PACIFIC RIM ADVISORY COUNCIL

Pacific Rim Advisory Council

JUNE 2023 e-Bulletin

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PRAC Let's Talk!

Virtual meeting - TBA

Conferences

New Delhi - October 7 - 10, 2023
Hosted by KOCHHAR & Co.

Paris May 25 - 28, 2024
Hosted by GIDE

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Let us know your plans to attend upcoming industry events
Prior to event start we will put you in touch with other attending PRAC Delegates.
Get on the List! events@prac.org

ABA Denver August 3 – 8 IBA Annual, Paris - Oct 29—Nov 3

Full Details
www.prac.org/events

Visit us online for the latest up-to-date, country specific information
www.prac.org/member_publications.php

MEMBER DEALS MAKING NEWS

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PRAC CONTACTS MEMBER DIRECTORY EVENTS

HAN KUN BOLSTERS FIRM'S PRIVATE EQUITY, MERGERS & ACQUISITION AND CAPITAL MARKETS CAPABILITIES

BEIJING/SHANGHAI 25 May, 2023:

Han Kun is pleased to welcome Ms. Jing Li and Mr. Ray Shi on board, further bolstering the firm's private equity, mergers & acquisitions and capital markets capabilities.

Ms. Li focuses her practice on representing strategic and private equity clients in complex China-related transactions, including mergers and acquisitions, divestitures, buyouts, bankruptcy restructurings, and joint ventures. Ms. Li works with a long-standing base of clients and has a strong track record across a variety of industries such as private equity/ venture capital, technology, software, telecommunications, pharmaceutical, healthcare, real estate, energy, agriculture, consumer products, chemicals, manufacturing, asset management, e-commerce, and advertising. Ms. Li has handled matters for many global major private equity clients.

Prior to joining Han Kun, Ms. Li practiced as a corporate partner at Allen & Overy LLP – Shanghai Lang Yue Joint Operation Office and Kirkland & Ellis International LLP and participated in the founding of A&O Lang Yue Joint Operation Office and Kirkland's offices in Hong Kong, Shanghai, and Beijing. Ms. Li is appointed by the School of Foreign Studies of China University of Political Science and Law as a supervisor for Master of Translation and Interpretation (MTI) candidates.

Ms. Li obtained her Bachelor of Arts degree from China University of Political Science and Law and a Master of Law degree from University of International Business and Economics, as well as an LL.M. degree from Columbia University School of Law (Harlan Fiske Stone Scholar) in 2016. In addition, Ms. Li has authored the "China" chapter of the 2016 and 2020 World Bank "Women, Business and Law Report" and other renowned publications. Ms. Li is a member of both the PRC Bar and the New York State Bar.

Mr. Shi has been practicing law at prominent PRC law firms for more than a decade, specializing in A-share and overseas capital markets, VC and PE investment, domestic and cross-border mergers and acquisitions, and other related transactions. During his professional career to date, Mr. Shi has established a sound professional reputation and has won considerable recognition for providing need-based legal solutions and handling complicated transactions.

Mr. Shi has acted as lead counsel of many influential transactions in various industries such as TMT, healthcare, finance, new energy, semiconductor, and high-end manufacturing, and thus possesses in-depth experience and unique insights into the business models, industry regulations, and market practices of these industries. He is particularly skilled in handling complex and unprecedented major transactions that require cross-border and cross-legal jurisdictional considerations, as well as the integration of legal, financial, and tax-related dimensions.

Mr. Shi graduated from Peking University with an LL.B. degree in 2008, and the University of Chicago Law School with an LL.M. degree in 2014. Mr. Shi is a member of both the PRC Bar and the New York State Bar. Over the years, Mr. Shi has been recognized by multiple renowned legal directories such as The Legal 500, China Business Law Journal, Legalband, and Dawkins

For additional information visit www.hankunlaw.com

HOGAN LOVELLS LAUNCHES CROSS-PRACTICE, CROSS-SECTOR GLOBAL AI TRENDS GUIDE FOR 2023

WASHINGTON, D.C., 31 May 2023 – Global law firm Hogan Lovells has introduced its Global Artificial Intelligence (AI) Trends guide, highlighting some of the key market-moving areas on which its lawyers are actively focused.

As innovation surges, the legal and regulatory landscape is evolving rapidly, with regulators applying existing frameworks to account for AI, or in some cases, developing new paradigms entirely. Complex regulatory frameworks are being developed in areas ranging from medical devices, to chatbots, to global supply chains. The Global AI Trends Guide utilizes Hogan Lovells' global reach, deep industry sector knowledge, and commercial-focused approach to help clients navigate a host of AI legal needs.

"Across the globe, businesses, consumers, and policymakers are grappling with the pace of AI innovation," said Hogan Lovells partner Mark Brennan, Leader of the firm's Tech and Telecoms sector. "Our clients are turning to us to help them understand both the legal and regulatory implications of AI on their key products and markets. As an integrated global law firm, we're proud to be able to provide comprehensive, practical legal counsel to our clients across industries and help them stay ahead of the market."

The global cross-practice, cross-sector guide provides a snapshot of considerations for AI technologies.

Notable insights include:

. Global AI policy developments;
. Ethical and responsible business applications;
. Data privacy considerations, including transparency, data minimization, accuracy, and other aspects;
. AI-enabled technologies' impact on health care, life sciences, medical devices, and data management;
. The role of AI in existing and future copyright and IP law;
. Regulation and risk management in the financial services sector, including on cloud-based hosting services, open-source AI software, and enhanced infrastructure;
. Legal risks in the space, satellite, and telecoms industry; and
. Applications for the automotive industry, including autonomous vehicles and connected technologies.

The Global AI Trends Guide is available here https://www.hoganlovells.com/-/media/hogan-lovells/pdf/2023-pdfs/hogan-lovells---artificial-intelligence-trends-guide.pdf

For additional information visit www.hoganlovells.com

ARIAS

ADVISES HOLCIM GROUP IN THE ACQUISITION OF LINERALS Y AGREGADOS

GUATEMALA CITY, 06 06 June 2023: Arias is pleased to announce its successful legal advisory role to the Holcim Group during the majority acquisition of the Guatemalan company Minerales y Agregados, S.A. This transaction represents a significant milestone for both companies and marks a significant step in Holcim Group's regional expansion strategy.

Minerales y Agregados, S.A. is a renowned company specialized in the production and commercialization of mortars, adhesives, and calcium carbonate solutions in Guatemala. Thanks to the trust placed in our firm, we were able to participate in this process to support Grupo Holcim in successfully and efficiently carrying out the acquisition, providing comprehensive legal advice throughout all stages of the transaction.

Our team rendered the advice natural in this sort of operations, meaning those related with the pre-acquisition revisions, as well as the preparation and negotiation of the acquisition documents and others related. Likewise, it conducted and coordinated the closing the operation, including those corresponding to post-closing actions. The collaboration between Arias and Holcim Group was essential in ensuring the successful completion of this operation.

This strategic decision reinforces Holcim Group's leadership in the Central American region and its commitment to innovation and sustainability in the construction sector. It further advances their vision of becoming the global leader in innovative and sustainable construction solutions, generating progress for both people and the planet.

We congratulate Holcim Group on the acquisition of Minerales y Agregados, S.A. and wish them great success in their business journey. We are honored to have been part of this process as their legal advisor.

Congratulations to the participating lawyers in Guatemala: Partners Luis Pedro del Valle, Rosa María Arenales; Senior Associate Maria Elena Barrientos; and Associates Florencio Gramajo; Francisco Zuluaga, Juan Carlos Batres and Carlos Flores Presa – Associate

For additional information visit www.ariaslaw.com

CAREY

HELPS CHILEAN INVESTOR LARRAINVIAL ACQUIRE LOCAL PHARMACY CHAIN FARMACIAS AHUMADA FROM WALLGREENS BOOTS ALLIANCE

SANTIAGO, 02 June 2023: Carey has helped Chilean investor LarraínVial buy local pharmacy chain Farmacias Ahumada from Wallgreens Boots Alliance, a US-UK holding company that invests in the pharmaceutical sector.

The seller and target relied on DLA Piper (Chile). The deal was signed on 16 May for an undisclosed amount. The transaction is subject to antitrust approval by Chile's competition authority FNE and is expected to close by the end of 2023.

LarraínVial is one of the main financial institutions in Latin America, with clients in Colombia, Chile, Peru and the US. It has more than US$6 billion worth of assets under management. In 2021, it bought a 50% stake in independent wealth management company Sherpa WMC.

Founded in 1968, Farmacias Ahumada has nearly 300 stores throughout Chile, in addition to outposts in Mexico and Peru.

Counsel to LarraínVial Carey Partners Salvador Valdés, Jorge Ugarte and Guillermo Carey, counsel José Ignacio Mercado and associates Pablo Bauer and Borja Ochagavía.

For additional information visit www.carey.cl

DAVIS WRIGHT TREMAINE

COURT DISMISSES FOREST COMPANY'S $100 MILLION DEFAMATION SUIT AGAINST GREENPEACE

April 21, 2023 – After seven years of litigation, a federal judge in Oakland has dismissed at summary judgment the remaining claims in a sprawling lawsuit that pitted the largest timber company in Canada with one of its fiercest critics, Greenpeace.

Greenpeace was jointly represented in the matter by Davis Wright Tremaine and Klaris Law. Lance Koonce (Klaris) argued the motion, and the case was led by Laura Handman at DWT, along with Chelsea Kelly, Sarah Burns, Meenakshi Krishnan, Roxanne Elings, Nicole Phillis, Thomas R. Burke, and (formerly of DWT) Lisa Zycherman.

The case was originally filed in Augusta, Georgia and the original, 400-page complaint included claims for alleged violations of the Racketeer Influenced and Corrupt Organizations Act (RICO) and state conspiracy laws, as well as defamation claims, all based on Greenpeace's environmental advocacy relating to the practices of Resolute Forest Products, Inc.

The Greenpeace Defendants successfully moved to have the case transferred to the Northern District of California, where Judge Jon S. Tigar dismissed all of Resolute's claims, without prejudice. Resolute then filed an amended complaint, and in January 2019, Judge Tigar dismissed Resolute's RICO and related claims, as well as the defamation claim based on 288 allegedly defamatory statements, leaving only two statements at issue, both of which related to the "Montagnes Blanches" region in northern Quebec.

Today, Judge Tigar dismissed the remaining claims on the grounds that after four years of fact and expert discovery, Resolute could not demonstrate that the two statements by Greenpeace were made with actual malice. Actual malice is a standard applied to public figures such as Resolute, and derives from the First Amendment protection for free speech.

In response to the decision, Ms. Handman said: "We are so gratified by this decision, which ends a protracted dispute that took resources and time away from the important advocacy work Greenpeace does around environmental issues. But we are beyond proud of Greenpeace's continued strong advocacy even in the face of such challenges, and in particular its advocacy for free speech issues."

Mr. Koonce added, "Today's decision demonstrates that the law can act not just as a sword, but also – especially in the case of the First Amendment – as a shield. While it is regrettable that this lawsuit was ever filed, we are hopeful that this ruling will discourage other similar lawsuits, and in any event we are thrilled for our clients, who throughout this long ordeal have lived by their maxim 'We Will Not Be Silenced'."

This lawsuit and others of its kind have acted as a catalyst for groups such as Greenpeace to mobilize against SLAPP suits targeting advocacy, especially environmental advocacy. Efforts such as the Protect the Protest taskforce seek to educate and mobilize individuals and organizations with respect to lawsuits designed to chill speech, and to get behind expanded anti-SLAPP legislation, especially at the federal level.

For more information visit us at www.dwt.com

ARIFA HELPS GUIDE BLADEX BOND PROGRAMME

PANAMA, 06 May 2023: Latin American supranational bank Banco Latinoamericano de Comercio Exterior (Bladex) has called on Arias, Fábrega & Fábrega to structure a US$300 million multi-currency revolving bond programme in Panama.

The structuring agent – local financial institution Banistmo – relied on Alemán, Cordero, Galindo & Lee. The deal closed on 6 March. The US$300 million programme is the only Panamanian bond programme registered by a New York Stock Exchange and US-registered issuer. It is also the largest bond programme registered in Panama so far in 2023 and the first of its kind to allow for issuances in multiple currencies.

Counsel to Banco Latinoamericano de Comercio Exterior (Bladex) Arias, Fábrega & Fábrega Partner Fernando Arias, associate Ana Isabel Quijano and international associate Donald Canavaggio.

Counsel to Banistmo Alemán, Cordero, Galindo & Lee.

For additional information visit www.arifa.com

GIDE

COUNSEL TO THE CONSORTIUM FORMED BY VAUBAN INFRASTRUCTURE PARTNERS AND CAISSE DES DEPOTS ET CONSIGNATIONS ON THEIR CONTIMPLATED ACQUISITION OF CORIANCE GROUP

PARIS, 07 June 2023

Gide has advised the consortium formed by Vauban Infrastructure Partners via funds it manages (Vauban), with a 50.1% stake, and Caisse des Dépôts et Consignations (CDC), with a 49.9% stake, on their entry into exclusive negotiations with Igneo Infrastructure Partners for the acquisition of the entire share capital of Coriance.

Founded in 1998, Coriance builds, develops and operates district heating and cooling networks supplied locally and mainly by renewable energies (such as geothermal energy and biomass) and recovered energy to support in the long term local authorities and industries in their energy transition .

With a portfolio of more than 40 networks in France, Coriance is the 3rd largest player in the French market.

The completion of the transaction is subject to the information-consultation process of Coriance's employee representative bodies and to any necessary regulatory approvals.

The Gide team is led by partner Alexis Pailleret, working with associates Chloé Bouhours and Axel Azoulay on M&A aspects; partner Marie Bouvet-Guiramand and associate Pauline Coulon on project aspects; partner Eric Cartier-Millon, counsel Sarah Whitley and associate Paul Highnam on financing aspects; partner Thomas Courtel, associates Sarah Assayag, Paul Margelidon and Anne-Laure Coirre on public law aspects; counsel Pierre-Guillaume Sagnol on the management incentive scheme; partner Foulques de Rostolan and associate Pauline Manet on employment law aspects; partner Emmanuel Reille, counsel Pierre-Antoine Degrolard and associate Maximilien Rodrigues on regulatory aspects. The London office was also involved on specific M&A aspects, with counsel Matteo Matteucci and on specific financing aspects with associate Rosalie Johnstone.

For more information visit www.gide.com

HAN KUN

ADVISES ISPIRE TECHNOLOGY ON ITS INITIAL PUBLIC OFFERING AND LISTING ON NASDAQ

BEIJING, 06 April 2023: Han Kun advised and acted as PRC counsel to Ispire Technology Inc. on its U.S. initial public offering and listing on The Nasdaq Capital Market under the symbol "ISPR".

Ispire Technology Inc. is an industry leader in vaping technology and products, driven by extensive research and development.

For more information visit www.hankunlaw.com

HOGAN LOVELLS

KEPT WELL: HONG KONG COURT HANDS KEEPWELL TRUSTEE SIGNIFICANT WIN

HONG KONG, 19 June 2023

A Hong Kong court has awarded a trustee enforcing obligations under a keepwell deed more than US$489 million after finding the keepwell provider to be in breach. The decision by the Honourable Mr Justice Harris in Citicorp International Limited v Tsinghua Unigroup Co., Ltd (紫光集團有限公司）[2023] HKCFI 1572 comes shortly after an earlier decision involving the Peking Founder Group which ruled that the obligations contained in these deeds are enforceable in Hong Kong. The ruling, one of the most important Hong Kong corporate insolvency matters in recent years, represents a significant victory for bondholders and creditors enforcing agreements containing Hong Kong exclusive jurisdiction agreements.

Hogan Lovells represented Citicorp in the proceedings.

In *Tsinghua*, the plaintiff trustee claimed for the defendant's breach of contractual obligations owed to it under a keepwell deed and equity interest purchase undertaking (EIPU) in respect of US$450,000,000 six per cent Guaranteed Bonds due in 2020, issued by Unigroup International Holdings Ltd (the issuer) and guaranteed by Tsinghua Unigroup International Co Ltd (the guarantor).

The defendant was a PRC company and the indirect 100 per cent owner of the guarantor (a BVI company) which was in turn the direct owner of the issuer (another BVI company). The keepwell and EIPU provider had undergone reorganisation proceedings in the PRC under the PRC Enterprise Bankruptcy Law. The onshore proceedings concluded on 13 July 2022 only after the commencement of the Hong Kong proceedings.

The plaintiff argued that pursuant to the keepwell deed and the EIPU, the guarantor and issuer were required to have sufficient liquidity and/or means to comply with their obligations in respect of the bonds at all times. The plaintiff claimed the defendant failed to perform its obligations and was thus liable to the plaintiff for damages. The defendant claimed the obligations were void or unenforceable or did not arise because they were subject to obtaining regulatory approvals that it said would have been impossible to obtain and/or that they were obligations that would have been terminated or discharged in any event under PRC law.

Both *Tsinghua* and the *Peking Founder* litigation (which trials were heard back-to-back), involved English-law governed deeds containing Hong Kong exclusive jurisdiction clauses. In both cases, proofs of debt had been submitted by the trustee in the onshore bankruptcy proceedings. In the *Peking Founder* case, the proof had been rejected but without any reasons being given by the PRC Administrator. In *Tsinghua* the Administrator gave the proof a "pending" status, effectively providing the trustee with no voting right, no participation in any creditors' meeting and no say in the substance of the onshore restructuring plan.

