

Pacific Rim Advisory Council  
**May 2023 e-Bulletin**

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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  
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INTA Singapore May 16-20

ABA Denver August 3 - 8

IBA M&A New York June 6 - 7

IBA Annual, Paris - Oct 29—Nov 3

Full Details

[www.prac.org/events](http://www.prac.org/events)

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**BRIGARD URRUTIA APPOINTS NEW MANAGING PARTNER**

**BOGOTA, 23 April, 2023:** Carlos Fradique-Mendez new Managing Partner at Brigard Urrutia



Brigard Urrutia's senior partner was unanimously elected as the firm's managing partner as of April, 2023.

Carlos is a recognized expert in financial law and has led the development of complex structures and financial instruments in matters such as project and infrastructure finance, capital markets, PE/VC funds, asset management and financial

derivatives, as well as in the successful resolution of complex disputes in the local and international market, among others. Carlos served as Chief Legal Officer of the Ministry of Finance/Treasury Department of Colombia as member of the Disciplinary Court of the AMV and as Director of several

Carlos has pioneered the design and structuring of many innovative financial products and instruments and implementing rules and regulations in the local and regional market including the first and largest REIT in the Andean region, the first issuance of local hedged bonds by a supranational issuer, the local master private and public derivatives agreement, the first hedge fund, the first corporate perpetual bond in Latin America and the first subordinated bond by a Colombian financial institution.

A licensed practitioner in Colombia and a member of the New York Bar. Carlos has consistently been selected as a top deal and regulatory lawyer in the Colombian financial market, including having been named a top capital market lawyer in Latin America by Latin Lawyer and a "star individual" in banking and finance by Chambers & Partners.

For additional information visit [www.bu.com.co](http://www.bu.com.co)

**BENNETT JONES OPENS MONTREAL OFFICE**

*From West to "Est": Bennett Jones Opens Office in Montréal*

**01 May, 2023:** Bennett Jones is expanding its national business law practice with the opening of an office in Montréal. This new office is the latest chapter in the development of Bennett Jones. Founded in Calgary in 1922, it is Canada's only leading national law firm to expand from West to East. Montréal joins existing offices in Calgary, Edmonton, Toronto, Ottawa, Vancouver and New York.

"The expansion of Bennett Jones' national reach is focused on our clients. We serve them where they do business," says Hugh MacKinnon, Chairman and CEO of Bennett Jones. "Québec is full of opportunities, both in established and emerging sectors. We are making a long-term commitment in Montréal and look forward to building strong relationships with the Québec business community."

The firm launches in Québec with a stellar team of client-focused and business-minded professionals, including:

**Pascale Dionne-Bourassa, Partner:** As the first partner in the Montréal office, Pascale brings over 25 years of experience in large-scale and complex civil and commercial litigation, as well as in construction law. She also has extensive experience in class actions in civil and competition law. Prior to joining Bennett Jones, Pascale was the founder of d3b Avocats in Montréal, and has acted in major litigation for private and public organizations in Québec, Canada and abroad.

**Monique Mercier, Senior Advisor:** Monique joins the firm to offer clients her extensive experience gained over three decades as a senior executive in the telecommunications, healthcare and information technology sectors. Most recently, she was Executive Vice-President, Corporate Affairs, Chief Legal and Governance Officer of TELUS. With extensive experience in mergers and acquisitions and risk management, Monique sits on several boards and enjoys a solid reputation within the Québec business community.

**Jacinthe Landry, Director of Administration:** With 25 years of experience in the legal and business sectors, Jacinthe began her career as a lawyer with a large national law firm before moving into executive roles in legal and business operations management. A member of the Bar and holder of an MBA from HEC Montréal, Jacinthe uses her strategic thinking and business acumen to ensure the efficient operation of Bennett Jones' Montréal office.

"The opportunity to build an office in Montréal and to develop within it a vibrant and authentic Montréal culture, true to the values that have defined Bennett Jones for 100 years—is what attracted me to Bennett Jones. I am delighted to be a part of a firm of such a high calibre with a national network of more than 500 highly talented lawyers and advisors," said the first Montréal-based Partner, Pascale Dionne-Bourassa.

"There is a perfect fit between Bennett Jones' expertise and our Québec, Canadian and international clients interested in the energy and energy transition, capital projects, construction, agribusiness, and technology sectors. The launch of our firm in Québec is a testament to the strength of the Québec economy and the interest of Canadian and foreign investors in it," added Senior Advisor, Monique Mercier.

Bennett Jones' Montréal office is located on the 18th floor of Maison Manuvie, an ultra-modern, first-class building where the firm will occupy a full floor of more than 20,000 sq. ft. The tower is strategically located in the heart of Montréal's financial district and is BOMA BEST® Platinum, LEED Gold® Core & Shell and ENERGY STAR® certified.

To learn more about the Montréal office or to express your interest in playing an active role in our expansion in Québec, please contact Jacinthe Landry at [landryj@bennettjones.com](mailto:landryj@bennettjones.com).

