXCEPTION NOT GROUNDED IN FEDERAL ARBITRATION ACT

Lisa Richman and Daniel Campbell

Arbitration as a method of dispute resolution is only as effective as the contractual provisions made to trigger it. Recent US case law has shed light on who gets to determine "threshold arbitrability", and whether or not the arbitration is "wholly groundless".

The newest Supreme Court Justice, Brett Kavanaugh, asked the following question on 8 January 2019, in *Henry Schein, Inc., et al. v Archer and White Sales, Inc,.*

> *Under the Federal Arbitration Act [FAA], parties to a contract may agree that an arbitrator rather than a court will resolve disputes arising out of the contract. When a dispute arises, the parties sometimes may disagree not only about the merits of the dispute but also about the threshold arbitrability question—that is, whether their arbitration agreement applies to the particular dispute. Who decides that threshold arbitrability question?*

Writing for a unanimous Court, Justice Kavanaugh explained that when parties to a contract delegate the "threshold arbitrability question to the arbitrator" in a clear and unmistakable manner, the arbitrator decides whether the dispute is arbitrable, even if the arguments in support of arbitration are "wholly groundless."

He did not, however, explain what constitutes a "clear and unmistakable manner" and what parties can do to protect themselves. *Schein* provides only limited guidance on the former issue, but it is possible to identify some of the steps that parties contemplating arbitration with a US seat can, and should, take to protect themselves.

LESSONS FROM SCHEIN

The case involved a dispute between Henry Schein, Inc., and Archer and White Sales, Inc. Archer and White entered into a contract with Schein's predecessor, and the contract contained the following dispute resolution clause:

> *This Agreement shall be governed by the laws of the State of North Carolina. Any dispute arising under or related to this Agreement (**except for actions seeking injunctive relief** and disputes related to trademarks, trade secrets, or other intellectual property of [Schein]), shall be resolved by binding arbitration in accordance with the arbitration rules of the American Arbitration Association [(AAA)]. The place of arbitration shall be in Charlotte, North Carolina. Authors' emphasis added.*

When the relationship between the parties soured, Archer and White sued Schein in Federal District Court in Texas, alleging antitrust violations, and seeking money damages and injunctive relief. Schein moved to compel arbitration, invoking the FAA and the dispute resolution clause in the contract, asking the court to refer the claims to arbitration.

Archer and White argued that the dispute was not subject to arbitration, and that the district court should decide the threshold arbitrability of the claims, stating that Schein's arguments in favor of compelling arbitration were "wholly groundless" because "actions seeking injunctive relief" were exempted from the arbitration agreement.

Relying on Fifth Circuit precedent, the court held that Schein's arguments in favour of compelling arbitration were "wholly groundless" and denied Schein's motion to compel arbitration. The Fifth Circuit affirmed the lower court's decision and Schein appealed. The Supreme Court accepted the case on the narrow question of whether or not a "wholly groundless" exception exists under the FAA.

GENESIS OF THE "WHOLLY GROUNDLESS" EXCEPTION

While the Fifth Circuit adopted the "wholly groundless" exception, this judicially created exception to the FAA gained prominence in *Qualcomm, Inc. v Nokia Corp.*, 466 F.3d 1366 (Fed. Cir. 2006).

Qualcomm concerned a denial of a motion to stay litigation pending arbitration. The Federal Circuit vacated the order and remanded for further proceedings, holding the district court failed to conduct an inquiry into whether or not the arguments in favour of arbitration were "wholly groundless." In *Qualcomm*, the parties' agreement clearly and unmistakably delegated the arbitrability question to the arbitrator, but the Federal Circuit, borrowing from a line of California state cases, decided that the court needed to determine, on remand, if the assertion of arbitrability was wholly groundless.

In addition to the Fifth and Federal Circuits, the Fourth and Sixth Circuits adopted some form of the "wholly groundless" test. The Tenth and Eleventh Circuits rejected it. The Supreme Court reviewed *Schein* to resolve the circuit split.

> "The Supreme Court rejected arguments that the "wholly groundless" exception was practical, saving time and costs."