The judgment

In his judgment, released just weeks after the decision in the *Peking Founder* litigation (see Hogan Lovells' alert ***Hong Kong court rules keepwell deeds are enforceable in first of its kind decision***), Mr Justice Harris noted that the issues dealt with in both trials were the same and the facts, although concerning unrelated business groups, were similar, with almost identical contractual documentation.

A major difference, however, was that the default on bonds issued by the Tsinghua Group and the consequent breaches of the keepwell deed and EIPU, which led to the claims, took place before it was ordered into reorganisation on 16 July 2021. This was not the case in respect of the claims brought by three of the plaintiffs in *Peking Founder*.

A further difference is that in *Tsinghua* the plaintiff sought a monetary judgment whereas in *Peking Founder* the plaintiffs only sought declaratory relief.

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HOGAN LOVELLS

KEPT WELL: HONG KONG COURT HANDS KEEPWELL TRUSTEE SIGNIFICANT WIN

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Harris J said there was no evidence of the company, the issuer or the guarantor ever making any efforts to comply with its keepwell or EIPU obligations "or, for that matter, giving any consideration to how they might do so". The breaches occurred in December 2020, well before the reorganisation commenced in July 2021. The defendant claimed it would not have been able to obtain the necessary regulatory approvals despite using its best efforts, but Harris J held that "in the present case there is no evidence of the defendant giving any consideration to what Regulatory Approvals were required, let alone making any effort to obtain any". The defendant "did not formulate a plan to ensure that the finance required by the Keepwell Deed was provided to the Issuer or Guarantor in 2020 and never explored with the Approval Authorities whether whatever consents were required were likely to be given".

In the view of Harris J, the "best efforts" obligation "required Tsinghua to consider the options that might be available to it in order to comply with the Keepwell Deed and the EIPU". The defendant would need to "demonstrate what steps it took to comply and why they were unsuccessful. Tsinghua has failed to do so".

The defendant had "adduced no evidence of any consideration being given to a means by which the Issuer or the Guarantor could be put in funds, which would enable them to comply with their obligations under the Bonds or the guarantee and it has not adduced any evidence to explain why it did not." The defendant had also failed to provide evidence as to its financial state in late 2020 or show what if any options were available.

Harris J said that in his view it was clear that the defendant had failed to demonstrate that it was not possible for it to perform its obligations under the keepwell deed and/or the EIPU because it could not obtain the necessary regulatory approval prior to 10 November 2020, a significant date since "it would have been necessary for Tsinghua to have been considering its options at least a month in advance of the last date by which the Issuer and the Guarantor needed funds to pay the Bonds when they matured" on 10 December 2020. On 7 December 2020, the guarantor (as lender) entered into a loan agreement with Tsinghua (as borrower) to lend US $523,000,000 to Tsinghua (Guarantor's Loan Agreement). The court found that the Guarantor's Loan Agreement demonstrated that in December 2020, Tsinghua had access to U.S. dollars that could have been used to comply with its obligations under the Keepwell Deed or EIPU but that instead of utilising the funds to settle its liabilities under the bonds, a decision was made to shift these funds back onshore.

Loss

As to the extent of loss suffered, Harris J said that the relevant question was "what was lost by the failure to comply with the Keepwell Deed and EIPU, the failure to comply being the failure to put the Issuer and/or the Guarantor in funds in order that they could pay the principal and interest due when they became due. There is no dispute that the Bonds matured and became payable on 10 December 2020. This is the date at which loss is to be assessed. The loss was the amount that should have been paid but was not."

In giving judgment in the trustee's favour, Harris J awarded the substantial sum of US$483,843,533 consisting of the principal amount, accrued interest and certain trustee costs.

A significant ruling

The decision represents a significant victory for bondholders and creditors demonstrating that material damages awards can be achieved from keepwell providers. The decision gives rise to a money judgment which may now be enforced directly against the defendant and its assets and the success in pursuing this will now be closely followed.

What is certain is that this landmark decision together with *Peking Founder* represents one of the most important developments in cross-border corporate insolvency matters and further opens the door to sensible interaction and cooperation between the Hong Kong and mainland courts.

Authored by Byron Phillips, Jonathan Leitch, and Nigel Sharman.

For additional information visit us at www.hoganlovells.com

KOCHHAR

ADVISES BASIC ADHESIVES SALE O PIDILITE INDUSTRIES LIMITED

NEW DELHI, 20 April 2023: Kochhar & Co. advised Basic Adhesives, LLC, a New Jersey-based American corporation, in the sale of its business to Pidilite Industries Limited.

The transaction involved sale of assets inter alia comprising technology, know-how, design, trademark, copyright, domain name, trade dress, customer book, inventory etc. Basic Adhesives has long been a prominent provider of adhesives and related products to the world's most prestigious luxury brands in the leather goods business. Following the transaction's completion, Basic Adhesives will provide transition support to Pidilite to ease its entry into the aforementioned domain.

The Kochhar team, led by Senior Partner Rajarshi Chakrabarti, Partner Sameena Jahangir, and Principal Associate Anushree Aditi, advised Basic Adhesives on all aspects of the transaction, including reviewing, drafting, negotiating, and finalising transaction documents (such as the Master Framework Agreement, Technology Transfer Agreement, Deed of IP Assignment, and so on) and all other legal formalities related to the pre-closing and post-closing stages.

For additional information visit www.kochhar.com

MUNIZ

ACTS IN PERUVIAN AGRIBUSINESS LOAN

LIMA, 04 May 2023: Peruvian agribusiness Icatom has enlisted Muñiz, Olaya, Meléndez, Castro, Ono & Herrera to obtain a loan for US$14 million.

Hernández & Cía advised the lenders, Banco de Crédito del Perú and Scotiabank. The transaction closed on 8 March.

Icatom received US$7 million from Banco de Crédito del Perú and US$7 million from Scotiabank. The company will use the proceeds to repay its outstanding debt and for general corporate purposes.

Established in 1995, Icatom specialises in the production of tomato paste, as well as fresh fruits and vegetables. The company exports its products to several Latin American jurisdictions, including Argentina, Brazil and Ecuador, and to oversea destinations like the US, Italy and Japan.

Counsel to Icatom Muñiz, Olaya, Meléndez, Castro, Ono & Herrera Partners Alfredo Lay-Tam Oyafuso, Yuri Vega Mere and Jorge Girao, and associates Giovanni Huamaní Suarez and Alejandro Muñiz Chvedine.

For additional information visit www.munizlaw.com

NAUTADUTILH

ADVISES FEMSA ON THE FULL DIVESTMENTS OF ITS STAKE IN HEINEKEN

AMSTERDAM, 05 June, 2023

NautaDutilh advised FEMSA in its EUR 3.3 billion accelerated bookbuild offering (ABB) of Heineken and Heineken Holding shares combined with a bilateral sale of EUR 333 million worth of Heineken shares to Heineken.

The ABB and the bilateral sale form an integral part of the series of strategic initiatives announced by FEMSA on 15 February 2023 as a result of a thorough strategic review of its business platform.

Petra Zijp, capital markets partner, comments "We are once again grateful to have assisted FEMSA with these transactions as to advance one step closer to their strategic plan. A big compliment to our team that advised FEMSA on these transactions."

For additional information visit us at www.nautadutilh.com

PRAC EVENTS
BULLETIN BOARD

Like millions around the globe, the COVID-19 pandemic has impacted our members and how we work.
Our industry follows others with a mix of restart and pause.
We meet in person where and when we can
while continuing to also meet and talk virtually face to face
Across the miles, oceans and regions
In varying places and at all hours of the day and night.
It isn't the same. We can all admit to that.
We pivot. We adapt.
What remains the same is our commitment to continue forming new bonds
and strengthening our long-standing ties with our friends and colleagues around the world.

Together, we will see it through.

PRAC Events — Stay Connected

As we reboot our own in-person conferences in line with other industry related events ,
PRAC delegates can ***STAY CONNECTED!***
Let us know your plans to attend upcoming industry events and we will put you in touch
with other attending PRAC Delegates prior to event start
Get on the List! Register for upcoming Event Connect: events@prac.org

PRAC Let's Talk!

Join us in 2023 for our live one-hour virtual meetings
PRAC - Let's Talk! events are open to PRAC Member Firms only
Register : events@prac.org

Visit www.prac.org for full event details

PRAC LET'S TALK!

PRAC @ NEW DELHI MICRO-CONFERENCE HOSTED BY KOCHHAR & CO.

NEW DELHI - November, 2022 PRACites around the globe gathered online for PRAC @ New Delhi micro-conference hosted by member firm KOCHHAR & CO. Congratulations to the entire Kochhar Team for a successful e-hosting!

Agenda
Opening Remarks - Jaap Stoop, PRAC Chair; Marcio Baptista, PRAC Vice Chair; Jeff Lowe, PRAC Corp Secretary
Greetings & Welcome - Rohit Kochhar, Chairperson and Managing Partner
Country Update - India - Pradeep Ratnam
Visual Presentation - Essense of India!
Kochhar Practice Update - M&A - Chandrasekhar Tampi
Kochhar Practice Update - Banking & Finance - Pradeep Ratnam
Firm update - Rohit Kochhar
Panel Discussion on "Regulation of Content on Social Media" - Moderator, Stephen Mathias, Kochhar & Co (Bangalore); Mark Brennan, Hogan Lovells (Washington); Mauricette Schaufeli, NautaDutilh (Amsterdam)

PRAC EVENTS


2019
PRAC
COSTA RICA


PACIFIC RIM
ADVISORY COUNCIL


PRAC @ SAO PAULO
PACIFIC RIM
ADVISORY COUNCIL


PRAC @ Taipei 2014


PRAC Let's Talk! online event


PRAC @ INTA


PRAC @ Vancouver


PRAC @ PDAC


PRAC @ IPBA

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www.prac.org

With over 12,000 lawyers practicing in key business centers around the world, including Latin America, Middle East, Europe, Asia, Africa and North America, these prominent member firms provide independent legal representation and local market knowledge.

Argentine government approves new Merger Control Procedure Regulation

Practice Areas:

Antitrust

Lawyers:

Julián Peña, Federico Rossi

On May 18, 2023, the Secretary of Trade published Resolution No. 905/2023 (?Resolution?), whereby it approved a new version of the Argentine Merger Control Procedure Regulation (?Merger Control Procedure Regulation?).

The Merger Control Procedure Regulation replaces that issued in 2001 and has taken into account more than 20 years of experience, the technological and legal changes that have taken place in the past two decades, and the comments received to a draft version from local and international organizations.

The main changes introduced by the Merger Control Procedure Regulation includes:

The implementation of the fast-track mechanism introduced by the Argentine Antitrust Law in its 2018 reform. This new mechanism, so-called ?Procedimiento Sumario? (equivalent to a fast-track procedure), allows the notifying parties, in the case of non-problematic transactions, the possibility to file a so-called ?Form F0?, which is simpler than the existing and the new ?Form F1?. The new procedure simplifies the analysis of the transactions, though it does not reduce the 45-business-days term the Antitrust Authority has to take a decision.

It sets much harder effects to the submission of incomplete information, allowing only a limited flexibility for time extensions and the involvement of the company?s top authorities in the justification of the delays.

The request to provide a greater amount of documentation regarding the goals of the transaction and the existing internal market analysis, with the risk of sanctions to the companies? management and of considering the filing as desisted in case of non-compliance, thus allowing the Antitrust Authority to impose the late-filing fines pursuant the Antitrust Law.

The introduction of additional reasons to suspend and/or interrupt the Antitrust Authority?s clock in case of the submission of incomplete information, including, among other reasons, the filing of spontaneous submissions by the notifying parties.

The introduction of a requirement to the notifying parties to prepare a draft resolution, which will have to follow a standard format and will be approved by the Antitrust Authority in the upcoming days.

It establishes the possibility for the notifying parties to introduce Non-Competition considerations in the analysis of the transaction, such as potential benefits to labor generation, salaries, import-substitution, investments, environmental protection, gender policies, among others.

According to the Resolution, the new Merger Control Procedure Regulation will enter into force 30 days after the day of its publication.

This report cannot be considered as legal advice or any other type of advice from Allende & Brea.

TOZZINIFREIRE
ADVOGADOS

Reapplication of the anti-dumping duty on imports of polyester textured filaments has been requested

June 01, 2023

On May 31, Circular SECEX No. 19 made public the request for reapplication of the anti-dumping duty on Brazilian imports of polyester textured filaments, commonly classified under subitems 5402.33.10, 5402.33.20, 5402.33.90 of the MERCOSUR Common Nomenclature (NCM), originating in China and India. The anti-dumping duties are currently suspended for reasons of public interest.

The product consists of Draw Textured Yarn (DTY), which is a synthetic continuous multifilament yarn obtained from polycondensation of terephthalic acid (PTA), and mono ethylene glycol (MEG).

Statements on the request in question can be submitted within 30 days.

The Ontario Court of Appeal Confirms the Narrow Confines of the Tort of Intrusion Upon Seclusion

Written By Sakina Babwani, Nina Butz and Mehak Kawatra

2022 continued to be positive for institutional clients involved in privacy breach class actions, with the Ontario Court of Appeal refusing to expand the tort of intrusion upon seclusion to impose liability on institutions whose databases were hacked by unauthorized third parties.

Plaintiffs claiming damages in privacy breach class actions have struggled to achieve certification due to the absence of losses beyond everyday inconveniences.

Accordingly, plaintiffs often relied on the tort of intrusion upon seclusion, which does not require proof of a compensable loss. However, some plaintiffs asked the court to extend the tort to apply to not only to the third-party hackers, but also to the database defendants who collected and stored the data in the first place.

In late 2021, the Divisional Court refused to extend the tort, finding that it could not apply to database defendants because they did not commit the "central element" of the tort—the intrusion.

In November 2022, the Ontario Court of Appeal endorsed the Divisional Court's approach in three appeals heard in tandem: *Owsianik v. Equifax Canada Co.* [*Owsianik*], *Obodo v. Trans Union of Canada Inc.* [*Obodo*], and *Winder v. Marriott International Inc.* [*Winder*]. Bennett Jones acted for Marriott and affiliated entities in *Winder*.

In each of the three cases, the defendants had collected and stored personal information of their customers for commercial purposes. The plaintiffs alleged that the defendants' failure to take adequate steps to protect personal information had allowed third-party hackers to access and/or use that information. There was no allegation that the defendants themselves had improperly used or disclosed the personal information.

In *Owsianik*, the plaintiffs argued that they had properly alleged the tort of intrusion upon seclusion because they pleaded that the defendants acted recklessly in storing the information. The Court of Appeal, however, found that unless the defendants' conduct

amounted to an unlawful intrusion of the plaintiffs' privacy, the "state of mind" requirement of the tort could not be satisfied and the tort could not apply.

Similarly, in *Winder*, the Court rejected the plaintiffs' argument that Marriott became an intruder when it allegedly failed in its duty to protect the privacy of its customers. In *Winder*, the plaintiffs had willingly disclosed information to Marriott for purposes relating to the operations of Marriott's facilities. No facts were pleaded that could support the allegation that Marriott had disclosed personal information to unauthorized persons, or caused the information to be disclosed. The plaintiffs instead asserted that their consent had been provided based on Marriott's representation that the information would be held confidentially, and because Marriott allegedly knowingly or recklessly failed to meet those representations, consent was vitiated. That assertion was found to have no merit.

In *Obodo*, the plaintiffs argued that the defendant was an "enabler" and urged the Court to impose the equivalent of the doctrine of vicarious liability upon Trans Union to hold it accountable for the actions of the hacker. But, for the doctrine of vicarious liability to apply, an employer-employee relationship had to exist between the hacker and Trans Union. In the absence of such a relationship, Trans Union was not liable for the tort of intrusion upon seclusion.

In short, facts of this trilogy of cases were distinguishable from the facts of Court of Appeal's landmark 2012 decision in *Jones v. Tsige* [*Jones*], where the Court established the tort of intrusion upon seclusion because, among other things, the defendant had continually accessed the private banking records of the plaintiff without her consent. There, the defendant intruded, without lawful justification, on the private affairs or concerns of the plaintiff such that a reasonable person would regard the invasion as highly offensive, causing distress, humiliation or anguish.

In the trilogy of privacy appeals, however, the defendants' allegedly negligent storage of information did not amount to an invasion of the plaintiffs' privacy interests.

The Court of Appeal held that to expand the tort of intrusion upon seclusion to apply to database defendants would create a broad and undesirable basis for liability in intentional torts, by imposing liability on database defendants for the conduct of unknown third parties. Doing so would not be a permissible "incremental development" in the common law but would instead be a "gigantic step in a very different direction". The Court noted that the facts of the database defendant cases simply did not "cry out for a remedy" in the same manner as the facts of *Jones*, including because the plaintiffs in database defendant cases had recourse under existing causes of action grounded in both statute and common law.

Looking Forward

While leave to the Supreme Court of Canada from the Court of Appeal's decisions remains pending, as the law in Ontario currently stands, plaintiffs seeking damages against database defendants have limited recourse to the tort of intrusion upon seclusion in the absence of a connection between the database defendant and the hacker.

That said, businesses that collect personal information of others must continue to maintain secure databases and avoid other grounds of liability that arise from a breach of those informational databases, as the tort of intrusion upon seclusion is but one piece of the potential liability puzzle. For instance, the Court of Appeal commented that database defendants could still be liable for damages

flowing from negligence or breaches of contractual or statutory duties, where plaintiffs have suffered compensable harm.