**DAVIS WRIGHT TREMAINE ELECTS NEW EXECUTIVE COMMITTEE**

*Davis Wright Tremaine Elects New Members of Executive Committee and Names New Chair, Vice Chair and Secretary; All three new leaders are diverse and include the firm's first Latino chair*

**SEATTLE – April 25, 2023:** Davis Wright Tremaine LLP is pleased to announce the new members of its Executive Committee. At the firm's annual partnership meeting, the partners elected two new members and re-elected two returning members. The Executive Committee elected new members to all three leadership positions: Camilo Echavarria as chair, Jaime Drozd as vice chair, and Sanjay Nangia as secretary, effective April 20, 2023.

Echavarria will become the first Latino in the law firm's history to be elected to chair its Executive Committee. An employment litigator, he also is the firm's Los Angeles partner-in-charge and a member of the firm's Diversity Executive Council, which oversees all diversity, equity, and inclusion efforts at the firm. Based in Seattle, Drozd is the firmwide co-chair of the Litigation practice and is a complex commercial litigator who advises and defends clients against a variety of consumer class actions. Based in San Francisco, Nangia is an experienced trial lawyer who represents a variety of high-profile companies with a special focus on the technology, financial services, energy, and healthcare industries.

The newly elected members of the committee are:

*Nicolas Jampol*  
*Sanjay Nangia (secretary)*

The re-elected returning members are:

*Jaime Drozd (vice chair)*  
*Jesse Lyon*

The remaining members are:

*Camilo Echavarria (chair)*  
*Scott MacCormack (firmwide managing partner)*  
*Nancy Libin*  
*Claude Goetz*  
*Pete Johnson*  
*Wendy Kearns*  
*Sheehan Sullivan*  
*Jean Tom*




"We welcome our new members Nick and Sanjay and look forward to Camilo and Jaime helping guide the firm's strategic direction," said MacCormack. "We are also incredibly grateful to outgoing committee chair Sarah Tune, who helped lead the firm through the pandemic and to new levels of success, and to outgoing member Thomas R. Burke for their years of service and guidance. We thank them both for the significant roles they played in helping shape a successful path forward for the firm."

For additional information visit us at [www.dwt.com](http://www.dwt.com)

## GIDE ANNOUNCES WARSAW PROMOTIONS

Gide promotes three lawyers to Counsel at Gide Warsaw office

**WARSAW, 25 April 2023:** Gide is pleased to announce the promotion to Counsel of three promising young lawyers in several practice groups : Piotr Brzeziński, PhD, Mateusz Gronau and Dawid Van Kędzierski, PhD.

	<p>Piotr Brzeziński, PhD is an attorney-at-law and a member of the litigation &amp; arbitration, public procurement, infrastructure and data protection teams at Gide Warsaw.</p> <p>He advises clients on regulated markets, in particular on the armament, petrochemical, gas, postal, and transport markets. He represents contracting authorities and contractors in proceedings before the National Appeals Chamber and before courts.</p> <p>For 16 years, Piotr has been a lecturer in commercial law at the Faculty of Commercial Law at Lazarski University in Warsaw. He has authored numerous professional publications on issues related to commercial contracts, in particular in such journals as Monitor Prawniczy, Przegląd Prawa Handlowego, Państwo i Prawo, Przegląd Ustawodawstwa Gospodarczego. He holds the degree of doctor in Law received from the Polish Academy of Sciences and is a graduate from the Faculty of Law and Administration at Lazarski University in Warsaw.</p>
	<p>Mateusz Gronau is an advocate and a member of the banking and finance practice at Gide Warsaw. He specialises in secured financing transactions and structured finance, as well as in contracts for the international sale of goods. He has also experience in insurance law, mergers and acquisitions, corporate and commercial law issues.</p> <p>He graduated from the Faculty of Law and Administration at Warsaw University, and from the School of German and European Law at Warsaw University. He is an author of numerous articles relating to the corporate and commercial law.</p> <p>He is recommended as the "Rising Star" by The Legal 500 EMEA and Chambers Europe.</p>
	<p>Dawid Van Kędzierski, PhD is an attorney-at-law and a member of the capital markets, corporate law and private equity / venture capital practices at Gide Warsaw.</p> <p>He specialises in capital markets law, corporate law and M&amp;A transactions, as well as in stock exchange law. He has represented issuers and financial institutions in connection with public and private offerings of securities, including shares, bonds and subscription warrants. He has advised issuers on fulfilling disclosure obligations on the stock exchange. He has participated in significant transactions on the public and private M&amp;A markets. He has taken part in projects for strategic investors, private equity and venture capital funds in connection with the implementation of investments and the sale of portfolio companies. He has advised on the regulations of financial markets (MAR, CRR, AIFMD, AML, MiFID and economic sanctions). He also has experience in financing and refinancing, and in restructuring the liabilities of companies in financial difficulties.</p> <p>He is a graduate of the Faculty of Law and Administration at the University of Warsaw and the British Law Centre at the University of Warsaw, organised in cooperation with the University of Cambridge. In 2019, he defended his doctoral dissertation on leveraged buyouts and recapitalisations and obtained a PhD in legal sciences. He is a member of the Polish Association of Economic Analysis of Law. He is the author of numerous publications on corporations in national media and specialist publications.</p>

For additional information visit us at [www.gide.com](http://www.gide.com)

**ARIAS**

ADVISES UNIVAR SOLUTIONS IN THE ACQUISITION OF CHEMSOL IN CENTRAL AMERICA

**COSTA RICA, 15 Mar 2023:** At Arias we provided legal advice to Univar Solutions Inc. in the acquisition of the regional chemical company Chemsol. Univar Solutions Inc. is a leading global distributor of specialty chemicals and ingredients representing a premier portfolio of the world's leading producers. Chemsol, on the other hand, has important companies in Panama and subsidiaries in Costa Rica, El Salvador, Guatemala and Honduras.