SUPREME COURT'S RATIONALE IN REJECTING THE "WHOLLY GROUNDLESS" EXCEPTION

The Supreme Court explained that, under the FAA, "arbitration is a matter of contract, and courts must enforce arbitration contracts according to their terms." The Court previously held that parties may agree to delegate to the arbitrator i) the merits of particular disputes, and ii) the threshold question of arbitrability.

The Court clarified that courts created the "wholly groundless" exception to block frivolous attempts to transfer disputes from the courts to arbitration. The judicially-created "wholly groundless" exception is, according to the Court, "inconsistent with the text of the [FAA] and with our precedent." Referencing *AT&T Technologies, Inc. v Communications Workers*, 475 U.S. 646, 649-50 (1986), the Court held that courts may not decide merits questions or threshold arbitrability questions when the parties contractually delegate those issues to the arbitrator(s).

The Supreme Court rejected the exception, holding that courts cannot read exceptions into the statutory text of the FAA, and stating that it is "not at liberty to rewrite the statute passed by Congress and signed by the President."

In relation to *Schein*, the Supreme Court rejected arguments that the "wholly groundless" exception was practical, saving time and money where an arbitrator would inevitably reject arbitration of "wholly groundless" claims. The reason for this was the Court's conclusion that two "fair-minded adjudicators" might reach different conclusions on the issue of whether or not claims are "wholly groundless." The Court also expressed concern over increases in collateral litigation regarding whether something is "wholly groundless" versus simply groundless, rendering the exception impractical.

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Finally, the Supreme Court rejected policy arguments that the "wholly groundless" exception was necessary to deter frivolous motions to compel arbitration. The Court explained that arbitrators are perfectly capable of disposing of frivolous claims, and that deterrents exist in arbitrations in the form of fee shifting.

"Notably, a court may also determine whether or not an agreement is subject to the FAA."

LESSONS LEARNED FROM *SCHEIN*

Based on the text of the FAA, the Supreme Court resolved the narrow issue that courts must enforce contractual provisions delegating to the arbitrator(s) the threshold question of arbitrability. The Court did not reach the issue of whether or not the parties "clearly and unmistakably" delegated the question of arbitrability to the arbitrator(s). As a result, it is still open to question whether or not incorporating arbitration rules, such as the AAA rules, is sufficient to "clearly and unmistakably" delegate the question of arbitrability. The answer to this still varies from circuit to circuit.

The *Schein* decision states that a court must determine whether or not a valid and enforceable agreement to arbitrate exists, and whether or not the parties "clearly and unmistakably" delegated the question of arbitrability to the arbitrator. That is all a court is permitted to do, and it cannot consider whether or not the claims are "wholly groundless"; that analysis is squarely within the province of the arbitrator(s).

Notably, a court may also determine whether or not an agreement is subject to the FAA. The Supreme Court explained this in its most recent arbitration decision on 15 January 2019, *New Prime, Inc. v Oliveira, No. 17-340*. The Court held that courts, not arbitrators, decide whether or not an agreement is excluded from the FAA, and that contracts of employment, including those with independent contractors, are excluded.

Some may read *Schein* and *New Prime* as inconsistent, but they are easily reconciled. *New Prime* holds that whether or not an agreement is excluded from the FAA is decided by a court, even when the arbitrability question is decided by an arbitrator. Schein holds that threshold issues of arbitrability are decided by the arbitrator(s) when an agreement is covered by the FAA (that is, it does not fall under any exclusion); when the arbitration agreement is valid; and when the parties "clearly and unmistakably" delegated arbitrability to the arbitrator, regardless of whether the arguments in favour of arbitration are "wholly groundless."

Schein serves as a reminder that parties should be aware of what they are agreeing to in their arbitration clauses. The question of whether or not the incorporation of a particular set of rules "clearly and unmistakably" delegates the arbitrability question to the arbitrator remains an open question. Parties should therefore carefully make their preferences clear in their arbitration agreements, especially where the arbitral rules identified by the parties delegate the arbitrability question to the arbitrator(s).

If there is any legitimate question as to whether or not the parties have "clearly and unmistakably" delegated the question of arbitrability to the arbitrator, a court will determine if such delegation was clear and unmistakable. These sorts of ambiguities regularly create inefficiencies and additional costs. The *Schein* decision should, nevertheless, reassure parties around the world that US courts will not disregard or overrule the contracting parties' delegation of an issue to arbitration.