Other Articles In This Series

- Ontario's Dismissal for Delay Regime—the Year in Review
- Securities Class Actions Round-Up
- Developments in General Causation Methodologies for Class Certification
- The Lack of Present Injuries and Reliable Scientific Evidence Proves Fatal in North American Pharmaceutical Impurity Litigation
- Discontinuance of a Class Action: A New Approach to Multijurisdictional National Settlements in Québec?

Authors

Sakina A.G. Babwani
416.777.6122
babwanis@bennettjones.com

Nina Butz
416.777.5521
butzn@bennettjones.com

Mehak Kawatra
416.777.7927
kawatram@bennettjones.com

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BILL 27 – MONEY JUDGMENT ENFORCEMENT ACT

By: Tommy Chan and Roan Wallace

Bill 27 underwent its first reading on May 1st 2023. This Bill proposes the *Money Judgment Enforcement Act*) (the "**Act**"), which is aimed to streamline collection efforts by successful litigants following civil and tribunal actions.

Under the current law, money judgments can be registered and executed against land owned by a judgment debtor, but it is more cumbersome to enforce and collect against the debtor's personal property.

Key Features of the Proposed Act:

1. ***A money judgment registry.*** The Act will create a new registry where creditors must register their judgment in order to enforce. The registry will also be accessible and searchable to the public.
2. ***Civil enforcement officers.*** The Act will create and authorize civil enforcement officers (bailiffs) to enter onto lands and seize personal property. This should facilitate debt collection in reducing the number of court appearances by the judgment creditor.
3. ***Charges on personal property.*** The Act will allow judgment creditors to pursue all forms of the debtor's personal property, including licences, intellectual property, and trade secrets.
4. ***A new limitation period.*** The Act will impose a general limitation period of not more than 2 years for creditors to register their money judgments in the new registry, with an ultimate limitation period of 15 years after the date the money judgment was granted. This is a marked change from the existing law that allow judgments to be generally valid for 10 years.

The Bill 27 is only in its preliminary stage, but there has been significant discussions surrounding the topic of a refreshed judgment enforcement system in recent years.

Creditors should carefully consider their existing remedies and keep apprised of the legislative developments.

Should you have any questions about this article, please contact Tommy Chan, Ryan Shaw, or Daniel Nugent.

/Carey

News Alerts

President of Chile exercises a partial veto power over the Economic Crimes Bill

June 15, 2023

On May 15, 2023, the Chilean Congress approved the Bill that Systematizes Economic Crimes and Attacks against the Environment (the "Bill"). Therefore, the Bill was sent to the President for its enactment into law, although it is subject to the preventive control that must be carried out by the Constitutional Court. During this period, the Executive has a deadline to exercise veto power over the bill prior to its enactment into law.

In this context, on Wednesday, June 14, the President of Chile made use of his faculties and submitted to Congress a veto of the Bill, indicating that the Government had noticed some errors that need to be amended. This is a "partial veto" which implies, in practice, that the corrections included in the veto must be submitted again to legislative discussion and voted separately in both Chambers. This could take several months, depending on the urgency and priority given to the bill.

The main observations to be amended include, among others, the following:

1. Correcting the omission of certain criminal offenses, which are predicated offenses of money laundering, that were incorporated during the year 2022.
2. Solving certain duplications or gaps in the lists of first, second and third categories of economic crimes, and adjusting the regime of confiscation in the law of criminal liability of the legal entities.
3. Correcting some formal errors in the modifications to the Stock Market Law, as well as in the bankruptcy offenses. In this last case, they proposed to make coincide the deferred enforcement established by the recent Law No. 21,563, which modernizes the bankruptcy procedures contemplated in Law No. 20,720 and creates new procedures for micro and small companies, with the new bankruptcy offenses.

AUTHORS: ***Guillermo Acuña, Rodrigo Aldoney, Pablo Albertz, Eduardo Alcaíno.***

Carey y Cía. Ltda.
Isidora Goyenechea 2800, 43rd Floor
Las Condes, Santiago, Chile.
www.carey.cl

Legal Commentary

June 2, 2023

HAN KUN
汉坤律师事务所
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Highlights on HGR Regulation Implementation Rules

Authors: Aaron GU | Pengfei YOU | Duzhiyun ZHENG | Fengqi YU[1]

On June 1, 2023, China's Ministry of Science and Technology ("**MOST**") officially released the *Implementation Rules for the Regulation of Human Genetic Resources Administration* ("***Implementation Rules***"), which will come into effect on July 1, 2023. Since the release of *the Rules for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comments)* in March 2022 by MOST ("*Draft Rules*"; for reference, please refer to *Han Kun • Perspective | Highlights on the Draft HGR Regulations Implementation Rules*), the industry has been eagerly awaiting the finalization of the policies outlined in the *Implementation Rules*. We closely followed the updates and noticed that some changes in the *Implementation Rules* have already been reflected in the regulatory practice. The long-awaited release of the *Implementation Rules* marks a new stage in China's regulation of human genetic resources.

The *Biosecurity Law* enacted in 2020, the *Regulations on the Administration of Human Genetic Resources* released in 2019 ("***HGR Regulations***"), and a series of administrative approval/filing service guidelines and regulations issued by MOST in recent years, including Frequently Asked Questions, together form the current overall regulatory framework for human genetic resources in China. However, until now, higher-level regulations such as the *HGR Regulations* lacked detailed implementation measures to further clarify the regulatory scope. The release of the *Implementation Rules* further refines China's overall framework for human genetic resources administration and provides more detailed compliance guidelines for the industry to carry out activities utilizing these resources.

This article will analyze and summarize the key provisions of the *Implementation Rules* such as administration, definition of human genetic resources information, definition of Foreign Parties, ethical review requirements, collection and biobanking requirements, international cooperation requirements, information provision and security review, supervision and administration, and punishment responsibilities.

[1] Shuwen Sun and Leyi Wang have contributions to this article.

Administration refinement

I. Delegation of regulatory authority

According to the *HGR Regulations*, the supervision and administration of human genetic resources in China is jointly carried out by the national competent departments and provincial competent departments in accordance with administrative authority. Meanwhile, the national competent departments are directly responsible for the administrative approval and filing of the collection, biobanking, international cooperation, and provision of human genetic resources to foreign parties. The *Implementation Rules* further explore the delegation and decentralization of China's HGR regulatory authority, which helps to enrich regulatory resources. Article 3 of the *Implementation Rules* stipulates that MOST may delegate relevant organizations to carry out formal review and technical review of HGR applications, as well as the administration of filing, prior reporting, supervision, inspection, and administrative penalty of HGR activities. Article 4 clarifies that provincial departments of science and technology, in addition to being responsible for the daily supervision and administration in their respective regions, can also review HGR approvals under the delegation of MOST. It is thus evident that under the *Implementation Rules*, **MOST can delegate its responsibility to review administrative approval to the provincial level and entrust its duties to review filing, supervision, and administration to relevant organizations**. For example, by the end of 2022, the Shanghai Science and Technology Commission, with the support of the National HGR Office, established the Shanghai Human Genetic Resources Administration Service Station, based on the Shanghai Biomedical Technology Development Center. The station primarily conducts HGR business consultations, HGR specialist training, and assists in the pre-, in-, and post-event HGR compliance.

II. Competent regulatory authorities

Notably, the *Implementation Rules* are promulgated by MOST, which is consistent with the long-standing practice of MOST supervising the utilization of human genetic resources in China. However, in March, 2023, the Central Committee of the Communist Party of China and the State Council issued the "Plan for the Reform of the Party and State Council," and decided to re-organize MOST and transfer China Biotechnology Development Center, which is responsible for the daily work of Human Genetic Resources Administration concerning biosecurity and biological resource administration, to be under the jurisdiction of the National Health Commission. This change may lead to the alteration of the competent department for the supervision and administration of human genetic resources in China. However, consistent with the current *Biosecurity Law* and *HGR Regulations*, Articles 3 and 4 of the *Implementation Rules* clearly stipulate that **the supervision of HGR is still the responsibility of MOST**. We understand that the institutional reform plan is still in the implementation phase, and the upper-level regulatory laws and competent departments for human genetic resources may still change in the future. However, given that the administrative approval and filing requirements for the collection, biobanking, international cooperation, and provision of human genetic resources to foreign parties are stipulated in the *Biosecurity Law*, the regulation framework of China's human genetic resources will not undergo fundamental changes unless the National People's Congress amends the law.

Definition of human genetic resources information

According to Article 2 of the *HGR Regulations*, human genetic resources information refers to data and other information materials generated from the use of human genetic resources materials. However, such criterion is relatively broad and brings uncertainties in practice.

In Article 2 of the *Implementation Rules*, human genetic resources information refers to data and other information such as human genes and genome data generated from the use of human genetic resources materials, **excluding clinical data, imaging data, protein data, and metabolic data.** This further clarifies the regulatory scope of human genetic resources information in China. The *Implementation Rules* specify that imaging data such as B-ultrasound and CT are not included in the human genetic resources information, which is consistent with the interpretations in the Q&A released by MOST in March and April 2022. However, it is worth noting that, according to our previous understanding, the regulatory authorities once considered adding "**biomarker**" data to the definition of human genetic resources information, but this was not included in the finalized *Implementation Rules*. We understand that biomarkers are not explicitly excluded from the scope of human genetic resources information by authorities, and the regulatory requirements still apply when the biomarker data contains human gene and genome data information. In addition, it remains uncertain whether the data analysis conclusions and other information generated from the research using human genetic resources fall under the scope of human genetic resources information. We understand that, based on the definition of the *Implementation Rules*, the analysis conclusions and other information materials, in the absence of gene and genome data information, will not be subject to human genetic resources regulatory requirements.

Clear definitions of human genetic resources are the prerequisites for the regulation applications. Only when the regulatory rules properly define human genetic resources can industry practitioners more accurately fulfill their compliance obligations. It can be seen that the current *Implementation Rules* have returned to the essence of regulating human genetic resources and have reasonably defined the regulatory scope of human genetic information, which is in line with MOST's HGR regulatory principle of "stringent regulation where necessary and reasonable flexibility where appropriate".

Scope of foreign parties

Pursuant to the *HGR Regulations*, foreign parties are facing more restrictions on utilizing human genetic resources than Chinese parties. For example, foreign parties are prohibited from collection and biobanking of human genetic resources, and it would be necessary to cooperate with Chinese parties and go through approval and filing procedures in order to conduct scientific research utilizing human genetic resources. MOST has always been treating entities with any foreign capital as foreign parties since the *Interim Measures for Administration of Human Genetic Resources* in 1998. The term "foreign party" was more clearly defined as "foreign organizations and institutions that are established or actually controlled by foreign organizations or individuals" by the current *HGR Regulations* promulgated in 2019, based on which the *Implementation Rules* have further improved the standards for recognizing foreign parties.

First, **the *Implementation Rules* clearly emphasize the "50%" ratio** for defining foreign parties, and stipulate that circumstances where an overseas organization(s) or an individual(s) **establishes** or **actually**

controls an institution include: "(1) an overseas organization or an individual holds or indirectly holds 50% or more of the shares, equity, voting rights, property shares or other similar rights and interests of the entity" or "(2) although the shares, equity, voting rights, property shares or other similar rights and interests of the entity directly held by an overseas organization or an individual do not reach 50%, the voting rights or other rights and interests it owns are sufficient to control or have significant influence on the resolutions, decision-making and internal management of the entity." After the *Implementation Rules* come into effect, an entity will no longer be regarded as a foreign party if overseas organizations or individuals have less than 50% of the equity and have no significant influence on the decision-making or internal management of the entity. This would potentially bring convenience to entities with only limited foreign ownership in utilizing human genetic resources. However, it remains to be seen how the regulatory authorities will determine the term "significant influence" in practice. In addition, the *Implementation Rules* have unified the criteria for recognizing foreign parties when they are **established** or **actually controlled** of overseas organizations and individuals compared with the Draft for Comments to make the provisions more reasonable.

Second, consistent with the Draft for Comments, **the *Implementation Rules* have made it clear that Chinese entities with VIE structures will be recognized as foreign parties**. The third paragraph of Article 12 of the *Implementation Rules* stipulates that "investment, agreements, or other arrangements by an overseas organization(s) and an individual(s) are sufficient to control or have significant influence on the decision-making, internal management and other major matters of an entity". Although pursuant to the *HGR Regulations*, VIE structures have already been covered as "actual control" in the definition of foreign parties, the *Implementation Rules* has put an end to the controversy about the nature of entities with VIE structures in practice, and such entities will be required to conduct their business activities related to human genetic resources in compliance with the regulatory requirements for foreign parties.

Third, Article 11 of the *Implementation Rules* stipulates that **entities in Hong Kong and Macau actually controlled by Chinese capital will be regarded as Chinese parties**. The definition of "actually controlled by Chinese capital" needs further interpretation from regulatory bodies, and from our point of view, the companies established in Hong Kong and Macau or the subsidiaries in Hong Kong and Macau actually controlled by Chinese companies may fall under the scope of Chinese parties, while as for subsidiaries established in Chinese mainland by Hong Kong and Macau companies, they will not fall under the scope of Article 11 and their status still need to be further examined based on the criteria stipulated in Article 12.

Ethics review requirements

The *Implementation Rules* have refined the ethics review requirements for the utilization of human genetic resources in China. Article 8 of the *Implementation Rules* stipulates that the collection, biobanking, utilization, and external provision of human genetic resources in China shall conform to the ethics principles, and the ethics review shall be conducted by the Ethics (Review) Committee, which has been filed by the relevant regulatory authorities. The ethics review shall be carried out in accordance with the law, administrative regulations, and other relevant provisions. Compared with the Draft for Comments, where the specific requirements for ethics review shall refer to the relevant provisions in the *Measures for the Ethical Review of Life Science and Medical Research Involving Humans* by the National Health

Commission, the *Implementation Rules* generally stipulate that the review should be conducted by the Ethics Committee filed with the relevant regulatory authorities and comply with relevant laws and regulations. From our understanding, **the *Implementation Rules* have left space for the technology ethics review regulations**, such as the *Technology Ethics Review Method (Pilot Implementation) (Draft for Comments)* issued by MOST in in April 2023. Given that the regulations of technology ethics review have not been officially promulgated, it is still uncertain about the application and relationship between the ethics review regulations issued by the Health Commission and the technology ethics regulations. The ethics review requirements in the utilization of human genetic resources in China in the future still need further observation to future legislations (for reference, please refer to *Han Kun • Perspective | Technology Ethics Review Method (Trial) (Draft for Comments): a Brief Overview* and *Han Kun • Perspective | New Ethics Review Regulations: Key Takeaways*).

Changes in collection and biobanking requirements

I. Changes in the scope of collection approval

In accordance with the *Biosecurity Law of the PRC* and the *HGR Regulations*, the collection of human genetic resources of important genetic families, in specific regions, or the specified categories and quantity shall be approved by relevant regulatory authorities. The *Guidelines for the Collection Approval of the Collection of Human Genetic Resources in China* (the "***Guidelines***") further stipulates the specific requirements in scope for the collection approval of human genetic resources. The *Implementation Rules* have updated the scope requirements for collection approval. Please see below the comparison:

	Guidelines	Implementation rules
Important Genetic Families	The group of people with blood relationship and with hereditary diseases or hereditary physical or physiological characteristics, and three generations and more than five members within the group have such hereditary diseases or hereditary physical or physiological characteristics.	The collection of human genetic resources of important genetic families. The term "important genetic families" refers to the group of people with blood relationship and with hereditary diseases or hereditary physical or physiological characteristics, and the three or more generations within the group have such hereditary diseases or hereditary physical or physiological characteristics. **Common diseases such as hypertension, diabetes, red-green color blindness, and hemophilia are not within the scope of important genetic families.**
Specific Regions	The human genetic resources originated from isolated or special environment for a long term and	The collection of human genetic resources in specific regions. The term "human genetic resources in

	Guidelines	Implementation rules
	have special physical characteristics or physiological adaptive characteristics. The specific regions are not divided based on whether they are ethnic minority inhabited areas.	specific regions" refers to human genetic resources that originated from isolated or special environment for a long term and have special physical characteristics or physiological adaptive characteristics. The specific regions are not divided based on whether they are ethnic minority inhabited areas.
Specified Categories	Rare diseases, special physical or physiological characteristics with significant differences	/
Specified Quantity	500 people or more	**The collection of human genetic resources for large-scale population studies with more than 3000 cases.** Such large-scale population studies include but not limited to cohort studies, clinical research, physiology studies, and etc. **The collection in clinical trial for the purpose of obtaining approval for marketing drugs and medical devices are exempted from collection approval for marketing drugs and medical devices are exempted from collection approval.**

The *Implementation Rules* have broadened the scope of collection in need of approval, and have clarified that common diseases such as hypertension, diabetes, red-green color blindness, and hemophilia are not within the scope of important genetic families. The *Implementation Rules* have also eliminated the collection approval requirements for specific categories such as rare diseases, and meanwhile, have raised the minimum requirement for the specified quantity for collection approval. It is stipulated that only collection activities for large-scale population studies with more than 3000 cases need to be declared for collection approval, and the collection in clinical trial for the purpose of obtaining approval for marketing drugs and medical devices are exempted from collection approval, for example, **the collection of human genetic resources in international cooperative clinical trials for obtaining marketing approval will no longer need collection approval even though the quantity of collection exceeds 3000**. The *Implementation Rules* will significantly ease the approval and regulatory burden of Chinese parties in collecting human genetic resources and conducting human genetic resource utilization activities and conserve the regulatory resources.