Univar Solutions chose us as their primary point of contact for the due diligence process and pre-closing stage; In addition, we advised them in the identification of risks and the coordination of corporate, labor and tax matters essential for the transaction. We also advised the buyer with antitrust assessments.

The deal consisted on a purchase of shares from the entire company, including affiliated target companies. This agreement involves a great deal of detail for the purchase of shares, and our office in Costa Rica was the coordinating law firm of the Central American jurisdictions.

The acquisition of Chemsol will enhance Univar Solutions Inc.'s geographic footprint in the Central American region, as well as its formulation and commercial offering in a wide range of key growth markets, including beauty and personal care, pharmaceutical excipients, groceries, coatings, adhesives, sealants and elastomers, lubricants and metallurgical fluids.

Our advice to Univar Solutions Inc. has been a success in legal and strategic terms, and we have demonstrated once again our leadership in corporate legal matters in the Central American region.

We congratulate Univar Solutions on this acquisition and wish them success in their business journey! We are honored to have been part of this process as your legal counsel.

Advising Univar: (Costa Rica) Andrey Dorado, Tracey Varela, Desiree Barahona; (El Salvador) Robert Gallardo, Ernesto Sanchez; (Guatemala) Luis Pedro Del Valle; Florencio Gramajo; (Honduras) Mario Aguero; Rodolfo Salgado; (Panama) Maria Fabrega; Paula Vives.

For additional information, visit us at [www.ariaslaw.com](http://www.ariaslaw.com)

**BRIGARD URRUTIA**

HELPS GUIDE CROSS-BORDER IT ACQUISITION

**BOGOTA, 14 May 2023:** Brigard Urrutia in Bogotá helped a set of investment funds managed by US venture capital group Recognize Partners acquire software company Moove-IT, which has operations in Uruguay and Colombia.

The deal closed on 14 April for a confidential amount.

Moove-IT provides customised software solutions to clients in the US, providing services from their facilities in Montevideo in Uruguay and the Colombian city of Cali. The buyer used its CLV Corp and CLV ZA to purchase an entire equity stake in Moove-IT. Both funds are incorporated both in Colombia and Uruguay as well as the US.

Following the purchase, Recognize aims to combine its business with Moove-IT in order to create a software development platform with a substantial presence in Uruguay. In a simultaneous transaction linked to the recent deal, Recognize also acquired another, undisclosed Uruguayan business.

Headquartered in New York, Recognize is a venture capital and private equity group that manages several funds. It primarily invests in technology companies, such as US marketing platform 2X.

Counsel to Recognize Partners (Colombia) Brigard Urrutia Partner José Francisco Mafla and associates Pablo Brando Espinosa and María Acelas Celis in Bogotá

Counsel to Recognize Partners (Uruguay); Counsel to Moove-IT - Mayer Brown LLP; Guyer & Regules

For additional information visit [www.bu.com.co](http://www.bu.com.co)

**BENNETT JONES**

VOLKSWAGEN AG SUBSIDIARY, POWERCO SE, INVESTS IN \$7B EV GIGAFACTORY IN CANADA

**TORONTO, 21 April, 2023**

Bennett Jones is advising Volkswagen AG and its battery subsidiary, PowerCo SE, in the establishment of its first battery cell manufacturing plant in North America—and its first outside of Europe. The gigafactory will be built in St. Thomas, Ontario.

This is the largest automotive industry investment in Canadian history. Volkswagen is the first original equipment manufacturer to enter Canada's automotive manufacturing sector in 35 years, and the first European one to do so. It is a historic investment that will benefit Canadians for generations, and benefit the world in the transition to zero emission vehicles.

"PowerCo SE's gigafactory in St. Thomas is a monumental investment in Canadian industry and its technology is on the cutting-edge of EV battery production," says Hugh MacKinnon, Chairman and CEO of Bennett Jones. "It is a prime example of how Bennett Jones' market-leading expertise can help clients succeed with complex, global, industry-shaping investments."

Key figures on PowerCo SE's gigafactory in St. Thomas:

Capital investment: C\$7 billion by 2030.

Size: The cell factory will cover an area of around 370 acres. The entire industrial park will be around 1,500 acres.

Annual production capacity: Up to 90 GWh in the final expansion phase.

Jobs: Up to 3,000 highly skilled jobs at the factory and tens of thousands more indirect jobs in the region.

More details on the gigafactory are available [here](#).

An official ceremony was held today in St. Thomas with Frank Blome, CEO of PowerCo SE; Canada's Prime Minister Justin Trudeau; the Honourable François-Philippe Champagne, federal Minister of Innovation, Science and Industry; Ontario Premier Doug Ford; the Honourable Victor Fedeli, Ontario's Minister of Economic Development, Job Creation and Trade; the Mayor of St. Thomas, Joe Preston; and other PowerCo SE Board members and dignitaries.