LISA RICHMAN
Partner
Washington, DC
lrichman@mwe.com

DANIEL CAMPBELL
Associate
Chicago
dcampbell@mwe.com

CHINA'S PHARMACEUTICAL MARKETING AUTHORISATION HOLDER MECHANISM

James Jiang and Joyce Xie

China's Pharmaceutical Marketing Authorisation Holder pilot programme has now been extended until November 2019, providing further opportunities for businesses to enter the rapidly expanding Chinese pharmaceutical market.

Based on the differences between types of approval, pharmaceutical licensing administrative systems can be divided into two categories.

The first type is segregated management, which is found in Pharmaceutical Marketing Authorisation Holder (MAH) systems in countries such as the United States, Japan, and across the European Union. Under this system, MAH and Production Authorisation Holders (PAHs) can be the same or different entities.

The second type is a hybrid model of pharmaceutical production and marketing licensing administrative systems. In these types of systems, a pharmaceutical marketing license can only be granted to a PAH. This is typical in countries such as China.

The regulatory system under the hybrid model has two key shortcomings when compared with that of the flexible segregated management system.

1. Pharmaceutical research and development institutions, and scientific research personnel, can only obtain short-term or hidden/unintended benefits of their research and development through licensing technology and pre-arranged sharing with pharmaceutical manufacturers. This leads to a lack of motivation to conduct research.
2. Originally, it was possible to meet pharmaceutical production goals by engaging pharmaceutical manufacturers that already had similar types of pharmaceutical production requirements. Owing to institutional restrictions, however, pharmaceutical manufacturers are continuously building new production lines in order to list drugs on the market, which has resulted in duplicate construction and a waste of industry resources.

"An MAH is permitted to manufacture or sell pharmaceuticals."

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With the rapid development of China's pharmaceutical market, the existing regulatory system can no longer meet the sector's mechanical demands. On 5 November 2015, an MAH mechanism pilot programme was launched in ten provinces and cities (the Pilot Areas) and has now been extended until 5 November 2019.

Scientific research personnel and pharmaceutical research and development institutions in the Pilot Areas can apply for an MAH qualification and thus obtain the required pharmaceutical marketing license and the drug approval number. An MAH is permitted to manufacture or sell pharmaceuticals, either on its own or through a manufacturer or distributor. An MAH also bears complete legal liability for pre-clinical research, clinical drug trials, production, distribution, and adverse drug reaction monitoring.

According to data released by the State Council in October 2018, as of the end of September 2018, 1,118 applications to become an MAH were filed in the Pilot Area. Of these applications

- 786 were made by pharmaceutical manufacturers, accounting for 70.3% of all applications.
- 331 applications were made by pharmaceutical research and development institutions, accounting for 29.6% of all applications.
- Only one application was made by a scientific researcher, accounting for 0.1% of all applications.

The application was eventually withdrawn. 186 drug clinical trials have already been approved, and 122 test products have applied for approval for market listing.

MAH SYSTEM DEVELOPMENT AND OUTLOOK

Although the MAH system is still in the pilot stage, the Chinese authorities have already begun preparations to fully implement it at all levels in the legal system and the pharmaceutical administration system. This includes incorporating the MAH system into the Pharmaceutical Administration Law (Amended Draft), issued in November 2018, and the Pharmaceutical Registration Administration Law (Revised Draft), released for public comment in October 2017. The Chinese Government has already completed a draft of the Administrative Measures for Pharmaceutical Marketing Authorisation Holders.

> "186 drug clinical trials have already been approved."

The government is also continuously issuing laws and regulations aimed at resolving problems encountered during the pilot programmes. For example, the National Medical Products Administration issued a public announcement in September 2018 to request implementation of the MAH report on adverse reactions.

Once these problems are resolved, the complete implementation of the MAH system will be imminent. It is expected that this will greatly promote the development of the medical service outsourcing industry in the Chinese market. Companies such as contract research organisations (CRO), contract manufacturing organisations (CMO) and contract sales organisations (CSO) will benefit greatly.