II. Changes in biobanking regulatory requirements

Regarding the regulatory requirements for the biobanking of human genetic resources, the *Implementation Rules* refined the provisions of the *HGR Regulations* in terms of the definition of biobanking activities and collection exemption permits. In terms of the definition of biobanking activities, Article 28 of the *Implementation Rules* stipulates that biobanking activities refer to the behavior of preserving legally obtained human genetic resources under suitable environmental conditions to ensure their quality and safety for future scientific research. It does not include temporary storage activities for teaching purposes or biobanking in accordance with legal requirements or clinical research protocol agreements after lab testing, which is consistent with the provisions of the *Chinese Human Genetic Resources Biobanking Approval Administrative Service Guide* ("*Biobanking Approval Guide*"). The *Implementation Rules* reiterate the distinction between biobanking and temporary storage activities at the regulatory level. Therefore, temporary storage of human genetic resource materials involved in clinical trials or investigator initiated trials (IIT) initiated by sponsors in cooperation with trial sites in practice does not require biobanking approval procedures to be performed. In terms of exemption for HGR collection approval, Article 29 of the *Implementation Rules* explicitly stipulates that if the requirements for biobanking approval application are met, applicants do not need to additionally apply for collection approval, which simplifies administrative approval regulatory requirements.

In addition, compared with the *HGR Regulations* and other regulations such as the *Collection Approval Guide* and the *Biobanking Approval Guide*, the *Implementation Rules* clearly stipulate the change procedures for the collection/biobanking of human genetic resource approvals, providing clear compliance guidance.

Section 6: Changes in International Cooperation Regulatory Requirements

Regarding the regulation of international cooperation, the *Implementation Rules* have detailed provisions on the approval/filing requirements, approval/filing process, and cooperation reporting requirements. Among them, the relaxation of international cooperation filing requirements and the changes in the definition of non-major changes in international cooperation approval are noteworthy. The key points of analysis and introduction are as follows:

1. Relaxation of international cooperation filing requirements for international cooperation

Firstly, the *Implementation Rules* further expands the scope of international cooperation filing. According to the *HGR Regulations*, compared with the international cooperation administrative approval process, only the filling process needs to be followed if the following conditions are met:

- In order to obtain the marketing license for relevant drugs and medical devices in China;
- Conducting international cooperative clinical trials using Chinese human genetic resources in clinical trial sites;
- Not involving the export of human genetic resource materials.

However, the *HGR Regulations* haven't clearly defined the scope of "conducting clinical trials in clinical

trial sites". According to the "Guidelines for the Filling of International Cooperative Clinical Trials on Chinese Human Genetic Resources" ("International Cooperation Filing Guidance"), "conducting clinical trials in clinical trial sites" are not limited to the internal processing of human genetic resources in clinical trial sites, but also include the collection of human genetic resources by clinical trial sites and the testing, analysis and disposal of residual samples by parties entrusted by clinical trial sites through written agreements. The *Implementation Rules* further expands the scope of "conducting clinical trials in clinical trial sites" to include not only internal processing within clinical medical and health institutions but also the collection of human genetic resources by clinical medical and health institutions and the testing, analysis and disposal of residual samples by domestic institutions **designated by the clinical trial protocol**. In view of this, in the future, the industry can make more flexible cooperation arrangements in international clinical trials, such as the sample testing service entrustment agreement, which does not have to be signed by clinical medical and health institutions and the entrusted parties, but can be signed by the sponsor or even the contract research organization ("**CRO**") on behalf of the sponsor and the entrusted parties, which is more in line with industry practice.

Secondly, the *Implementation Rules* further clarifies that the human genetic resource information generated from international cooperation can be shared among cooperative partners. Paragraph 3 of Article 28 of the *HGR Regulations* stipulates that the human genetic resource information generated from the use of China's human genetic resources in international cooperations can be used by both partners. Based on this, Article 36 of the *Implementation Rules* clearly stipulates that during the implementation of international cooperations that has obtained administrative approval or has completed filings, the Chinese party provides the foreign party with the human genetic resource information generated from the cooperation, if it has been agreed in the international cooperation agreement that the information can be used by both partners, there is no need to submit a separate prior reporting and information backup. This position is consistent with previous regulatory practice and is now reflected in the *Implementation Rules.*

In addition, the *Implementation Rules* have added provisions for the change of filing procedure for international cooperation filings. Previously, according to the *International Cooperation Filing Guidelines*, significant changes in international cooperation required re-filing, while non-significant changes **only required uploading an explanation of the change on the platform**. The newly introduced Article 53 of the *Implementation Rules* supplements the provisions for non-significant changes, requiring the uploading of a change report in advance on the platform, and stipulating that the record-keeper should promptly submit change filings in case of significant changes, which is conducive to reducing the compliance burden of applicants.

2. Definition of non-significant changes for international cooperation approval/filing

The *HGR Regulations* stipulate that changes in major matters such as the cooperating partners, research objectives, research content, and cooperation period of international cooperation activities should be subject to change approval procedures. However, the major changes listed in the *HGR Regulations* are relatively general and have a broad scope. Therefore, the *Implementation Rules* provide criteria for non-significant changes, which are useful for practical reference. Non-significant changes mainly include the following situations:

- Changes that only involve a total amount not exceeding 10% of the approved amount of HGR without changing the research content or research plan;
- Changes in participating parties other than the sponsors, leading sites, CROs, and third-party laboratories;
- Changes in the name of the legal entity of the cooperating partner;
- Changes in the research content or research plan without changes in the type, quantity, and purpose of human genetic resources or without exceeding the approved scope after the change.

In the case of non-significant changes, the parties only need to submit relevant materials to MOST for explanation and filing, without the need for change approval procedures. Therefore, in situations where the research activities only involve changes within 10% of the approved amount or changes in participating units such as the Electronic Data Collection System (EDC) supplier, the simplified explanation procedure for non-significant changes can be applied.

3. Intellectual property sharing provisions

The Article 17 of the *Draft Rules* had explicitly stipulated that the cooperation parties could agree on the use rights, transfer rights, and profit-sharing methods of other scientific and technological achievements such as works, data, standards, and process flows generated by international cooperations through agreements. The relevant provisions were deleted in the *Implementation Rules*. From the perspective of legislative methodology, the *Implementation Rules* have deleted many overlapping and repetitive provisions in the *Draft Rules* and the *HGR Regulations*. Considering the current regulatory positions on patent rights and other intellectual property rights in the *HGR Regulations*, we understand that unlike patents, research results such as clinical trial data may not necessarily be jointly owned by Chinese and foreign cooperation parties. The Chinese and foreign parties have more autonomy in determining data ownership. Well aware of the value and importance of research data and other information materials for pharmaceutical companies, we understand, on the one hand, such research data is likely to be used to support future drug market authorization submissions to drug regulatory authorities of different jurisdictions; on the other hand, such data may have significant value in pharmaceutical companies' subsequent licensing and cooperative research and development projects, as an integral part of technology transfer. Furthermore, it may even become the basis for payment of royalties when licensing patents expire, as licensed know-how.

Information provision and security review

A significant change in the regulation of information provision is that the *Implementation Rules* **modified the filing procedure stipulated in the *HGR Regulations* to a prior reporting procedure**. Under the previous filing procedure, in practice, completing the filing procedure for the external provision or open utilization of human genetic resources information usual took several weeks. Since the *Implementation Rules* adjusts the filing procedure to a prior reporting procedure, it remains to be seen whether the time limits will be shortened.

Furthermore, Section 4 of the *Implementation Rules* also supplements the regulations for the changing

report procedure. Going forward, after a company has completed the backup and reporting procedures for external provision of information, any changes regarding the usage purpose of information provision or the recipients, among others, will require prior reporting.

The improvement of the security review is another significant provision in the *Implementation Rules*. While the *HGR Regulations* only stipulate that security review should be conducted when the provision of information might affect public health, national security, and public interest of China and provides corresponding penalties, the *Implementation Rules* **elaborate the applicable scope and procedures of security review**, as follows：

1. **Applicable scope of security review:**

- Human genetic resource information of important genetic families;
- Human genetic resource information in a specific area;
- Human exome sequencing and genome sequencing information resources of more than 500 individuals;
- Other situations that may affect public health, national security, and public interest of China.

2. **Procedures of security review：**

- Formulate security review principles and establish an expert pool: MOST, in collaboration with relevant departments, will formulate security review principles, establish an expert pool, and enhance the expert administration systems;
- Conduct security review: Randomly select review experts from the expert pool and conduct security reviews through online reviews (under normal circumstances) or through meetings, on-site inspections, and other methods;
- Security review decision: MOST, in collaboration with relevant departments, will organize experts from relevant fields to conduct security reviews and make review decisions based on the security review opinions.

Administrative supervision and penalty

I. Enforcement requirements

The *Implementation Rules* reflect the ongoing trend in China of continuously emphasizing and strengthening the regulation of human genetic resources. Since the promulgation of the *HGR Regulations*, MOST has only published one administrative penalty case, which involved sanctions for submitting false application materials to obtain approval. However, from the provisions of the *Implementation Rules*, it is evident that the future regulation of human genetic resources in China will display a stronger regulatory intensity. It can be observed that from Article 57 to Article 61 of the *Implementation Rules*, detailed arrangements have been made for the supervisory and inspection work of the competent authorities, including the **annual supervision and inspection plan, key supervision and inspection requirements, random supervision and inspection arrangements,**

specific supervision and inspection actions, and the supervision and inspection information archiving. This signifies a clear strengthening of the trend towards enhanced enforcement.

The *Implementation Rules* further refine the enforcement focus of the regulatory authorities regarding human genetic resources. Notably, the second paragraph of Article 56 in the *Implementation Rules* supplements the focus of supervision and inspection for human genetic resources regulation regarding "**the exportation, external provision, open utilization and usage after exportation of materials or information**". This addition, compared to the *Draft Rules*, highlights the regulatory authorities' focus on the external provision of human genetic resources. In the future, the industry should pay more attention on fulfilling compliance obligation when engaging in human genetic resource-related activities, with particular attention to the requirements of prior reporting before providing human genetic resource information to foreign parties.

While strengthening enforcement, the *Implementation Rules* also adhere to the regulatory authorities' targeted approach as demonstrated through past communications and practices. MOST clearly emphasizes in the document *Policy Interpretation of the Rules for Implementation of Regulations on the Administration of Human Genetic Resources* that, while firmly safeguarding national biosecurity, the administration of human genetic resources shall adhere to the principle of "**stringent regulation where necessary and reasonable flexibility where appropriate**". Additionally, Article 66 of the *Implementation Rules* emphasizes that the regulatory authorities should standardize the exercise of administrative penalty discretion, ensure penalty proportionality, and prevent over-punishment or under-punishment. Furthermore, MOST will formulate and publish separate discretion criteria for the administrative penalty of human genetic resources, which deserves further attention.

II. Penalty calculation basis

"Illegal income" serves as the basis for calculating fines under the *HGR Regulations*. However, the current *HGR Regulations* do not provide a specific definition of "illegal income". The Implementation Rules further specify the concept of "illegal income" by stipulating that it should be calculated by **deducting reasonable expenses from the total income obtained through the implementation of illegal activities**; and if such calculation is impractical, the value of the human genetic resources involved in the illegal activities or the amount of funds invested in those resources can be used as a basis for determining the amount of the fine. Compared to the *Draft Rules*, the *Implementation Rules* prioritize the calculation method for determining "illegal income" by deducting "reasonable expenses" from the "total income". Given that the income obtained from the utilization of human genetic resources is usually relatively limited, the fines are more likely to be reasonable in amount. This provision is consistent with the enforcement principle of preventing over-punishment or under-punishment, as stipulated in Article 66 of the *Implementation Rules* mentioned earlier.

Conclusion

The *Implementation Rules* have further refined and implemented the relevant regulatory provisions of the *HGR Regulations*, taking into account the industry's concerns and practical needs. From the provisions of the *Implementation Rules*, it is evident that regulatory authorities are dedicated to implementing a regulatory approach that firmly safeguards national biosecurity while effectively adhering to the principle of "stringent regulation where necessary and appropriate flexibility where applicable": On the one hand, the *Implementation Rules* optimize many administrative approval and filling requirements and procedures for human genetic resources-related activities, facilitating the fulfillment of compliance obligations for the industry and alleviates their compliance burden. On the other hand, the *Implementation Rules* strengthen the necessary regulatory force by specifying administrative requirements and implementing supervision and inspection measures, leading to a significant enhancement of the trend towards regulatory enforcement.

The finalization of the *Implementation Rules* signifies a new phase in the regulation of human genetic resources in China, and the regulatory requirements outlined in the *Implementation Rules* deserve due attention from the industry. We will also actively participate in discussions with regulatory authorities and industry entities, accompanying the industry in comprehending and acknowledging this regulation, as well as China's constantly evolving regulatory requirements for human genetic resources. With the continuous enhancement of regulatory measures concerning human genetic resources, we are committed to assisting the industry in effectively utilizing China's human genetic resources and facilitating the smooth operation of their business activities.

Important Announcement

This Legal Commentary has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

If you have any questions regarding this publication, please contact:

Aaron GU

Tel: +86 21 6080 0505
Email: aaron.gu@hankunlaw.com

Brigard Urrutia

Bill Approved on Environmental Liabilities

On June 12th, 2023, Bill N° 117/2021 (Chamber) and N° 226/2022 (Senate) was approved. Its objective is to *"establish the definition of an environmental liability, set guidelines for its management and dictate other provisions".*

The Bill seeks to satisfy the need to establish a definition of the term environmental liability as required by multiple administrative and judicial bodies. Furthermore, it will provide clear guidelines for cooperative, adequate and timely management.

The Bill defines environmental liability as *"the environmental effects caused by atropic activities, authorized or not, cumulative or not, capable of being measurable, located and geographically delimitable, which generates a risk to life, human health or the environment, and for whose control there is no environmental instrument or current sector".*

Moreover, it creates the Information System for Environmental Liabilities through which information on environmental liabilities and environmental damage will be managed. This information management instrument will record the location of the liabilities and the parties responsible for the negative environmental impact, among other data.

Likewise, the Bill stipulates different guidelines to follow when dealing with environmental liability. Through this it allows the information collected on the location of said environmental impact and the person responsible for it to be organized. The foregoing in order to establish the time the person or persons in charge have to design and file the corresponding management plan.

In conclusion, the Bill approved will give a clear definition of *environmental liability* allowing a common understanding of the term permitting a homogeneous understanding within the Colombian legislation.

For more information contact our team.
info@bu.com.co

Arias

El SALVADOR

ISSUANCE OF REGULATIONS FOR PROMOTION OF INNOVATION AND MANUFACTURING OF TECHNOLOGIES

Jun/2023

On June 2 of this year, the President of the Republic issued the Decree No. 25 containing the Regulations of the Law for the Promotion of Innovation and Manufacturing of Technologies (the "Regulations"), with the purpose to develop and facilitate the application of the rules contained in the Law for the Promotion of Innovation and Manufacturing of Technologies (the "Law").

Among the main provisions framed in the Regulations, we mention the following:

- The following procedure is established to obtain the qualification agreement before the Ministry of Economy ("MINEC") to access the benefits of the Law:

(a)The person who meet the requirements set forth in the Law shall submit the corresponding application, attaching the required documentation in accordance with the Regulations.

(b)Once the application is received, the MINEC shall have a maximum term of 5 business days to admit it or warn the applicant to comply with the missing requirements.

(c)Once the application is admitted, the MINEC shall request an opinion from the Ministry of Treasure through the General Directorate of Customs ("DGA") and the General Directorate of Internal Taxes ("DGII") to verify that the applicant, partner or shareholder thereof, has no formal or substantive tax obligations pending, having a term of 10 business days to issue a favorable opinion when applicable, and if no notification is received from any of the above mentioned Directorates, it shall be understood that the applicant has no pending tax obligations.

(d)The MINEC shall issue a technical opinion on the technological innovation or manufacturing project and its inclusion within the activities covered by the Law, within a term not to exceed 10 business days as from the business day following the day the application was admitted, being able to request any additional information it deems necessary for the preparation of such opinion.

(e)Upon expiration of the above term, the MINEC shall resolve within a maximum term of 5 business days, issuing the qualification agreement granting the benefits or denying it, stating the reasons for its decision.

- The beneficiaries must maintain an electronic inventory register and an online system available to the MINEC and the DGA, and for such purposes the beneficiary must issue the documents of entry and exit of assets, in compliance with the corresponding tax and customs legislation.

- Assets that have been imported exempt from import duties and taxes may not be transferred to third parties before the term of 5 years in the case of machinery, and 2 years for equipment, tools or other assets; terms counted from the date of their introduction into the country.

- To verify compliance with the obligations of the beneficiaries, the MINEC may require documentation regarding operating permits, authorizations, registrations, among others, related to such obligations, through monitoring or inspections that may be carried out during the term of the qualification agreement.

- The beneficiaries must electronically submit quarterly reports on the amount of investment made, details of the projects, value and origin of imports, number of jobs, sales to the local and foreign market, as well as any other information required by the MINEC.