The Bennett Jones team advising PowerCo SE is led by Michael Smith and Ian Michael, and includes Tyler McAuley, Jane Helmstadter, Leonard Griffiths, Sharon Singh, Jessica Horwitz, Andrew Jeanrie, Jason Roth and Philip Ward.

For additional information visit [www.bennettjones.com](http://www.bennettjones.com)



**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](http://www.dwt.com)

**ARIFA** HELPS GUIDE BLADDEX 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](http://www.arifa.com)



**GIDE**

ADVISES GROUPE BENETEAU IN CONNECTION WITH ENTRY INTO EXCLUSIVE NEGOTIATIONS WITH GROUPE TRIGANO FOR THE SALE OF ITS HOUSING BUSINESS

**PARIS, 05 May 2023:** Groupe Beneteau announced on May 5 that it has entered into exclusive negotiations with the Groupe Trigano, a European market leader for leisure vehicles, concerning the sale of its Housing business, specialized in manufacturing leisure homes for the camping tourism sector in particular.

The operation would be based on taking over full control of its subsidiary BIO HABITAT, including the O'HARA, IRM and COCO SWEET brands, as well as all of its employees in France and Italy, and its current leadership team. It remains subject to the procedures for informing and consulting with the employee representative bodies and obtaining approval from the competition authorities.

The Gide team was led by partners Olivier Diaz and Charles de Reals, associates Corentin Charlès and Rosalie Schwarz for the M&A aspects; partner Franck Audran, counsel Elizabeth Gautier and associate Martin Roger for the antitrust aspects; partner Magali Buchert, associates Charles Ghuysen and Gauthier Plattelet for the tax aspects; and partner Foulques de Rostolan, associates Pauline Manet and Gheorghe Big for the employment law aspects.

Groupe Trigano was advised by August Debouzy.

For more information visit [www.gide.com](http://www.gide.com)

**HAN KUN**

ADVISES ISPIRE TECHNOLOGY INC. 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](http://www.hankunlaw.com)

**HOGAN LOVELLS**

ADVISES HELION IN WORLD'S FIRST FUSION ENERGY PURCHASE WITH MICROSOFT

**WASHINGTON, DC., 15 May 2023:** Global law firm Hogan Lovells represented Helion Energy in the company's agreement to provide Microsoft electricity with its first fusion power plant. Constellation will serve as the power marketer and will manage transmission for the project. Read more from Helion here <https://www.businesswire.com/news/home/20230510005311/en/>

The plant is expected to be online by 2028 and will target power generation of 50 MW or greater after a 1-year ramp up period. The planned operational date for this first-of-its-kind facility is significantly sooner than typical projections for deployment of commercial fusion power.

The development of a commercial fusion power facility is a crucial step in the transition to a sustainable energy future, and also supports the development of a new clean energy source for the world.

Helion, which is committed to creating a new era of zero-carbon electricity through fusion, has been advancing its fusion technology for more than a decade. The company has previously built six working prototypes and was the first private fusion company to reach 100-million-degree plasma temperatures with its sixth fusion prototype.

Hogan Lovells' cross-practice, cross-border team was led by Global Co-Head of the Energy and Natural Resources industry sector Brian Chappell and included Amy Roma, Mariana Amaral, Gary Stapleton and Polly Sims.

For additional information visit us at [www.hoganlovells.com](http://www.hoganlovells.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](http://www.munizlaw.com)

**SANTAMARINA**

ADVISES IN ASSET PURCHASE BETWEEN MARRIOTT AND HOTELES CITY EXPRESS

**MEXICO CITY, 08 May 2023:** Santamarina y Steta, S.C., with a firm-wide team led by Aarón Levet V., Alberto Saavedra O., partners, and Martín Cortina, as senior associate, with the support of Efrain Olmedo, counsel, and David Raziel Celis, associate from the M&A team, along with lead counsel, Gibson, Dunn & Crutcher (the team of which was led by partners Stephen Glover and Alexander Orr) advised Marriott International, Inc., as local counsel, on its purchase of certain assets from Hoteles City Express, S.A.B. de C.V., for an amount of \$100 million dollars including, among others, its brand portfolio —City Express, City Express Plus, City Express Suites, City Express Junior, and City Centro— associated trademarks, domains, and the City Premios loyalty program.

The transaction was announced in October 2022 and formally closed on May 2, 2023, following regulatory approval from Mexico's Federal Economic Competition Commission. Vicente Grau A., partner, and our associates Yakov Y. Kobets and Sofía Ramírez also assisted Marriott International in obtaining such approval.

Santamarina + Steta's strong technical expertise and experience in the hotels and hospitality industries shall likely continue playing a fundamental part in supporting players across the sector.