PRACTICAL IMPLICATIONS

Because an MAH authorisation means fast-track treatment and an accelerated marketing process during the pilot period, many companies immediately converted their existing applications to MAH applications once the MAH pilot programme started.

Companies that wish to explore the Chinese pharmaceutical market and possess pharmaceutical technology but do not currently hold the proper pharmaceutical production qualifications in China, will need to become an MAH. They first need to be recognised as a Pharmaceutical Research and Development Institution (PRDI). According to current regulations, a PRDI should be

- A pharmaceutical research and development institution established in the Pilot Area and capable of undertaking the liabilities independently and responsibly
- Able to assume liability for drug quality and safety.

These standards are rather vague, which has created uncertainty and room for maneuver in practice.

The competent government science and technology supervising departments usually determine whether or not an entity qualifies as a Research and Development Institution. There are clear standards in place for the original value of fixed assets for research and development (R&D), the number and positions of R&D personnel, and R&D fund investment. The criteria for the identification of a *Pharmaceutical* Research and Development Institution is, however still unclear (authors' emphasis). In practice, it is quite possible for a Chinese subsidiary company of a foreign pharmaceutical company that is equipped with R&D personnel and facilities to apply for the MAH qualification under the existing pharmaceutical administration system.

Pharmaceutical companies that already have manufacturing facilities in China can also apply for the MAH qualifications for pharmaceutical products that are outside their existing manufacturing capacity by engaging a third party CMO.

LICENSE TRANSFERS

As long as the MAH system is fully implemented under China's national pharmaceutical administrative regulations, relevant examination and approval formalities regarding pharmaceutical license transfers are expected to be further simplified.

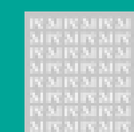
Under the current regulations, the original license holder must first apply to cancel its license, and then the transferee company has to apply for a new license. Under the MAH regulations, it is expected that the pharmaceutical license will be transferable directly via a change registration system, as long as certain statutory MAH requirements are met.

THE FUTURE IS BRIGHT, BUT CAUTION IS KEY

While the MAH system can certainly facilitate pharmaceutical transfer deals among pharmaceutical companies in China, it should be noted that the MAH must bear full legal liability for the entire pharmaceutical production chain and subsequent sales, as well as the entire life span of the pharmaceutical product management cycle.

If the MAH trusts other enterprises to manufacture the pharmaceutical product, the MAH will face issues of product consistency, effective supervision, and the compliance of the other entity with its obligations under their agreed upon method of cooperation.

JAMES JIANG
Partner, MWE China Law
Shanghai
jjiang@mwechinalaw.com



JOYCE XIE
Associate, MWE China Law
Shanghai
jxie@mwechinalaw.com

US ▸ FOREIGN INVESTMENT

FOREIGN INVESTMENTS IN US BIOTECH NOW COVERED BY CFIUS

Linda Ji, David Levine and Raymond Paretzky

"The enactment of FIRRMA… puts the US biotech sector in the crosshairs of CFIUS."

The expansion of CFIUS's jurisdiction to cover the biotechnology sector presents an additional regulatory hurdle for foreign investors that requires careful advance planning.

The Committee on Foreign Investment in the United States (CFIUS) is a United States federal interagency committee chaired by the US Treasury Department. CFIUS is charged with reviewing and addressing any adverse implications for US national security posed by foreign investment in US businesses.

The enactment of the Foreign Investment Risk Review Modernization Act (FIRRMA) in 2018 strengthened CFIUS' mandate and broadened its jurisdiction over a range of foreign investment transactions involving various US industries, including the US biotech industry. Prior to the enactment of FIRRMA, US biotechnology companies were largely unconcerned with CFIUS in relation to transactional matters. These companies generally focus on research and development, mainly the discovery of therapeutics and diagnostics for diseases, which are activities of little or no concern for US national security outside the limited areas of bioterrorism and toxins.

The enactment of FIRRMA in late 2018, and Treasury's implementation of FIRRMA via interim rules establishing a temporary Pilot Program, abruptly put the US biotech sector in CFIUS' cross-hairs. The interim rules specify 27 industries for focused scrutiny, including nanotechnology (NAICS Code: 541713) and biotechnology (NAICS Code: 541714). All 27 specified industries can be found in Annex A to the interim regulations.