The decree was published in the Official Gazette on June 2 of this year and will become effective 8 days after its publication.

If you have any questions or would like to learn more about this matter, please do not hesitate to contact us.

Mario Lozano
Partner, El Salvador
Mario.lozano@ariaslaw.com

Ernesto Sánchez
Senior Counsel, El Salvador
Ernesto.sanchez@ariaslaw.com

Julissa Castro
Senior Associate, El Salvador
Julissa.castro@ariaslaw.com

GIDE

GIDE LOYRETTE NOUEL

Climate change litigation | ClientEarth v Shell: a step towards questioning the decisions of directors concerning a company's Environmental, Social and Governance ("ESG") policy?

9 June 2023

On 12 May 2023, the High Court handed down its judgment in the case brought by ClientEarth, an environmental organisation, against the Directors of Shell Plc ("Shell").

ClientEarth sought a declaration of breach by the Directors of their duties to the company and a mandatory injunction requiring the Directors of Shell Plc (a) to adopt and implement a strategy compliant with certain climate-related goals and (b) to comply with an order from a Dutch Court to reduce emissions by 45% by 2030. The case relied on establishing the existence of six climate-related duties, incidental to the general statutory duties codified in Part 10, Chapter 2 of the Companies Act 2006, which Shell's Directors were said to have breached.

ClientEarth is a minority shareholder in Shell and brought the action by way of a derivative claim. Derivative claims under Section 260 Companies Act 2006 enable shareholders to bring proceedings against directors in respect of a cause of action vested in the company (for breach of duties owed by the directors to the company, for example). As an initial step, the court is required to determine whether the application discloses a *prima facie* case for the shareholders to proceed with a substantive application to pursue the derivative claim. The present application fell at this first hurdle; the judge held that the application did not establish a *prima facie* case for the alleged breach of duties by the directors.

The existence of climate-related Duties incidental to the statutory duties owed by Directors under the Companies Act 2006

Under Section 172 Companies Act 2006, directors owe a duty to the company to act in the way the director concerned considers in good faith would be most likely to promote the success of the company for the benefit of its members as a whole. The directors are required to have regard to a non-exhaustive list of matters.[1] Under Section 174 Companies Act 2006, directors owe a duty to the company to exercise the care, skill and diligence that would be exercised by a reasonably diligent person with the general knowledge skill and experience that may reasonably be expected of a person carrying out the functions they carry out, and the general skill and experience that director actually has.

ClientEarth pleaded the existence of six necessary incidents of the statutory duties "*when considering climate risk for a company such as Shell*": i) a duty to make judgments regarding climate risk that are based upon a reasonable consensus of scientific opinion; ii) a duty to accord appropriate weight to climate risk; iii) a duty to implement reasonable measures to mitigate the risks to the long-term financial profitability and resilience of Shell in the transition to a global energy system and economy aligned with the global temperature objective of 1.5°c under the Paris Agreement on Climate Change 2015; iv) a duty to adopt strategies which are reasonably likely to meet Shell's targets to mitigate climate risk; v) a duty to ensure that the strategies adopted to manage climate risk are reasonably in the control of both existing and future directors; and (vi) a duty to ensure that Shell takes reasonable steps to comply with applicable legal obligations.

Mr Justice Trower considered that ClientEarth was seeking to impose specific management obligations on the Directors, "*notwithstanding the well-established principle that it is for directors themselves to determine (acting in good faith) how best to promote the success of a company for the benefit of its members as a whole*". It is not the court's place to impose management obligations: "[t]*he weighing of all these considerations* [as set out in s.172] *is essentially a commercial decision, which the court is ill-equipped to take, except in a clear case*". The Directors are required to display the care, skill and diligence according to the subjective and objective standards in Section 174 Companies Act 2006 but "[t]*he law does not superimpose on that duty more specific obligations as to what is and is not reasonable in every circumstance*".

As regards the Dutch Order, ClientEarth pleaded that a director who is aware of a court order is under a duty to take reasonable steps to ensure that the order is obeyed. The judge agreed with Shell that there is no recognised English law duty owed by directors to a company in which they hold office to ensure that they comply with the orders of a foreign court. A director is under a legal obligation to take reasonable steps to ensure that an order made by an English court is obeyed, but this is not a duty that the directors owe to the company, separate and distinct from the general duties codified in the Companies Act 2006.

Specific breaches alleged by ClientEarth

ClientEarth's claim for breach faced a high bar. The judge considered that ClientEarth was required to show a *prima facie* case that there is no basis on which the Directors could reasonably have come to the conclusion that the actions they have taken have been in the interests of Shell.

ClientEarth's central allegation was that by adopting and pursuing an inadequate energy transition strategy, the Directors are mismanaging the material and foreseeable risk that climate change presents to Shell. The specific breaches alleged by ClientEarth fall into three categories: (i) firstly, a failure to set an appropriate emissions target to be met before 2050 and a measurable and realistic pathway to meeting the net zero target consistent with the Paris Agreement on Climate Change 2015; (ii) secondly, a failure to establish a reasonable basis for achieving the net zero target;[2] and, (iii) failure to comply with the Dutch Order.

The judge held that ClientEarth's allegations in relation to breaches by the directors do not establish a *prima facie* case.

The evidence did not support a *prima facie* case that there is a universally accepted methodology to achieve emission reduction targets. As a result, it was difficult to conclude that no reasonable board of Directors could properly conclude that the pathway to achievement is the one they have adopted. While the judge acknowledged the fundamental disagreements as to the right way to achieve net zero targets, he also noted that "*the law respects the autonomy of the decision making of the Directors on commercial issues and their judgments as to how best to achieve results which are in the best interests of the members as a whole*". ClientEarth had not established a *prima facie* case that the way in which Shell's business is being managed by the Directors could not properly be regarded by them as in the best interests of Shell's members as a whole.

It was accepted that the Directors did in fact have policies and targets to achieve net zero by 2050; ClientEarth's argument was that the policies and targets were manifestly unreasonable. However, the very fact that such policies and targets exist was inconsistent with any suggestion that the Directors had not considered what is in the best interests of Shell and its members as a whole when addressing climate risk. According to the judge, ClientEarth's allegations "*completely ignore the fact that the management of a business of the size and complexity of that of Shell will require the Directors to take into account a range of competing considerations, the proper balancing of which is classic management decision with which the court is ill-equipped to interfere*". ClientEarth's evidence did not engage with how the Directors' approach to climate risk was said to have gone so wrong, in the context of the many other risks to which the business will be exposed.

As regards the Dutch Order, although it is "*in some respects results-based*", the Dutch Court had accepted that Shell is not currently acting in an unlawful manner. Shell has discretion as to how to comply with its reduction obligation. This is consistent with the statutory duty of the Directors in the UK to do that which they consider in good faith would be most likely to promote the success of Shell for the benefit of the its members as a whole.

Relief sought

The judge also considered that the court would be most unlikely to make a mandatory injunction in the terms sought because it was too imprecise for suitable enforcement. The judge envisaged that disputes over compliance with the order would have a series adverse impact on Shell's success, the very thing that ClientEarth asserted the proceedings were designed to avoid. Although this reasoning did not apply to a declaration, "[i]*t is not the court's function to express views as to the Directors' conduct which have no substantive effect and which fulfil no legally relevant purpose*". The proper forum for that type of view is the company's general meeting.

Discretionary factors

There are further discretionary factors that the court is required to take into account when considering an application for permission to bring a derivate action. Amongst these, the court is required to consider whether the member is acting in good faith in seeking to continue the claim (Section 263(3)(a) Companies Act 2006). The judge considered that there was substance in Shell's submission that ClientEarth's motivation was "*driven by something quite different from a balanced consideration as to how best to enforce the multifarious factors which the Directors are bound to take into account when assessing what is in the best interests of Shell*". ClientEarth had not adduced sufficient evidence to counter this inference.

Under Section 263(4) of the Companies Act 2006, "[i]*n considering whether to give permission (or leave) the court shall have particular regard to any evidence before it as to the views of members of the company who have no personal interest, direct or indirect, in the matter*". The Court referred to the Shell's AGM on 18 May 2021 at which support for its Energy Transition Strategy ("ETS") received 88.4% of the votes cast by members. At the AGM held on 24 May 2022, support fell to 80% when a progress report on the ETS was under consideration. ClientEarth, on the other hand, had received support for its claim from members holding 12.2 million shares amounting to approximately 0.17% of Shell's shares, with letters from another 12.5 million shares who have stated that their position is aligned with the arguments made by ClientEarth. The judge considered that the level of member support for the ETS would count strongly against the grant of permission to continue the claim and there had not been a demonstration of member support for action of the type contemplated by the application.

The judge found that application and evidence did not disclose a *prima facie* case for giving permission to continue the claim and so the court was required to dismiss the application. The court has since granted ClientEarth an oral hearing to reconsider the decision and that hearing is pending. ClientEarth's claim is a notable addition to recent ESG cases.

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[1]Specifically, "*(a) the likely consequences of any decision in the long term, (b) the interests of the company's employees, (c) the need to foster the company's business relationships with suppliers, customers and others, (d) the impact of the company's operations on the community and the environment, (e) the desirability of the company maintaining a reputation for high standards of business conduct, and (f) the need to act fairly as between members of the company.*"

[2]ClientEarth made specific criticisms of the directors: "*In particular ClientEarth criticises (a) the Directors' proposals to make significant new investments in fossil fuel projects, (b) their reliance on carbon capture and storage and nature based solutions which will not mitigate the economic risks to Shell's underlying business model, (c) the proposed capital expenditure on renewable energy expenditure which is said to be opaque and insufficient and (d) the absence of measures sufficient to respond rapidly to changes to the legal, regulatory and financial conditions so as to ensure that their strategy is sufficiently robust.*"

Contacts


Didier G. Martin


Rupert Reece


Gabriel Hannotin


Hannah Mcirvine


James Casey

Hogan Lovells

Engage

Legal insight and analysis

Petition barred - Hong Kong CFA confirms primacy of exclusive jurisdiction clause in bankruptcy

8 May 2023

The Hong Kong Court of Final Appeal (CFA) has confirmed a Court of Appeal finding that the court should respect the effect of an exclusive jurisdiction clause in bankruptcy proceedings, just as it does in ordinary civil actions.

In rejecting an appeal against the overturning of a bankruptcy order made against the debtor in Re Guy Kwok-Hung Lam [2022] HKCFA 9, the Court of Final Appeal (The Hon Chief Justice Andrew Cheung, the Honourable Messrs Ribeiro PJ, Fok PJ, Lam PJ and French NPJ), said the parties had clearly agreed that their disputes should be determined in another forum, and that this should include the question of whether there was a "bona fide debt disputed on substantial grounds."

The appellant in the appeal was an exempted limited partnership formed and registered in the Cayman Islands. The respondent was Mr. Guy Kwok-Hung Lam (林國雄), a Hong Kong solicitor and founder of two groups of companies providing senior care services on the Chinese mainland and in the United States, CP China and CP U.S. through various cross-shareholdings involving a Cayman Islands-incorporated group company, CP Global Inc.

The dispute concerned a credit and guarantee agreement that was entered into between, amongst others, the appellant, Lam and CP Global for term loans in the sum of US$29.5 million with Lam providing a personal guarantee and security for the loans.

Following a default, the judge in the Court of First Instance (CFI) held that the respondent had failed to show there was a bona fide dispute on substantial grounds in respect of the debt and made a bankruptcy order.

The respondent appealed, arguing that the alleged debt should be determined by a New York court under an exclusive jurisdiction clause (EJC) in the agreement. The Court of Appeal agreed, setting aside the orders made by the CFI judge and dismissing the petition on the basis of the EJC (see Hogan Lovells alert *Show some respect – Court of Appeal affirms primacy of exclusive jurisdiction clause in bankruptcy proceedings*).

Court of Appeal

The Court of Appeal's dismissal of the petition employed two different lines of reasoning.

The majority, as expressed in the judgment of the Honourable Mr. Justice Godfrey Lam, took note of the position set out in *Re Southwest Pacific Bauxite (HK) Ltd* [2018] HKCFI 426 (the *Lasmos* case), that a winding up petition should be dismissed if it can be shown that there is a *prima facie* dispute that ought to be referred to arbitration under the agreement between the parties.

Lam J said a similar approach should be adopted in winding up and bankruptcy petitions. In the words of the CFA judgment, Lam JA "rejected the argument that there were public policy concerns arising from the alleged curtailment of creditors' rights" and that there was "no strong reason to allow the petition to proceed."

For the minority, the Honourable Mr. Justice Anderson Chow JA arrived at the same conclusion from an alternative angle. "His Lordship did not consider that an EJC should be given conclusive or near conclusive weight in the exercise of the court's discretion" but agreed that the appellant's petition "was caught by the EJC".

Court of Final Appeal

Before the CFA, the appellant submitted that in insolvency proceedings, different considerations were in play from those informing the upholding of EJCs in private actions. The law also "requires as a general principle, that parties cannot contract out of insolvency legislation" and that "to give presumptive weight to EJCs was to erode the insolvency regime".

The CFA noted that what was at issue was the jurisdiction of the CFI in bankruptcy matters, which was "not amenable to exclusion by contract". However, subject to certain statutory constraints, the CFI could decline to exercise its jurisdiction in favour of another forum.

The determination of whether a debt is bona fide disputed on substantial grounds was a "threshold question" which left room for the exercise of the court's discretion "to decline to exercise the jurisdiction to determine that question".

It was at that stage that the public policy interest in holding parties to their agreements came into play. Where, as here, the CFI had "undertaken the equivalent of a summary judgment determination, it (had) assumed the jurisdiction to decide a question which the parties had agreed would be determined in another forum".

The significance of the public policy of the legislative scheme for bankruptcy jurisdiction was "much diminished where the petition is brought by one creditor against another and there is no evidence of a creditor community at risk". It would always be possible for the appellant to sue on the debt in New York and to apply there for summary judgment. The absence of other creditors pursuing the respondent was an indicator that the public interest would unlikely be adversely affected by the delay incurred.

The CFA held that the petitioner and the debtor should be held to their contract and on that basis, dismissed the appeal. The majority view of the Court of Appeal was the correct one in the view of the CFA.

Key takeaways

Creditors should take careful note of this decision when developing their enforcement strategies. Now the Hong Kong courts have affirmed the primacy of EJCs in bankruptcy proceedings, much time and effort can be saved by issuing proceedings in line with the parties' agreement, especially where it concerns forum.

Authored by Jonathan Leitch and Nigel Sharman.

Contacts

Jonatham Leitch
Partner
Hong Kong
jonathan.leitch@hoganlovells.com

Chris Dobby
Partner
Hong Kong
chris.dobby@hoganlovells.com

Mark Lim
Partner
Hong Kong
mark.lin@hoganlovells.com

Antonia Croke
Partner
Hong Kong
antonia.croke@hoganlovells.com

Byron Phillips
Partner
Hong Kong
byron.phillips@hoganlovells.com

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THE HON'BLE SUPREME COURT CLARIFIES LAW IN RELATION TO THE APPOINTMENT OF ARBITRATOR UNDER SECTION 11 OF THE ARBITRATION & CONCILIATION ACT, 1996 (AS AMENDED)

Author: Deepesh[1]

SUMMARY

The Hon'ble Supreme Court in the case of NTPC Ltd. Vs. M/s SPML Infra. Ltd.[2] ("SPML") referred to its earlier decisions and held that while exercising jurisdiction under Section 11(6) of the Arbitration and Conciliation Act, 1996 (the "**Act**") the courts must ensure that the parties are protected from frivolous and untenable claims and are not compelled to arbitrate a dispute which is non-arbitrable.

I. BACKGROUND FACTS

The Hon'ble Supreme Court was hearing an appeal from an order passed by the Hon'ble Delhi High Court[3], where the Hon'ble High Court had appointed an arbitrator on an application under Section 11(6) of the Act. Before the Hon'ble Supreme Court, NTPC Ltd. raised a contention that there were no existing disputes in view of a settlement arrived between the parties.

II. OBSERVATIONS OF THE HON'BLE SUPREME COURT OF INDIA

The Hon'ble Supreme Court while referring to its earlier decisions[4] *inter alia* held as under:

[1] The author is a partner in the dispute resolution team of the Firm's Delhi office.
[2] In Civil Appeal No. 4778 of 2022 dated April 10, 2023.
[3] In Arbitration petition No. 477 of 2020 dated April 08, 2021.
[4] Vidya Drolia and Ors. v. Durga Trading Corporation (2021) 2 SCC 1; BSNL and Anr. v. Nortel Networks India (P) Ltd. (2021) 5 SCC 738; Secunderabad Cantonment Board v. B. Ramachandraiah & Sons (2021) 5 SCC 705

(a) The jurisdiction of the courts under Section 11(6) of the Act is narrow and the courts have to thoroughly examine the existence and the validity of an arbitration agreement (which includes an inquiry as to the parties to the agreement) and applicant's privity to the said agreement.
(b) The courts need to adjudicate the issue of non- arbitrability of the dispute.
(c) The courts may reject claims which are manifestly and ex-facie non-arbitrable.
(d) The courts must not undertake full review of contested facts.
(e) The courts need to examine whether the assertion on arbitrability is bona fide or not.
(f) The courts must prima facie reach a conclusion that the claim is non-arbitrable. However, in case of doubt the dispute is to be referred to arbitration.
(g) The courts must protect the parties from being forced to arbitrate when the matter on the face of it is non-arbitrable.