For additional information visit [www.santamarinasteta.mx](http://www.santamarinasteta.mx)



PRAC 68th International Conference

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Event exclusive to member firms

**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

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## 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

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Country Update - India - Pradeep Ratnam

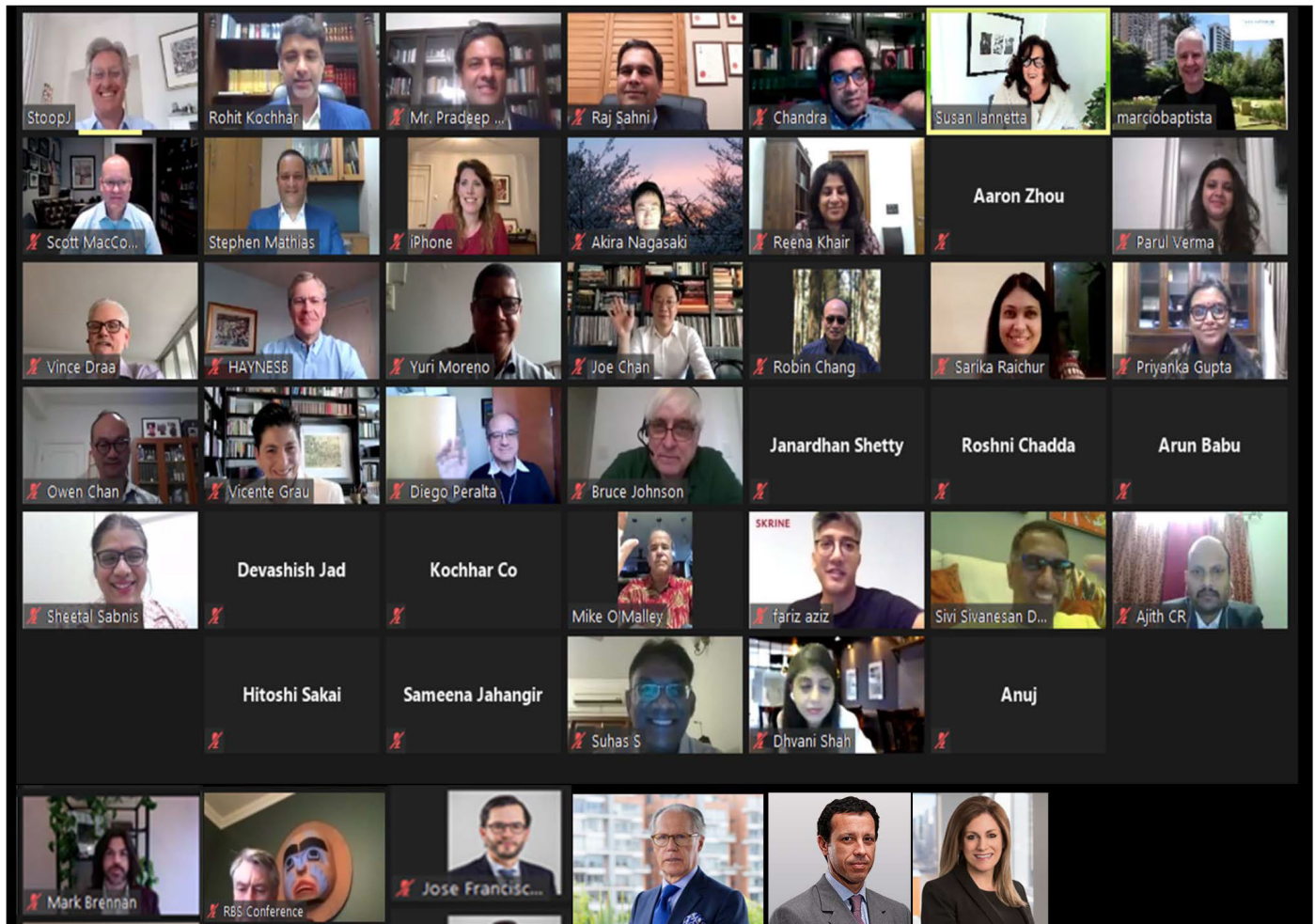
Visual Presentation - Essence of India!

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)

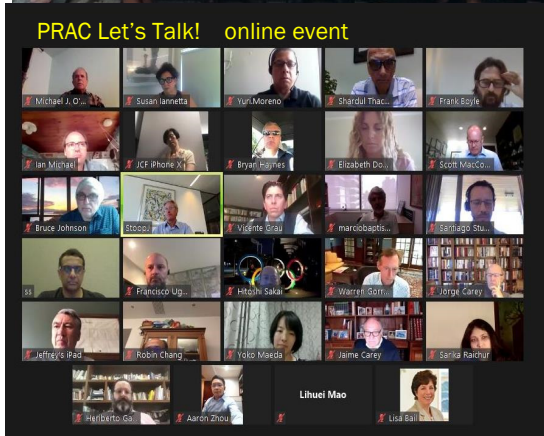


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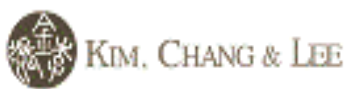
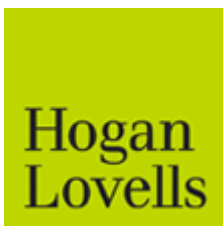


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## THE FISCAL REGISTRY FOR MINING COMPANIES

### Lawyers:

Nicolás O. Procopio, Raúl Fratantoni

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On March 14, 2023, General Resolution No. 5333/2023 of the Argentine Tax Authorities (hereinafter referred to as "AFIP") was published in the Official Gazette, implementing the Fiscal Registry for Mining Companies (hereinafter referred to as the "Registry").