Prior to the enactment of FIRRMA, CFIUS only reviewed transactions that could result in direct control of a US business by a foreign person. FIRRMA and the interim rules expanded the scope of CFIUS reviews to include certain foreign investments in US businesses, even in cases where the investment does not result in a controlling interest.

As a result of FIRRMA, mandatory, not voluntary, filings with CFIUS will be required for controlling and non-controlling investments that fall within the definition of "Pilot Program Covered Transactions," and violations of the new rules could result in substantial penalties.

APPLICATIONS OF THE NEW RULES TO INVESTMENTS IN US BIOTECH

Direct Inbound Investments

A direct inbound investment in a US biotech company would constitute a "Pilot Program Covered Transaction" if it meets either one of the following criteria:

1. Any non-controlling (*e.g.*, 5% equity interest) direct or indirect investment by a foreign person in an unaffiliated US business that produces, designs, tests, manufactures, fabricates, or develops one or more "critical technologies" either used in connection with, or designed specifically for

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use in, the biotechnology and/or nanobiotechnology industries that affords the foreign person one of the following:

- Access to any material nonpublic technical information in the possession of the target US business
- Membership or observer rights on the board of directors or equivalent governing body of the US business, or the right to nominate an individual to a position on the board of directors or equivalent governing body of the US business
- Any involvement, other than through voting of shares, in substantive decision-making of the US business regarding the use, development, acquisition, or release of critical technology

2. Any transaction by or with any foreign person that could result in foreign control of a US business as described in point 1, including such a transaction carried out through a joint venture.

As it relates to the biotech industry, the term "critical technologies" under the Pilot Program may include

- Civilian/military dual-use technologies subject to the Export Administration Regulations (EAR), administered by the US Department of Commerce's Bureau of Industry and Security (BIS), that relate to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology, excluding EAR99 items, which are items not covered by a specific Export Classification Control Number in the EAR).

- Select agents and toxins.
- "Emerging and foundational technologies" controlled under section 1758 of the Export Control Reform Act of 2018. As of February 2019, the definition of emerging and foundational technologies has not been finalised.

BIS announced in November 2018 an Advance Notice of Proposed Rulemaking (ANPR) inviting public comments on the scope of "emerging technologies." This ANPR specifically listed nanobiology, synthetic biology, genomic and genetic engineering, and neurotech as the representative categories of biotechnology for which BIS sought to determine whether or not they are essential to US national security. BIS received over 200 comments, and while the Bureau has not indicated a particular timeline, it will probably be at least late spring 2019 before it issues new regulations or otherwise clarifies whether or how it will establish newly controlled classifications for "emerging technologies," biotech-related or otherwise.

Prior to BIS releasing its next round of rulemaking or further clarification, some foreign investors in the biotech industry are taking a wait-and-see approach and some are taking a conservative approach in treating a broad range of biotechnology, particularly the four categories named in the ANPR, as potentially within the scope of CFIUS and US export controls.

BIS plans to issue a separate ANPR for "foundational technologies."

Indirect Investments by Foreign Persons *via* US Investment Funds

The interim rules establish an exemption from the mandatory declaration requirement for certain passive investments in US businesses made through investment funds that meet several conditions. One of the key conditions is that the investment fund must be managed exclusively by a general partner, managing partner, or equivalent, who is not a foreign person.

Outbound Licensing of US Technologies

Outbound licensing of intellectual property or technology only by a US business to a foreign person does not by itself fall within CFIUS' jurisdiction, unless it constitutes or accompanies an acquisition of, or investment in, a US business.

It is important to note that technology involved in such outbound licensing may itself be subject to US export controls requirements, depending on the classification of the technology under the EAR. US businesses must carefully determine the export classification of any technology before transferring or releasing, *e.g.*, under a licensing agreement, such technology to any foreign person. The pending announcement by BIS of what constitutes "emerging" and "foundational" technologies has added complexity and uncertainty in this area.

THE NEW MANDATORY DECLARATION PROCEDURE

Parties to a Pilot Program Covered Transaction must submit to CFIUS either an abbreviated declaration or a long-form notice. CFIUS has released a five-page declaration form for parties. The filing must be made at least 45 days prior to the expected completion date of the transaction to ensure that CFIUS has an opportunity to review it. The fine for failing to file can be up to the entire amount of the investment.