Basis the above, the Hon'ble Supreme Court held that the Section 11 application filed by SPML before the Hon'ble High Court was not bona fide and there were no pending claims between the parties for submission to arbitration.

The Hon'ble Supreme Court further held that SPML's case is an attempt to initiate ex-facie, meritless and dishonest litigation and accordingly set aside the order passed by the Hon'ble High Court.

III. CONCLUSION

The present case law passed by the Hon'ble Supreme Court is a move in the right direction to curtail the reference of every matter to arbitration since the general tendency of the courts was to allow Section 11(6) applications and leave the parties to challenge the jurisdiction of the arbitrator by way of filing a Section 16 application under the Act in the arbitration proceedings. However, with the above guidelines and clarifications, the courts would be more cautious while dealing with Section 11(6) applications and the claims which are frivolous and untenable would be knocked down.

NautaDutilh

The law on the use of digital tools and processes in company law

19-06-2023

Written by

Luxembourg


Margaretha (Greet) Wilkenhuysen
Partner


Romain Sabatier
Partner


Caroline Notté
Partner


Aline Nassoy
Counsel


Vincent Wellens
Partner

The law transposing Directive (EU) 2019/1151 of the European Parliament and the Council of 20 June 2019 (the "**Directive**") amending Directive (EU) 2017/1132 as regards the use of digital tools and processes in company law (the "**Law**") has just been adopted by the Luxembourg Parliament. It will result in modifications to a number of pieces of legislation, in particular the Companies Act of 10 August 1915, as amended, and the Trade Register Act of 19 December 2002.

Objective

The purpose of the Directive is to facilitate digitalisation in the Member States of incorporation formalities, the execution of notarial instruments, the registration of branches, and the filing of documents and information related to companies and branches. The Directive requires Member States to provide user-friendly information (e.g. standard incorporation documents) free of charge, on an online portal or easily accessible website, and to ensure that the fees applicable to online procedures are transparent.

Scope

The Directive requires Member States to ensure that a company can be incorporated - and notarial instruments executed - completely online, without the founders having to appear in person before a competent authority or civil

law notary. While the Directive provides for this possibility only for limited liability companies, such as the Luxembourg public limited company (*société anonyme*), the partnership limited by shares (*société en commandite par actions*) and the private limited liability company (*société à responsabilité limitée*), the Luxembourg legislature decided to extend it to other corporate forms, such as the limited partnership (*société en commandite simple*) and civil companies (*sociétés civiles*), and to other types of notarial instruments (excluding wills).

Online incorporation and execution of notarial instruments

The Law facilitates the online incorporation of limited liability companies such as the Luxembourg public limited company (*société anonyme*), the partnership limited by shares (*société en commandite par actions*), the private limited-liability company (*société à responsabilité limitée*), and other company forms. However, it will remain possible to have an in-person meeting with a Luxembourg civil law notary to set up a company.

The Law further stipulates that:

- even if the incorporation formalities are carried out online, the Luxembourg notary may still require that a meeting be held by videoconference toverify such matters as the identity and legal capacity of the founders.
- Luxembourg notaries may request any additional supporting documents they deem necessary.
- notaries are free to require the electronic signature of their choosing on a notarial instrument.

Lastly, the Law introduces an ad hoc electronic exchange platform for Luxembourg notaries, which will become the main platform for all types of notarial documents (with the exception of wills) going forward.

Deadline for online incorporation

When a company is formed by natural persons using model

documents (in Luxembourg these are the standard articles of association provided by the Luxembourg Chamber of Notaries), the Law states that online incorporation must be completed within five working days from the later of the two following dates: (i) the date of completion of all formalities required for online incorporation or (ii) the payment date of the registration fee and the share capital, in cash or in kind. Otherwise, the incorporation process must be completed within ten working days. The Law does not stipulate deadlines by which the online incorporation process must be completed, although this information may be set out in a future Grand Ducal regulation.

NautaDutilh's Corporate team remains at your disposal to answer any questions related to this topic.

OFFICIAL MEXICAN STANDARD ABOUT TELEWORKING: OCCUPATIONAL HEALTH AND SAFETY CONDITIONS

JUNE 2023

EXECUTIVE SUMMARY:

- On June 8, 2023, the Mexican Official Standard NOM-037-STPS-2022 was published, which establishes the occupational health and safety conditions that must be respected in the Teleworking modality.
- Its objective is to prevent accidents and diseases, as well as to promote a safe and healthy environment in the work setting.
- The Standard will come into effect on December 5, 2023.

On June 8, 2023, the Mexican Official Standard NOM-037-STPS-2022 was published in the Official Gazette of the Federation, which establishes the occupational health and safety conditions that must be respected in places outside the workplace where employees will perform their activities under the Teleworking modality, in order to prevent accidents and diseases, as well as to promote a safe and healthy environment in their work setting.

The main employer obligations that will be subject to inspection and possible sanctions in case of non-compliance are:

+ Keep an updated list of teleworkers containing at least: name of the employees; gender, marital status, and activities to develop; job position and profile; percentage of the employment relationship used for teleworking; contact telephone number; address of the employees under the Teleworking modality; workplaces proposed by the employees under the Teleworking modality and agreed with the employer; company name and workplace address; as well as the computer and ergonomic equipment given to the employee.

+ Maintain evidence that: (a) the employees have means of connectivity and that they handle Information and Communication Technologies (ICTs); (b) that the workplace or places of work that by common agreement were established are permanent and have occupational health and safety conditions, with emphasis on the proper condition of the electrical installations, lighting, ventilation and adequate ergonomic conditions; c) the change of modality from teleworking to in-person and vice versa is documented; d) training is provided at least once a year on safety and health conditions; and, d) follow-up is given to the notices of occupational accidents that, if applicable, are reported by teleworkers.

- Keep a checklist of safety and health conditions in Teleworking, which allows certifying that there is a clean and tidy area, illuminated, with comfortable temperature and ventilation, with a noise level that does not prevent concentration, and with furniture that prevents injuries, including a desk, table or workspace where the employee can comfortably support their arms (sitting and/or standing) without accessories or obstacles below as well as an ergonomic chair appropriate to the activities to be developed.
- Provide facilities to the Mixed Committee for Safety and Hygiene to validate the checklist, either by a personal visit to the workplace, remotely using ICTs or by means of periodic self-assessments.

Several appendices are included to support compliance with the obligations, the most relevant of which are: 1) Checklist for safety and health conditions in the workplace, 2) Teleworking Policy, and 3) Recommendations for selecting an ergonomic chair.

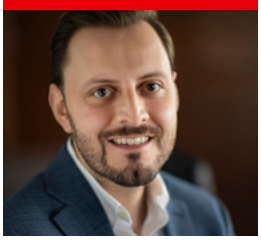
The Standard will come into effect 180 calendar days after its publication in the Official Gazette of the Federation, this is December 5, 2023.

The full text of NOM-037 can be consulted directly at the following link: https://www.dof.gob.mx/nota_detalle.php?codigo=5691672&fecha=08/06/2023#gsc.tab=0

Should you require additional information, please contact the partner responsible for your matters or one of the attorneys listed below:

Juan Carlos de la Vega
Partner
Mexico City
Monterrey
+ 52 55 5279 5429
+52 81 8133 6005
jdelavega@s-s.mx

Andrés Rodríguez
Partner
Mexico City
+52 55 5279 5413
arodriguez@s-s.mx



Francisco Udave
Partner
Mexico City
+52 55 5279 5435
fudave@s-s.mx

Ernesto de la Puente
Associate
Mexico City
+52 55 5279 5424
edelapuente@s-s.mx

Emily Manzewitsch
Associate
Querétaro
+52 442 290 0297
emily.manzewitsch@s-s.mx

SyCip Salazar Hernandez & Gatmaitan

Banking Bulletin

MAY 2023

SEC Adopts the ASEAN Sustainable and Responsible Fund Standards and Establishes Rules on Recognition of Foreign Collective Investment Schemes

On April 13, 2023, the Securities and Exchange Commission ("***SEC***") issued Memorandum Circular No. 4, Series of 2023 ("***MC 4-23***") to adopt the ASEAN Sustainable and Responsible Fund Standards ("***ASEAN SRFS***") and establish rules on the qualifications of local investment companies under the ASEAN SRFS and the recognition of foreign investment collective schemes qualified under the ASEAN SRFS that seek to offer in the Philippines under the ASEAN Collective Investment Scheme ("***CIS***") framework ("***ASEAN CIS Framework***").

MC 4-23 took effect on April 27, 2023, after its publication in two newspapers of general circulation in the Philippines.

MC 4-23 applies to (i) investment companies, including sub-funds of an umbrella fund, and fund managers that seek to qualify under the ASEAN SRFS and want to either offer locally or on a cross-border basis under the ASEAN CIS Framework, and (ii) CIS Operators and Foreign SRFs that seek to offer in the Philippines under the ASEAN CIS Framework.

General

1. What is the ASEAN CIS Framework?

The ASEAN CIS Framework is an initiative of the ASEAN Capital Market Forum ("***ACMF***") which allows fund managers operating in ASEAN member jurisdictions to offer CIS, such as unit trust funds or mutual funds, constituted and authorized in that jurisdiction, in other member jurisdictions under a streamlined authorisation process. This process is covered under the Memorandum of Understanding on the Streamlined Authorisation Framework for Cross-border Public Offers of ASEAN Collective Investment Schemes, as supplemented

("***MOU***").

2. What is the ACMF?

The ACMF is composed of a group of capital market regulators from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Singapore, Thailand, Vietnam, and the Philippines.

3. Which ASEAN member jurisdictions have adopted the ASEAN CIS Framework?

As of the date of this bulletin, there are four signatories to the MOU: Securities Commission Malaysia, Monetary Authority of Singapore, the Securities and Exchange Commission of Thailand, and the Securities and Exchange Commission of the Philippines (the jurisdictions of the ACMF members that are signatories to the MOU are collectively referred to as "***Member Jurisdictions***").

4. What is the ASEAN SRFS?

The ASEAN SRFS was developed by the ACMF, in line with the growing importance of sustainable finance in ASEAN and the actionable recommendations in the Roadmap for ASEAN Sustainable Capital Markets, to provide the minimum disclosure and reporting requirements for CIS that seek to qualify under the ASEAN SRFS and to address the need for a comparable, uniform and transparent disclosure of information to mitigate the risk of, among others, greenwashing (the process of conveying a false impression or misleading information about how a company's products are environmentally sound[1]).

Philippine Investment Companies

5. What kinds of Philippine entities may qualify under the ASEAN SRFS?

Investment companies (in general terms, this means any issuer which is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities), including any sub-fund of an umbrella fund, may qualify under the ASEAN SRFS by showing satisfactory compliance with the following:

(a) registration under the Investment Company Act (Republic Act No. 2629 or "ICA") and the Securities Regulation Code ("Republic Act No. 8799 or "SRC") and their respective implementing rules and regulations ("IRR");

(b) compliance with SEC Memorandum Circular No. 11, Series of 2022 on Sustainable and Responsible Investment Funds ("SRIF") and any amendments thereto (the "Local SRIF Rules"); and

(c) compliance with the ASEAN SRFS and any amendments thereto.

6. What is the process for qualification?

The qualification process is initiated by the entity (referred to in item 5) submitting a notarized and complete SEC ASEAN SRF Form (attached as Annex B of MC 4-23) signed by at least the majority of the Board of Directors of the investment company and the fund manager.

The application is subject to a filing fee of PhP10,000.00 plus 1% Legal Research Fee ("***LRF***").

If the SEC is satisfied that the applicant complies with the aforementioned requirements, the SEC will issue a letter qualifying the investment company or sub-fund as an SRF.

7. How may Philippine investment companies qualified under the ASEAN SRFS make offers under the ASEAN CIS Framework?

Philippine entities that intend to offer shares on a cross-border basis under the ASEAN CIS Framework must:

(a) comply with the requirements for qualification in Q4 above; and

(b) comply with SEC Memorandum Circular No. 9, Series of 2021 or the Rules on Authorization of an Investment Company as a Qualifying CIS and Recognition of a Foreign CIS under the ASEAN CIS Framework ("***MC 9-21***").

If the SEC is satisfied that the applicant complies with the aforementioned requirements, the SEC will issue a Standard Letter recognizing the applicant as qualified to make offers under the ASEAN CIS Framework.

Foreign Collective Investment Schemes

8. Which foreign collective investment schemes may be offered in the Philippines under the ASEAN CIS Framework?

The foreign collective investment scheme must be a

[1] https://www.investopedia.com/terms/g/greenwashing.asp

Foreign SRF as defined in MC 4-23. This refers to a Foreign CIS that has also been qualified as an ASEAN SRF in a Member Jurisdiction other than the Philippines.

A Foreign CIS refers to a Qualifying CIS under the ASEAN CIS Framework constituted in a Member Jurisdiction other that the Philippines and is permitted/authorized to be offered to the general public of that Member Jurisdiction.

A Qualifying CIS means a CIS constituted or established in its Home Jurisdiction which has been approved by its Home Regulator for offer to the public in the Home Jurisdiction and assessed by its Home Regulator as suitable to apply to a Host Regulator for its shares/units to be offered to the public cross-border in the Host Jurisdiction pursuant to the ASEAN CIS Framework.

In addition, the Foreign SRF must show satisfactorily show compliance with the following:

(a) the Foreign SRF and CIS Operator (the person or entity which is licensed/registered with, or approved by, the securities regulator in the ASEAN jurisdiction to operate or manage CIS that may be offered in that jurisdiction) should both comply with SEC MC 9-21, and any amendments thereto, with respect to the approval and recognition of Foreign CIS to be offered in the Philippines;

(b) proof of qualification as an ASEAN SRF, which is in the form of the Standard Letter issued by its home regulator that it has qualified as an ASEAN SRF;

(c) submission of a duly accomplished SEC ASEAN SRF Form (attached as Annex B of MC 4-23);

(d) payment of an application fee of PhP80,000.00 plus 1% LRF; and

(e) compliance with requirements under the Local SRIF Rules in relation to the (i) name of the Foreign SRF and (ii) incorporation of additional disclosures in the prospectus.

9. How do qualified Foreign SRFs apply for recognition to be offered in the Philippines under the ASEAN CIS Framework?

Foreign SRFs should apply for recognition to be offered locally in the Philippines.

The application for recognition must be made by the Foreign SRF/CIS Operator or appointed local representative to the SEC, by submitting, in both electronic and physical form:

(a) a duly completed SEC ASEAN SRF Form (attached as Annex B of MC 4-23);

(b) a copy of the prospectus reflecting the additional disclosure requirements referred to in Q8 above; and

(c) other relevant documents that may be required.

If the SEC is satisfied that the Foreign SRF meets the requirements under MC 4-23, the SEC shall issue a letter recognizing the Foreign SRF.

10. What are the guidelines for the Foreign SRF's marketing materials and disclosures?

The following guidelines will apply to information regarding the Foreign SRF to be included in the marketing materials, advertisements, publications, and communications, including website content, which targets existing or potential Philippine investors:

(a) it must present a fair, balanced, and consistent description of the Foreign SRF;

(b) the sustainability aspects mentioned should be consistent with regulatory documents filed with the SEC; and

(c) the marketing materials and other communications should not include untrue statements of material facts, or false or misleading statements.

11. Are there additional reportorial requirements for Foreign SRFs based on MC 4-23?

The following information must be included in the annual and interim reports of a Foreign SRF submitted to the SEC in compliance with MC 9-21:

(a) description of how the Foreign SRF attained its sustainable investment objective during the reporting period, including a brief description of actual non-ESG investments and their percentage of the Foreign SRF's net asset value ("***NAV***");

(b) description of the strategy that is most reflective of the Foreign SRF's sustainable investment strategies, if multiple strategies are used; and

(c) description of divested investments to rectify any breach of the threshold or inconsistency/ies in the investment policies and strategies made during the reporting period and their percentage out of the foreign SRF's NAV, where applicable.

12. What should Foreign SRFs do when there is a breach of ESG investment thresholds and/or inconsistencies with sustainability investment objectives?

The Foreign SRF/CIS Operator or its local representative shall inform he SEC within five business days after it becomes aware of any of the following:

(a) a breach of the ESG investment threshold where the Foreign SRF's investments in ESG account for less than 2/3 of the NAV of the Foreign SRF, including a description of the action taken or to be taken to rectify the breach; or

(b) inconsistency of an undertaking investment/s with the Foreign SRF's stated sustainable investment objective, including any divestments made or any other action taken or to be taken to rectify the inconsistency.

The Foreign SRF/CIST Operator shall rectify the breach/inconsistency as soon as practicable, but shall not be more than 30 business days from date of discovery of the breach/inconsistency.

Once the breach/inconsistency has been rectified, the Foreign SRF/CIST Operator or its local representative must also notify the SEC through the filing of a SEC Form 17-C (Current Report) within five business days from rectification, together with a presentation of investments vis-à-vis the sustainable investment objective of the Foreign SRF, to be made in accordance with the template provided in Annex C of MC 4-23.

SEC Administrative Actions

13. What are the consequences for non-compliance with the Local SRIF Rules and/or the ASEAN SRFS?

For investment companies, including any sub-funds of an umbrella fund, the SEC may revoke the qualification as an ASEAN SRF.