The Registry is intended for (i) entities engaged in mining activities under the Mining Code and/or Law No. 24,196; (ii) suppliers to mining companies; (iii) service companies registered as beneficiaries under Law No. 24,196, providing services to mining producers; (iv) mining producers providing services to third parties; (v) suppliers to companies providing project management services to the mining sector; and (vi) holders of exclusive permits for exploration or prospecting in a specific area.

Entities must register through the AFIP website in one of the following sections: mining companies, suppliers to mining companies, and exploration or prospecting permit holders.

It should be noted that the Registry establishes withholding regimes for Value Added Tax and Income Tax, applicable to mining companies registered as taxpayers for these taxes, as well as companies providing project management services to the mining sector. Additionally, it identifies suppliers to mining companies and suppliers to companies providing project management services to the mining sector as subjects subject to withholding.

The withholding rates for Value Added Tax are 10.5% or 21%, depending on the registration in the Registry. As for the withholding regime for Income Tax, the rates are 20%, 30%, or 35%, depending on the registration in Income Tax and the Registry.

Furthermore, the Registry establishes a semi-annual reporting regime that holders of exploration or prospecting rights granted by mining authorities must comply with. The first submission must be made within 30 consecutive days from the registration in the Registry.

Finally, it should be noted that the Registry came into effect on April 1, 2023, and according to the established schedule, registration can be carried out until May 10. The withholding regime for Value Added Tax and Income Tax will come into effect on May 16.

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# The Ontario Court of Appeal Upholds the Use of “Powerful” Epidemiological Data to Infer Causation in the Absence of Scientific Certainty

Written By Cheryl Woodin and Alexander Payne

The Court of Appeal for Ontario in *Levac v James*, 2023 ONCA 73 [*Levac*] has unanimously upheld a trial judgment in a common issues trial regarding an infectious disease outbreak in respect of which the allegedly negligent cause was linked to a very high statistical increase in risk, and for which no alternative and non-negligent cause was presented.

The Court of Appeal's decision clarifies the circumstances in which statistical evidence, particularly epidemiological evidence, may be used to infer causation. Epidemiology is the study and analysis of the distribution of patterns and determinants of health and disease conditions in a defined population—it examines associations between health risks and outcomes in a population. The Court of Appeal concluded that where there is (1) a proven breach of the standard of care in negligence; and (2) a proven injury, then “powerful” epidemiological evidence can be used to infer causation, even if it cannot be proven with scientific certainty.

## Background and Trial Decision

The treating physician and appellant, Dr. James, was an anesthesiologist who administered epidural injections into the area around his patients' spines as a pain relief treatment. Some of his patients developed meningitis, an acute inflammation of the protective tissue surrounding the spine typically caused by a bacterial or viral infection, or other serious infections, after receiving injections.

A class proceeding was commenced on behalf of a class of patients who developed signs or symptoms clinically compatible with bacterial meningitis, epidural abscess or cellulitis of a bacterial origin and/or bacteremia (collectively, the Injuries) after receiving an epidural injection administered by Dr. James.

The class was divided into subclasses, including (1) patients who were infected by a rare strain of CC59 *Staphylococcus aureus*



bacteria that genetically matched the bacteria that colonized Dr. James himself (the Genetically Linked Patients); and (2) the remaining patients, who suffered Injuries but could not scientifically prove that they were infected by the same rare CC59 strain that colonized Dr. James (the Remaining Patients).

Following a five-week common issues trial, the trial judge, Justice E.M. Morgan, found against the anesthesiologist on all the common issues: negligence (duty of care, standard of care and breach, and causation), fiduciary duty, limitation period and entitlement to punitive damages.

In the context of the negligence analysis, the trial judge made detailed factual findings about Dr. James' failure to take reasonable precautions to prevent the transmission of healthcare-associated infections, including failures to use aseptic techniques. The trial judge also found that Dr. James failed to report suspected infections linked to his practice. The trial judge accordingly found that there was a breach of the standard of care.

The causation aspect of the negligence analysis was hotly disputed at trial, with Dr. James submitting that "causation is a crucial hurdle on which the Class's claim falters".<sup>1</sup> For the Genetically Linked Patients, the trial judge had "no hesitation" in concluding that the Genetically Linked Patient's Injuries were caused by Dr. James, given the genetic match between the *Staphylococcus aureus* CC59 strain infecting the Genetically Linked Patients and colonizing Dr. James.<sup>2</sup>

The analysis regarding the Remaining Patients required an inference of causation, however, using what the trial judge referred to as the "risk ratio" approach discussed by Justice Lax in *Andersen v St. Jude Medical, Inc.*, 2012 ONSC 3660 [*Andersen*] and in other cases, including *Stanway v Wyeth Canada Inc.*, 2012 BCCA 260. In *Andersen*, Justice Lax found that a breach of the standard of care that more than doubled the risk of harm (i.e., a risk ratio of 2.0) presumptively established causation for the class, subject to proof to the contrary.<sup>3</sup>

In *Levac*, the epidemiological evidence at trial revealed that patients of Dr. James had either a 49 times or 69 times greater risk of developing a serious infection than pain clinic patients not exposed to Dr. James' substandard infection prevention and control (risk ratios of 49.0 and 69.0, respectively). The trial judge concluded that this evidence is "so overwhelming that it cannot be ignored",<sup>4</sup> and that a rebuttable presumption of causation was established.