After CFIUS receives a declaration, the CFIUS staff chair will initially assess its completeness and decide whether or not to accept it as complete.

After it has been accepted, CFIUS must take one of the following actions within 30 days:

- Request that the parties file a full written notice.
- Inform the parties that CFIUS cannot conclude action on the basis of the declaration, and that the parties may file a full written notice.
- Initiate a unilateral review of the transaction.
- Notify the parties that CFIUS has concluded, *i.e.*, approved, the transaction.

TAKEAWAYS

Parties to cross-border transactions involving US biotech businesses, whether simple licensing arrangements or full M&A transactions, should carefully consider all US regulatory implications, including application of the new CFIUS rules and US export controls. This will enable the parties to develop optimal strategies for effectively and efficiently addressing these regulatory requirements while also achieving their business objectives.

LINDA JI
Partner
Boston
lji@mwe.com

DAVID LEVINE
Counsel
Washington, DC
dlevine@mwe.com

RAYMOND PARETZKY
Partner
Washington, DC
rparetzky@mwe.com

BEYOND CFIUS: FOREIGN INVESTMENT REVIEWS OUTSIDE THE UNITED STATES

David Levine, Raymond Paretzky and Louise Aberg

The United States isn't the only country bolstering its protections against foreign investment that may compromise national security.

US legislation recently strengthened the law that authorises the President, through the Committee on Foreign Investment in the United States (CFIUS), to review and possibly block foreign investments if CFIUS finds they adversely affect US national security.

Other governments are following suit, adopting or enhancing CFIUS-like regimes to review foreign direct investment (FDI) in businesses deemed to involve sensitive or critical industries, technology, or infrastructure.

In the European Union, a regulation laying out an FDI framework for EU Member States was adopted on 5 March 2019. The regulation sets out basic procedural requirements that Member States with an FDI system will need to follow with respect to transparency, timeframes, protection of confidential information, and judicial redress.

The European Commission will also be able to issue an opinion to Member States on FDI likely to affect projects of EU interest. This new framework will coexist with the national regimes.

In December 2018, Germany revised its FDI regime to lower the thresholds applicable to certain industries. It had already tightened its regime in 2017 by adding critical infrastructure, such as energy and telecommunications, to its scope of review.

At the end of 2018, France adopted a decree extending the breadth of its screening process to new sensitive areas, such as research and development in cybersecurity, artificial intelligence, and robotics.

Reacting to Chinese investment in the Hinkley Point nuclear project, in 2018 the UK Government published a white paper to review FDI in sectors that pose national security risks, such as advanced technologies, dual-use technologies, and national infrastructure.

FDI regulatory requirements vary widely in the Asia-Pacific region and in the Middle East.

Australia has a protectionist approach, and focuses its review on acquisitions of Australian real estate, agricultural land and agribusiness, and investments in sensitive industries, such as media, telecommunications, transport, and defence.

"More restrictive control of FDI creates new regulatory obstacles for cross-border deals."

In China, foreign investment laws designate industries as "encouraged," "restricted," or "prohibited." FDI is prohibited, for example, in the media, natural resources, and military sectors.

In Japan, the government will review FDI in a variety of sensitive industries, including military, aerospace, and nuclear energy, as well as in critical infrastructure, such as electricity, gas, communications, and broadcasting.

Israel announced in early 2019 that it would adopt an FDI screening system, notably to counter Chinese investment in technology companies.

The global trend in many countries towards more restrictive control of FDI creates new regulatory obstacles for companies engaged in cross-border deals. Foreign investors should carefully consider reporting and review requirements and procedures in advance of any such transaction. If an FDI filing is required or advisable, foreign investors should engage authorities as early as possible, as FDI review procedures may impact timing and other strategic elements of cross-border transactions.

DAVID LEVINE
Counsel
Washington, DC
dlevine@mwe.com

RAYMOND PARETZKY
Partner
Washington, DC
rparetzky@mwe.com

LOUISE ABERG
Associate
Paris and Washington, DC
laberg@mwe.com

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