For Foreign SRFs, the SEC may suspend or revoke the recognition of a Foreign SRF if:

(a) it is no longer compliant with MC 4-23;

(b) its qualification as an ASEAN SRF has been revoked by its home regulator;

(c) it fails to comply with the reporting and rectification requirements relating to breach of ESG investment threshold or inconsistency with the sustainable investment objective;

(d) its authorization as a Qualifying CIS has been suspended or revoked by its home regulator; and

(e) the approval or recognition for the sale or offering of units of the Foreign CIS in the Philippines has been suspended or revoked by the SEC.

In addition, the suspension or revocation of an investment company's qualification or a Foreign SRF's recognition as an ASEAN SRF shall be cause for removal of its name in the SEC website/microsite dedicated for investment companies as an ASEAN SRF.

The suspension or revocation of the qualification of an investment company as an ASEAN SRF shall likewise be cause for the removal of its name from the list of ASEAN SRF in the ACMF microsite dedicated for the ASEAN SRFS.

14. May an investment company or a Foreign CIS whose qualification or recognition as an ASEAN SRF has been revoked by the SEC apply for re-qualification or re-recognition?

Yes. These entities re-qualify or be recognized anew and be reinstated list of ASEAN SRF in the ACMF microsite, subject to the following:

(a) a letter request to requalify/be recognized anew as an ASEAN SRF has been filed with the SEC which states, among others, the reasons why the disqualified/derecognized entity should be reinstated;

(b) all outstanding monetary penalties have been paid;

(c) the requirements for qualification and recognition (as mentioned above) have been complied with; and

(d) there has been compliance with any other directives of the SEC.

15. May entities voluntarily withdraw their qualification as an ASEAN SRF/recognition as a foreign SRF?

Yes. The withdrawing entity must notify the SEC in writing within five days after approval of its Board of Directors, or in case of a foreign SRF, its equivalent officers, of such intention which shall include information on the timeline and procedures to implement such withdrawal.

16. What penalties are imposed on investment companies and/or its fund manager, as well as CIS Operators/Foreign SRFs?

Violation of MC 4-23 shall subject the investment company and/or its fund manager to the same sanctions

provided under Local SRIF Rules, aside from the removal of its name in the SEC and ACMF microsite dedicated for ASEAN SRFS.

The CIS Operator/Foreign SRF shall be subject to the penalties ranging from a reprimand up to fines of at least PhP20,000 up to PhP200,000 for violations of MC 4-23 in relation to

(a) overemphasizing sustainability or ESG features in any communication or advertising materials;

(b) failure to report or delays in report of breaches of recited ESG threshold or inconsistency with sustainable investment objectives of the ASEAN SRF within the time limit under MC 4-23; or

(c) failure to rectify or delay in rectifying breaches within the time limit under MC 4-23.

These penalties are without prejudice to other actions and sanctions that the SEC may impose under the IRA, SEC, their respective IRRs, the Revised Corporation Code of the Philippines, and all other laws that may subsequently implemented by the SEC, and all other rules and regulations that the SEC may issue in the exercise of its mandates. ■

BSP Clarifies Exclusions from Real Estate Loan Limit and Stress Test

On 28 April 2023, the Bangko Sentral ng Pilipinas ("***BSP***") issued Memorandum No. M-2022-039 and clarified the definition of infrastructure projects for public use as indicated in Section 363-A of the Manual of Regulations for Banks ("***MORB***") on Limits on Real Estate Exposures of Universal and Commercial Banks.

1. What are the Real Estate Loan Limit and the Real Estate Stress Test?

Under Section 363-A(a) of the BSP's Manual of Regulations for Banks (the "MORB"), the "real estate loans" of a universal bank or commercial bank must not exceed twenty-five percent (25%) of its total loan portfolio, net of interbank loans.

Under Section 363-A(b) of the MORB, the "real estate exposure" of a universal bank or commercial bank must not exceed certain percentages of its capital. Currently, the thresholds are six percent (6%) of a universal bank or commercial bank's Common Equity Tier I capital ratio and ten percent (10%) of its risk-based capital adequacy ratio, on a solo and consolidated basis (after assuming that twenty-five percent (25%) of the bank's real estate exposure is written off).

2. What are considered "real estate loans"?

For purposes of determining compliance with the real estate loan limit, the term "real estate loans" (or "RELs") refers to loans granted to land developers, construction companies or other borrowers for the acquisition and development of land and/or construction of buildings and structures, including housing units for sale/lease and/or for use in retail/wholesale, manufacturing or other income-generating purposes, including loans for the land development and construction of residential properties. Purchases by banks of receivables under contracts to sell executed between the real estate developers and home buyers on a with recourse basis shall be considered loans to real estate developers and shall be classified as commercial RELs.

Technically, the MORB also classifies "loans extended to individual households for purposes of financing the acquisition, construction, and/or improvement of housing units and acquisition of any associated land that is or will be occupied by the borrower, regardless of amount" as RELs, but these are expressly excluded for purposes of determining compliance with the twenty-five percent (25%) limit. The following are also excluded in reckoning compliance with the REL limit:

(i) loans extended to land developers/construction companies for the purpose of development and/or construction of socialized and low-cost residential properties as defined under existing guidelines of the Department of Human Settlements and Urban Development for the implementation of government housing programs, which are intended for sale to individual households;

(ii) loans to the extent guaranteed by the Philippine Guarantee Corporation; and

(iii) loans to the extent collateralized by "non-risk assets," as defined by the BSP under existing regulations (e.g., cash, debt securities issued by the Bangko Sentral or the Philippine government, and deposits maintained in the lending bank and held in the Philippines).

3. What are considered part of the "real estate exposure" of a universal bank or commercial bank?

For purposes of determining compliance with the REST, the term "real estate exposure" refers to:

(a) *commercial real estate loans*, or loans granted for purposes of financing real estate activities to: (i) individuals, other than residential real estate loans granted to individual households for occupancy; (ii) land developers/construction companies; and (iii) other corporate borrowers, such as real estate brokers, real estate lessors, and property management companies;

(b) investments in *debt securities issued by land developers/construction companies and other corporate borrowers* for purposes of financing real estate activities; and

(c) investments in equity securities issued by land developers/construction companies and other corporate borrowers for purposes of financing real estate activities. Equity securities issued by holding companies are likewise covered, if proceeds from the issue shall be/has been invested by the holding company in its subsidiary corporation/s that is/are engaged in real estate activities.

"Real estate activities" refer to the acquisition, construction and improvement of real estate; buying and selling of real estate; rental of self-owned or leased real estate; and management of real estate/real property.

4. Are infrastructure loans included in determining compliance with the 25% REL limit and REST limit?

In addition to the loans mentioned in items (i) through (iii) in the response to question 2 above, for purposes of the 25% REL limit, RELs generally do *not* include "loans to finance infrastructure projects for public use." These are loans which "finance the construction, rehabilitation and improvement of highways, streets, bridges, tunnels, railways, railroad, transport systems, ports, airports, power plants, hydropower projects, canals, dams, water supply, irrigation, telecommunications, land reclamation projects, industrial estates or townships, government buildings and housing projects, public markets, slaughterhouses, warehouses, civil work components of information technology networks and database infrastructure projects, solid waste management, sewerage, flood control, drainage, dredging and other infrastructure projects that are intended for public use."

Similarly, for purposes of the REST, the real estate exposure of banks generally does not include loans and investments in debt and equity securities, the proceeds of which are used to finance "infrastructure projects for public use" (as defined above).

5. Are all loans and investments to finance infrastructure projects intended for public use excluded from the computation of RELs and real estate exposures that are subject to the prescribed REL and REST limits?

No, only loans and investments to finance the *construction, rehabilitation and improvement of real estate* relating to infrastructure projects that are intended for public use such as fixed assets, permanent structures, immovable facilities or physical improvements thereon shall be excluded.

6. What items relating to infrastructures intended for public use are not allowed to be excluded from the prescribed prudential limits on real estate and large exposures?

Loans and investments to finance the *general administration and maintenance of operations* of entities

operating or working on such infrastructure projects including, among others, the cost of equipment, machineries and the like, as well as the services and related items are not allowed to be excluded from the prescribed prudential limits.

However, such loans and investments shall be excluded if the expenditure/cost is needed to build, rehabilitate, or improve an infrastructure project for public use and is allowed to be *capitalized* as part of the cost of the fixed asset, permanent structure, immovable facility, or physical improvement.

7. The MORB also provides that loans to finance telecommunications and civil work components of information technology networks and database infrastructure projects are excluded from RELs and real estate exposures of a bank for purposes of determining compliance with the REL and REST limits. What do these exclusions refer to?

These refer to the costs to *construct*, *rehabilitate*, *and improve* the related fixed assets, permanent structures, immovable facilities, or physical improvements thereon such as but not limited to the terrestrial and satellite stations, data center facilities, data recovery sites, or telecommunication towers. Loans to finance such costs are excluded from a universal bank or commercial bank's RELs and real estate exposures for purposes of the REL and REST limits.

However, expenses relating to the *general administration and maintenance of operations* of telecommunication and/or information technology companies including, among others, their expenditures for equipment and services and related items cannot be excluded from the prescribed prudential limits. ■

This bulletin was prepared by SyCipLaw's Banking, Finance and Securities Department. Severino Miguel B. Sanchez and Nicole Kate P. Tan assisted in the preparation of this bulletin.

For more information about the legal issuance discussed in this bulletin, please contact:

Philbert E. Varona
Partner and Head of Banking, Finance and Securities Department
+632 8982 3500
pevarona@syciplaw.com

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Longevity – a discussion from the Singapore legal perspective

DENTONS RODYK

May 8, 2023

I. Introduction

This article is the first in our multi-part series centring around the topic of longevity from the perspective of Singapore law.

As a preliminary framework, the longevity industry consists of several distinct but intersecting segments and domains, including the following:

a. geroscience;
b. biomedicine (i.e. personalised, preventive, and regenerative medicines);
c. progressive clinics and progressive wellness centres;
d. AgeTech; and
e. finance.

We believe that the relevance and significance of the longevity industry in Singapore cannot be overstated, and is underscored by several factors, of which the following are key:

a. Singapore's demographic is rapidly ageing, with Singaporeans living longer and healthier lives as Singapore has an efficient and widespread system of healthcare. As of 2021, Singaporean women can expect to live 85.9 years with 75.8 years in good health, while Singaporean men can expect to live 81.1 years with 72.6 years in good health.
b. Singapore plans to mitigate the challenges of an ageing society by becoming the global leader implementing best practices related to longevity, with a particular focus on slowing down the biological ageing process.[1] Singapore will also continue to embrace technology to improve the quality of life of its elderly population. This will generate a "longevity dividend" in the form of health and economic gains accrued to the country. [2] Singapore will therefore be a market of interest for the longevity industry.
c. With its geopolitical landscape and meritocratic governmental structure, Singapore is well-placed to implement industry development and policy-based initiatives and reforms in accordance with an effective national development plan.[3]
d. Singapore is a flourishing international longevity biotechnology hub, evidenced by the fact that the longevity industry landscape in Singapore now comprises around 100 companies, 80 investors, 15 longevity research and development centres and 10 non-governmental organisations.[4]

II. Regulation of longevity health products in Singapore

Many companies in the longevity industry are developing prescription drugs and novel therapeutics (such as stem cell

A. Current regulatory framework

therapy) to stave off ageing. AgeTech, which refers to technological solutions to improve the quality of life of older people, has contributed to the development of less intrusive treatment options, in the form of external devices, for many age-related diseases or conditions. Companies in the longevity industry need to be aware of the regulatory framework surrounding the commercialisation of health products and services in Singapore, including but not limited to the Health Products Act 2007 (HPA).

Medicinal products are further regulated by the Health Sciences Authority (HSA) under various laws in Singapore including the Medicines Act 1975 (MA), the Medicines (Advertisement and Sale) Act 1955, the Sale of Drugs Act 1914, the Poisons Act 1938, the Tobacco (Control of Advertisements and Sale) Act 1993 and their subsidiary legislation.

B. Clinical trials of therapeutic products and medicinal products

Biotechnology companies have been attempting to develop longevity drugs, including senolytic drugs, which are a class of drugs that selectively clear senescent cells that accumulate in many tissues with aging and at sites of pathology in multiple chronic diseases. These are likely be considered as “therapeutic products” or “medicinal products” which are regulated by the HPA or MA respectively. Currently, clinical trials on therapeutic products are regulated under the Health Products (Clinical Trials) Regulations 2016 (HP(CT)R), while medicinal products are regulated under the Medicines (Clinical Trials) Regulations 2016 (M(CT)R).

It should also be noted that observational clinical trials for such therapeutic and medicinal products are excluded from the regulatory framework under the HP(CT)R and the M(CT)R, respectively. Companies that are seeking to employ clinical trials for their therapeutic products and/or medicinal products should be familiar with their duties under the relevant regulations, and also be mindful about whether their clinical trial would amount to an observational trial as defined in the (HP(CT)R) and the (M(CT)R).

C. Cell, tissue and gene therapy products (CTGTPs)

Several longevity experts have proposed that human stem cells have the ability to regenerate damaged tissues and enhance cellular functions. They are therefore seen as promising candidates by biotechnology companies in the longevity industry for the development of CTGTPs to reverse the effects of aging. While CTGTPs were previously not regulated under the HPA, recent amendments to the HPA and the passing of the Health Product (Cell, Tissue and Gene Therapy Products) Regulations 2021 have seen CTGTPs fall under the scope of the HPA.

D. Commercialisation of longevity health products

The licence required by a company for dealing in health products under the HPA will be based on the types of activities the company conducts with respect to such products:

a. For the manufacture of health products, local manufacturers of health products have to obtain a manufacturer’s licence from the HSA.
b. For the sale of health products, product registration is also generally required for all health products imported or sold in Singapore, where they must be registered with the HSA, subject to certain exceptions. The onus of obtaining such product registration lies with the company which seeks to market the relevant health product in Singapore.
c. For the import of health products (including the import of health products for export purposes), the general rule is that only registered health products may be imported. Any person who wishes to import such health products must obtain an importer’s licence.
d. The wholesale of health products requires a wholesaler’s licence.

In addition, the HSA may also impose additional advertising requirements on licence holders. The HSA has also issued various guidelines that set out the additional procedures for the registration of therapeutic products which are biological in nature.

III. Artificial Intelligence (AI) in drug development and longevity research

AI has been playing an ever-increasingly important role in expediting decision-making in medical sciences by means of advanced machine learning (ML) algorithms. AI has revolutionised the drug discovery process and is being used to create the structure of new drugs based on the specific structure of the target disease-causing compound. ML techniques are also increasingly used in aging and longevity research to develop models for biological processes associated with aging including senescence, apoptosis, oxidative stress, telomere shortening and DNA damages. As with all new, cutting-edge technology, there are questions on how such technology will fit with our current legal structure, and whether there will need to be changes to the law to adapt to novel situations arising from ever-evolving technologies. We discuss below, some of the current legal considerations concerning AI in drug development and longevity research.

A. Patent protection for novel drugs invented by AI

AI has allowed companies in the field of biotechnology to develop drugs as well as therapeutic medicine to counteract the effects of aging and age-related diseases. As companies focus on using AI to identify novel drug targets for untreated age-related diseases, there may be legal implications regarding such use of AI by companies.

From the outset, companies should protect their novel drug inventions created by their AI through the patent application process. The protection accorded by the patent would prevent anyone else from making, using, importing or selling the patented invention unless allowed by the applicant, for 20 years from the date of filing.

Companies should ensure that the novel drugs invented by their AI are kept confidential before patents are filed. Apart from protecting confidential information through data encryption, non-disclosure and confidentiality agreements should be prepared and entered into with the relevant parties to ensure that confidential information does not enter the public domain.

B. Personal data protection issues from the use of AI for longevity research

As health and biological data continue to grow, the use of AI in aging and longevity research will enable us to investigate the biological mechanism associated with the aging clock. Companies involved in this field should be aware that medical and health data will constitute personal data under the Personal Data Protection Act 2012 (PDPA) if such data (whether true or not) is capable, or would be capable with other information which the company has or is likely to have access, of identifying specific individuals. Such data, such as DNA profile and medical information, may be individually-identifiable and constitute personal data if it comprises human biological material or health information which may identify specific individuals with other information that an organisation (such as a research institution or a tissue bank) has or is likely to have access.

Companies which deploy AI algorithms for ageing and longevity research must be aware of their obligations under the PDPA. They must manage and monitor the personal data collected, used or disclosed by their AI algorithms as well as eliminate all potential security issues with their AI solutions through regular review. A data breach management plan should also be put in place to identify and deal with data breaches from the use of AI algorithms.

IV. New legislation for preventing age discrimination

In line with Singapore's support for its growing longevity industry, Singapore's current policies will aim to drive home the message that age is malleable and chronological age is increasingly becoming a poor measure of what it means to be old. The introduction of new legislation to combat ageism in the workplace can therefore be expected. Currently, there is limited legislation against ageism in the workplace, with guidelines and best practices providing some protection against hiring, promotion and dismissal based on age. However, in the Interim Report by the Tripartite Committee on Workplace Fairness published in February 2023, the Tripartite Committee on Workplace Fairness has recommended that new legislation be passed for:

a. stronger protection against discrimination based on age;
b. providing protection against discrimination based on age for all stages of employment, namely, the stages of pre-employment (recruitment), in-employment (promotion, performance appraisal, training) and end-employment (dismissal); and
c. prohibiting prospective employers from using words or phrases that indicate a preference based on age in job advertisements such as "youthful working environment".