## The Appeal Decision

The causation criterion was the central issue on appeal, with the appellant challenging the trial judge's use of statistical evidence to infer causation in negligence in respect of the Remaining Patients.

The Court of Appeal for Ontario upheld the trial judge's causation analysis on the basis that (1) there was "powerful" circumstantial evidence on which to conclude that a statistical association represented a causal link on a balance of probabilities; and (2) Dr. James had not put forward a viable, non-negligent explanation for the outbreak as a whole.

The Court of Appeal found no error in the judge's reliance on statistical evidence in drawing a class-wide rebuttable inference that Dr. James' substandard infection prevention and control caused the Remaining Patients' Injuries. It will be open to Dr. James to rebut the presumption in the subsequent individual issues phase of the proceeding.



## Takeaways and Analysis

The Court of Appeal's decision in *Levac* clarifies the circumstances in which epidemiological evidence may give rise to a rebuttable presumption of causation, and the role of epidemiological risk ratios in the analysis.

Epidemiological, statistical data has increasingly featured prominently in medical device and pharmaceutical class proceedings,<sup>5</sup> notwithstanding that Canadian courts, including the Supreme Court of Canada, have generally encouraged restraint in the use of statistical evidence to establish causation.<sup>6</sup>

There is currently no specifically-delineated risk ratio that gives rise to a rebuttable presumption of general causation. While several cases (including *Levac*) used the 2.0 risk ratio as a benchmark, in *Wise v Abbott Laboratories, Ltd.*, 2016 ONSC 7275, Justice Perell cited a 2015 decision of the British Columbia Court of Appeal in cautioning against equating legal degrees of proof with mathematical probabilities, noting that “there are no hard and fast rules for inferring causation in any case.”<sup>7</sup>

In *Levac*, the epidemiological evidence was largely undisputed, and in the trial judge's words “overwhelming.” Regardless of whether the 49.0 or 69.0 risk ratio applied, it was multiple times higher than the *Andersen* 2.0 risk ratio benchmark.

In this context, which included a finding of clear breach of the standard of care, manifested injury and the absence of any other plausible non-negligent causal alternatives, the Court of Appeal upheld the use of “powerful” statistical epidemiological evidence to rebuttably infer causation.

The role of epidemiological and other statistical evidence in drawing legal inferences of causation is a critical but sensitive area of the law which requires judicial diligence both in fact finding and legal analysis. The Court of Appeal's decision illustrates the importance of clear factual and legal safeguards around the use of such evidence and leaves open the question whether the relatively modest 2.0 risk ratio benchmark applied in *Andersen* could be appropriate in another case.

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<sup>1</sup> *Levac v James*, 2021 ONSC 5971, at para 113

<sup>2</sup> *Levac v James*, 2021 ONSC 5971, at para 126

<sup>3</sup> *Levac v James*, 2021 ONSC 5971, at para 134

<sup>4</sup> *Levac v James*, 2021 ONSC 5971, at para 139

<sup>5</sup> See, for example, *Wise v Abbott Laboratories, Ltd.*, 2016 ONSC 7275, *Price v H. Lundbeck A/S*, 2022 ONSC 7160

<sup>6</sup> *Andersen v St. Jude Medical, Inc.*, 2012 ONSC 3660, at paras 393-95; *Benhaim v St-Germain*, 2016 SCC 48, at paras 74–76

<sup>7</sup> *Wise v Abbott Laboratories, Ltd.*, 2016 ONSC 7275, para 353

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This update is not intended to provide legal advice, but to high-light matters of interest in this area of law. If you have questions or comments, please call one of the contacts listed.

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Posted on: April 20, 2023

## COPYRIGHT ISSUES IN THE ARTIFICIAL INTELLIGENCE ERA

By: Sze-Mei Yeung

With the increasing use and adoption of generative artificial intelligence (“AI”) technologies, copyright issues require careful consideration by the creators and users of these applications. The premise of sophisticated AI technologies is that they ingest and analyse (also known as “training” of the AI system) potentially immense quantities of pre-existing content and works to generate new works or content, which may include text, artistic works or other forms of output. Such new works can be AI-assisted, which incorporates some level of human contribution, or may be solely generated by an AI system, with no human contribution. The U.S. Copyright Office has indicated that providing text prompts (instructions from a human user) to AI systems is insufficient as a means of creative control by the user, to constitute human authorship and attract copyright protection in the United States<sup>[1]</sup>.

Various class action lawsuits have been initiated in various U.S. courts<sup>[2]</sup>, alleging, *inter alia*, copyright infringement due to the unauthorized use of copyrighted works (such as artwork, photos or source code) as training data in order to build and operate each AI platform, without the consent of, or any compensation to, the copyright holders of such copyrighted works. Prevalent use of AI technologies such as ChatGPT can also result in the inadvertent disclosure of confidential business information and trade secrets by individual users to these AI systems, as recently experienced by businesses. The nature of AI-powered systems raises some very interesting legal issues and risks to consider, such as:

- Can text and data mining, which is the backbone of AI technologies for training purposes, be performed without infringing copyrights in the original source materials?
- Do AI systems continue to store copies of copyrighted materials, during training and after the system is trained and commercialized?
- How can copyright rights-holders continue to license, enforce and monitor unauthorized use of their copyrighted works, with the increasing popularity of AI technologies?
- Even if AI-generated works may not necessarily infringe existing copyrights, do they directly compete with the market for the original copyrighted works and cause detrimental effects on such works and their copyright holders?