The proposed laws under the new framework will coexist with the current framework for dealing with workplace discrimination under the Tripartite Guidelines on Fair Employment Practices. Employers should be more careful about how they recruit prospective employees when the proposed legislation comes into effect.

V. Concluding remarks

Longevity research and management have been receiving massive funding, particularly in the areas of age reversal research by biotechnology firms. As the longevity industry emerges, it will begin to take the form of several distinct segments such as biomedicine, geroscience, AgeTech and finance. As these individual segments intersect with each other, as well as with other domains like AI and government legislations and policies, we can expect new legislation and regulations to emerge to deal with the multidimensional nature of the industry.

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1. Professor Andrew Scott, "A Longevity Agenda for Singapore" *Prudential Ready for 100* (October 2019) at p 2.↩
2. Professor Andrew Scott, "A Longevity Agenda for Singapore" *Prudential Ready for 100* (October 2019) at p 2.↩
3. Aging Analytics Agency, "Longevity Industry in Singapore – Landscape Overview 2019" (2019). ↩
4. Aging Analytics Agency, "Longevity Industry in Singapore – Landscape Overview 2019" (2019). ↩

Your Key Contacts

Marian Ho
Senior Partner, Singapore
D +65 6885 3610
marian.ho@dentons.com

Joonkee Bahng
Partner, Singapore
D +65 6885 3782
joonkee.bahng@dentons.com

Sean Gallagher
Legal Executive, Singapore
D +65 6885 3716
sean.gallagher@dentons.com

Wei En Tan
Associate, Singapore
D +65 6885 3692
weien.tan@dentons.com

The Role of “Experts” in the Newly Amended Intellectual Property Case Adjudication Act

05/31/2023

Hsiu-Ru Chien

The newly amended Intellectual Property Case Adjudication Act (the "IPCAA"), which will come into force on 30 August 2023, brings in two new systems to address the role of "experts" in intellectual property civil litigation. One is the introduction of the "expert investigator" system, which is based on the provisions of Japanese Patent Law, while the other is the "expert witness" system as provided in the Commercial Case Adjudication Act, which shall be applied mutatis mutandis to intellectual property civil litigation proceedings.

Under current practice, the Intellectual Property and Commercial Court (the "IPCC"), when conducting civil litigation on intellectual property, especially patent infringement litigation, often appoints professional authorities or individual experts to participate in the litigation at the request of the parties, either to conduct testing and analysis on the infringing products in dispute, provide professional opinions on relevant legal or technical issues, or even to enter the defendant's premises to collect and investigate financial information and provide opinions on the calculation of damages. It is also common for judgment to include expert opinions submitted by the parties themselves as evidence. Under the current Code of Civil Procedure, the only methods of evidence relating to "persons" are "witnesses", "assessors" and "assessment witnesses.” However, the legal nature of the various types of expert participation in litigation described, and the differences and similarities thereamong, do not appear to have been consistently applied by the IPCC in past practice. The Intellectual Property Case Adjudication Act (the "IPCAA"), as amended, provides clarity for the different functions and tasks of "experts" in litigation.

Article 19 of the newly amended IPCAA stipulates that "In order to determine the truth or falsity of the facts to be proved in patent infringement cases, the court may, at the petition of the party concerned, appoint an expert investigator to examine the instruments or devices in the possession of the other party or third parties.” According to the legislative rationale, the expert investigation system is designed to address situations in which evidence is often in the possession or management of the alleged infringer or a third party, making it difficult for the patentee to gain access thereto practice (i.e. "evidence bias"). The court shall evaluate whether the petitioner has shown "substantial grounds for infringement or risk of infringement of the patent right" (i.e. "cogency"), its "inability to find evidence on its own or by other means" (i.e. "complementarity"), "the necessity of the matter or method of conducting the expert investigation" (i.e. "necessity"), and "whether the time, cost or burden on the person

conducting the expert investigation would be disproportionate" (i.e. "proportionality") before selecting a suitable expert investigator, and shall not be bound by the views of the parties concerned.

With regard to the implementation of expert investigation, Article 22 of the newly amended IPCAA stipulates that the expert investigator “not only may enter the location of the subject matter of the investigation, and conduct court-approved investigation methods towards the documents or devices, but also may raise questions to the party subject to investigation or request them to submit documents necessary for the investigation.” If the party subject to the investigation or the third party refuses or hinders the investigation without justified reason, for the former, the court may, at its discretion, recognize the fact asserted by the petitioner which should be verified in accordance with the investigation to be true. For the latter, the court may even impose penalties of up to NT$100,000.

After an expert investigator submits an investigation report, it is necessary for the petitioner to present the investigation report as documentary evidence in the proceedings in accordance with Article 25 of the newly amended IPCAA. There is no provision in the IPCAA governing whether a party can request attendance of the expert investigator to present opinions or conduct cross examination.

Expert Witnesses

Article 28 of the newly amended IPCAA stipulates that the provisions of the Commercial Case Adjudication Act (hereinafter the CCAC) concerning expert witnesses shall apply mutatis mutandis to intellectual property civil matters. According to the design of the CCAC, after the party declares an expert witness and obtains permission of the court (Article 47 of the CCAC), the expert witness shall in principle issue an expert opinion in writing (Article 49 of the CCAC), wherein in the period specified by the court, the party may question other experts in written forms, and the court may, ex officio or upon request, compel the expert witnesses to present their opinions (Article 50 of the CCAC). In addition, with the permission of the presiding judge, expert witnesses may question other expert witnesses or assessors at the oral hearing (Article 52 of the CCAC). In addition, when the court deems it necessary, it may order the expert witnesses of the two parties to discuss the issues or other necessary matters within a limited period, and jointly issue professional opinions in writing (Article 51 of the CCAC).

After the implementation of the IPCAA, further observations and practices remain to be made and developed concerning how various evidence methods involving "persons" such as expert investigators, expert witnesses, and assessors and assessment witnesses in the current civil procedure law will be employed properly in the court evidence investigation procedures, how to allocate proper missions to such persons in order to make the most of these evidence methods, and what the differences will be between actual practice and legal effect.

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ADVISORIES

Electronics Right to Repair Laws Are Here – New York and Minnesota Lead the Way

Original equipment manufacturers must now provide diagnostic and repair information and parts to independent repair shops

By Martha Phelps and Stasia Skalbania

06.21.23

On December 28, 2022, New York Governor Kathy Hochul signed the state's Digital Fair Repair Act into law. The Minnesota legislature quickly followed, passing its own version in May 2023. Interest in "right to repair" legislation for digital electronics equipment has been increasing in recent years, and the New York and Minnesota statutes are the first to require original

equipment manufacturers (OEMs) to provide diagnostic and repair information, tools (including software), and parts for digital electronic equipment to independent repair providers and consumers. Right to repair laws are designed to provide greater flexibility for consumers by requiring OEMs to make tools, parts, and documentation for repair of digital electronic equipment equally available to equipment owners and independent repair shops, instead of exclusively available to OEM-authorized repair providers. The laws also provide protection from liability for OEMs for damage or injury caused by repairs carried out by the equipment owner or an independent repair shop.

Both the New York and the Minnesota laws apply to "[d]igital electronic equipment," defined as "any hardware product" that relies or depends on "digital electronics embedded in or attached to the product." Both laws also limit the application to equipment for which the OEM makes tools, parts, and documentation available to its own employees or any authorized repair provider.

Each law contains certain exclusions, and neither applies to motor vehicles, medical devices, or off-road equipment (including farming equipment). Protections for OEMs were built into the laws, and each specifically clarifies that an OEM is not required to divulge any trade secrets or license any intellectual property to any repair providers; make any tools, parts, or documentation available for the purposes of modifying any digital electronic equipment; or provide repair information that goes beyond what is provided to its own authorized repair shops.Each also provides some flexibility for OEMs who may wish to provide replacement products or parts assemblies instead of individual replacement parts. Additionally, the two laws include exceptions for the provision of information that would disable or override anti-theft security features.

Both laws will also apply retroactively once in effect: New York's Digital Fair Repair Act goes into effect on December 28, 2023 with respect to

equipment first manufactured on or after July 1, 2023, and Minnesota's Digital Fair Repair Act will take effect July 1, 2024 with respect to equipment sold on or after July 1, 2021. The Minnesota law requires that OEMs make parts, tools, and documentation for repair of digital electronic equipment "sold or used in Minnesota" available "within 60 days after the first sale of the digital electronic equipment in Minnesota," while the New York law appears to leave open the question of whether the information, tools, and parts must only be provided upon request.

This trend is likely to continue, with at least 21 other states having a pending ballot measure or bill for electronics right to repair laws. OEMs and their authorized repair shops and industry groups will be watching for regulations that may offer additional compliance guidance. In the short term, OEMs should review their product repair manuals for updates and begin planning for making parts, documentation, and tools more widely available.

Please contact the DWT Technology practice group for additional guidance on right to repair laws or other upcoming legislation.

Non-Competes: New NLRB General Counsel Memorandum Puts Hawaii Employers Between a Rock and a Hard Place

01 June, 2023|

It's time for Hawaii employers to revisit their non-compete agreements. Again.

Last February the Hawaii Supreme Court invalidated an employer non-compete in part because it prohibited a real estate agent from opening her own practice, but did not *also* go farther and prohibit her from working as an agent for another brokerage. https://www.goodsill.com/blog/2022/02/hawaii-supreme-court-inconsistent-implementation-sinks-non-compete-enforcement-attempt-also-violation-of-non-solicitation-agreement-requires-active-initiation-of-contact/. This told Hawaii employers, if you want your non-compete to be viable, you must prohibit the employee from competing, whether as an owner or as an employee of a competing business.

Earlier this week employers got the **opposite** message from the General Counsel of the National Labor Relations Board: employers can potentially prohibit former employees from having an ownership interest in a competing business, but most non-competes with non-managerial, non-supervisory employees are otherwise unlawful under the National Labor Relations Act because such agreements interfere with employee rights protected by the NLRA. https://www.nlrb.gov/news-outreach/news-story/nlrb-general-counsel-issues-memo-on-non-competes-violating-the-national. (Keep in mind that the NLRA does not generally protect supervisory or managerial employees. So the NRLB GC memorandum does **not** address non-competes with those employees. But also remember that the reach of the NLRA goes beyond union workplaces and protects non-supervisory employees even when not in a union.)

So, what about sales staff, account representatives, and other non-supervisory employees who are the face of the business with customers? These employees are often subject to non-competes, which serve to provide the business with time to put another face of the company before the customers and give that new face a chance to secure the relationship before the former employee begins to target the customers they serviced.

While the NLRB GC is not the final word on the legality of non-competes for non-supervisory employees, what this does mean is that when word of this memorandum reaches line employees who do have non-competes, there is likely to be a spate of unfair labor practice charges challenging these agreements filed with the NLRB. Expect complaints to be filed regardless of whether there are current efforts to enforce a non-compete. In the view of the NLRB GC: "Except in limited circumstances, I believe the proffer, maintenance, and enforcement of such agreements violate" the NLRA (emphasis added).

So, what should Hawaii employers be doing? It may be time to forgo the blunt instrument of a non-compete that prevents an employee from even working in competition with your business, in favor of a more targeted non-solicitation restriction. Unfortunately, in last year's decision, the Hawaii Supreme Court also made non-solicitation provisions more difficult to enforce, confining conduct employers can prohibit as improper solicitation to instances of "active initiation of contact" with an off limits employee or, presumably, customer.

For businesses that have been relying on non-compete agreements with non-supervisory, non-management employees, to protect customer goodwill, trade secrets, training investment and other valuable company resources, now is the time to get those agreements to an employment lawyer for review and a discussion about the best way to protect those assets going forward. For businesses that have non-competes with low-wage workers who do not present a legitimate threat to unfairly take business if they depart, it is past time to be rid of those agreements.

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FDA draft clinical trial guidance promotes decentralized studies, digital tech use

GCP guidance comes ahead of FDA DCT webinar

20 June 2023

Last week, the U.S. Food and Drug Administration (FDA) issued draft guidance on Good Clinical Practice (GCP), adopting the International Council for Harmonisation's (ICH) "E6(R3)" guidelines. Below we summarize how the draft guidance would modernize GCP trial standards and promote the use – as well as the agency oversight – of digital health technology (DHT) and decentralized clinical trial (DCT) elements while maintaining fundamental data integrity and human subject protection considerations central to clinical research.

FDA seeks comments on the draft guidance through September 5, and is separately hosting a webinar on its decentralized clinical trial draft guidance today.

Good Clinical Practice (GCP) is the international, ethical, scientific, and quality standard for the conduct of trials that involve human participants. Last week, FDA published the 81-page draft guidance "E6(R3) Good Clinical Practice (GCP)" (Draft E6 GCP Guidance) which aims to update and supplement the 69-page March 2018 guidance "E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)." The new draft guidance is adopted from ICH's May 2023 E6(R3) draft guideline, and it expands upon FDA's April 2022 final guidance, "E8(R1) General Considerations for Clinical Studies," which is based on ICH guidelines of the same name.

FDA's new draft guideline expands on the roles and responsibilities of institutional review boards (IRBs), investigators, and sponsors in the context of rapidly developing technological and methodological innovations in the clinical trial enterprise.

Digital Health Technology oversight

The most significant enhancements FDA proposes in the Draft E6 GCP Guidance are those clarifying the use of computerized systems in clinical trials, the roles and responsibilities of trial sponsors and investigators with respect to data governance, and requirements for obtaining and documenting electronic informed consent (in paper or electronic format).

FDA's Draft E6 GCP Guidance encourages the use of digital health technologies (DHTs) that could assist with data collection or patient recruitment, such as wearable sensors. It says clinical trial design should use "risk-based proportionate approaches" that determine which protocols are most important for the protection of patient safety and data, and the guidance urges investigators to take an early focus on ensuring the clinical trial data quality.

The Draft E6 GCP Guidance includes a section named "Data Governance – Investigator and Sponsor," which offers recommendations on procedures and processes for the use, security, and validation of computerized systems. This section also provides guidance about how to develop processes to ensure data integrity, traceability, and security throughout the full data life cycle. Rather than placing data governance responsibilities squarely at the feet of the sponsor or the investigator, the Draft E6 GCP Guidance references the "responsible party," which could be either the sponsor or the investigator, or both; FDA is signaling here that both parties may share responsibility for data integrity.

FDA's focus on DHT oversight in the Draft E6 GCP Guidance can be viewed as a continuation of the agency's initiatives in this space. For instance in March, FDA issued separate draft guidance on electronic records that similarly prioritized DHT oversight, which we analyzed online here. Indeed, in a statement announcing the new electronic records guidance, FDA Commissioner Robert M. Califf, M.D., said "modernized GCP recommendations encourage the use of fit-for-purpose innovative...DHTs, such as wearable sensors [that] could potentially facilitate more agile data collection and assist with patient recruitment."

The greater emphasis on processes & procedures to promote data integrity in the Draft E6 GCP Guidance is worth viewing in light of FDA's expanded authority to inspect a wider range of parties involved in clinical research, such as contractors who provide biostatistical support or database services, which we recently analyzed online here. Accordingly, clinical trial sponsors, CROs, vendors, and clinical trial sites must take extra care in ensuring compliance with FDA GCP expectations.

Decentralized Clinical Trial use

FDA's Draft E6 GCP Guidance includes many references to decentralized clinical trials (DCTs). In a traditional clinical trial, a study subject would engage

in study activities at a single, centralized site (often research medical centers) that was under the immediate supervision of a site-based health care professional. By contrast, DCT trials are those where some or all trial activities take place at a location other than a traditional site. Examples of how a clinical trial may be decentralized include obtaining laboratory tests at a local facility rather than a research medical center, or conducting a clinical follow-up visit in the study subject's home using telemedicine (including DHTs).

The Draft E6 GCP Guidance notes that consent for participation in a trial can be obtained remotely and that auditing of a trial process can as well. According to the guidelines, clinical trial design should include a discussion of whether decentralized elements will be involved. Monitoring during a study "may include site monitoring (performed on-site or remotely) and centralised monitoring, depending on the monitoring strategy and the design of the clinical trial" and it "may include secure, remote, direct read-only access to source records, other data acquisition tools and essential record retention systems," the draft guidance states.

FDA recently issued other documents that complement these draft recommendations and promote innovative trial designs; for example, last month the agency released draft guidance proposing recommendations for the implementation of DCTs, which we analyzed online here. We see the agency's move toward promotion of DCTs as a historic sea change that will lead to major changes in how clinical research is conducted in the U.S., with the emerging DCT framework embracing a distributed model where study-related activities can take place at the clinical site, a patient's home, the office of another health care professional, or even a local pharmacy.

FDA seeks comments on the Draft E6 GCP Guidance through September 5, 2023. If you may wish to submit a comment or have any questions on Good Clinical Practice standards more generally, feel free to contact any of the authors of this alert or the Hogan Lovells attorney with whom you generally work.

Authored by Blake Wilson, Stephanie Agu, Heidi Gertner, and Lowell Zeta

Contacts

Blake Wilson
Partner
Philadelphia
blake.wilson@hoganlovells.com

Heidi Gertner
Partner
Washington, D.C.
heidi.gertner@hoganlovells.com

Lowell Zeta
Partner
Washington, D.C.
lowell.zeta@hoganlovells.com

Stephanie Agu
Associate
NW Washington, D.C.
stephanie.agu@hoganlovells.com