In 2021, the Government of Canada conducted a public consultation to consider the modernization of





Canada's copyright framework, considering potential ways to support innovation via AI and other emerging technologies, while continuing to respect rights holders of copyrighted works. To date, there have been no current proposed statutory amendments to the Copyright Act, R.S.C., 1985, c. C-42 (the "**Copyright Act**") dealing specifically with copyright ownership of AI-generated works, or creating any AI-specific statutory exceptions to copyright infringement.

On June 16, 2022, Bill C-27<sup>[3]</sup>, was introduced, which includes a proposed *Artificial Intelligence and Data Act* ("**AIDA**"). *AIDA* regulates persons within Canada that are responsible for the design, development or making available for use of, or manage the operation of, AI systems, by requiring the adoption of measures to anonymize data, assess harm to individuals, report actual or potential material harm and maintain business records. Under *AIDA*, an artificial intelligence system is defined as a "technological system that, autonomously or partly autonomously, processes data related to human activities through the use of a genetic algorithm, a neural network, machine learning or another technique in order to generate content or make decisions, recommendations or predictions."<sup>[4]</sup>

#### **Copyright Protection for AI-Generated Works**

On December 1, 2021, the Canadian Intellectual Property Office ("**CIPO**") accepted a copyright registration for a painting entitled "SURYAST" published in India, owned and co-authored by Ankit Sahni, where the co-author is an AI program called RAGHAV Artificial Intelligence Painting App. This is not a definitive or precedential position however, since CIPO does not typically examine copyright applications to the same extent as trademark applications that are examined by CIPO prior to registration, or in the same analytical manner as the U.S. Copyright Office, as discussed below. It is also unclear whether CIPO would accept a copyright registration that was created solely by AI, as opposed to being co-authored with a person.

The *Copyright Act* does not currently contemplate or show parliamentary intent for potential authorship by a machine, and the current legislation implies that an author needs to be a natural person. For example, copyright subsists in a work, in accordance with section 5 of the *Copyright Act*, where the author was, at the date of making of the work, a citizen or subject of, or ordinary resident in, a treaty country. The statutory term of copyright protection was recently expanded to endure for the lifetime of an author, plus 70 years following the end of the calendar year of death of the author. Given these inherently human elements of the legislation, it is unclear whether copyright protection would be afforded within Canada to works generated or contributed to by AI. There would also be challenges with determining who would be the first author (and/or copyright owner, as the case may be) of an AI-generated or AI-assisted work. In the case of an AI-assisted work, what level of human contribution would be required to qualify as joint authorship, and also to satisfy the "originality" requirement of copyright protection?







The U.S. Copyright Office released a policy statement<sup>[5]</sup> on March 16, 2023 to provide guidance for whether works containing material generated by AI would be eligible for copyright protection. The U.S. Copyright Office denied an application for a visual work created solely by AI, on the basis that the work lacked the traditional human authorship necessary to support a successful copyright claim, and was made “without any creative contribution from a human actor”. This decision is currently being challenged by Stephen Thaler, who has filed various lawsuits in the U.S., U.K.<sup>[6]</sup> and around the world to dispute his entitlement to receive intellectual property protection for various works and inventions generated by DABUS, an AI neural system developed by Thaler.

With regard to AI-assisted works, the U.S. Copyright Office determined that a graphic novel that included AI-generated images could receive copyright protection, but only to the extent of the human-authored portions, i.e. the original text and the compilation of the end product. The Office refused copyright protection for the images since they were solely generated by AI, and has clearly stated that “authors” exclude non-humans. The Office also indicated that if an AI-assisted work was the subject of a copyright application, non-copyrightable components (created solely by AI) should be disclaimed, and there is a duty on applicant to disclose AI-generated materials and provide details about human contribution to works that are the subject of any copyright application. Concurrently with the publication of its policy statement, the U.S. Copyright Office also launched a new AI public consultation initiative to further examine copyright law and policy issues raised by AI, including the use of copyrighted materials in AI training.

### **Conclusion**

Without further legislative changes or judicial consideration, copyright ownership over AI-generated works still remains unclear in Canada. Though consideration and monitoring of other jurisdictions provides useful insight, businesses need to be aware of the differences in copyright laws across jurisdictions. HathiTrust and Google, Inc. were successful in the U.S. courts<sup>[7]</sup> against the Authors Guild with regard to their respective use and digitization of books, and online display of excerpts from such books, complying with fair use under U.S. copyright laws. However, the U.S. fair use doctrine is generally broader than the existing fair dealing exception from copyright infringement under Canadian copyright laws.

As the demand for AI technologies increases, businesses that harness AI systems can mitigate their intellectual property infringement risks by AI training via text and data mining licenses that only use authorized databases of content, and conducting internal audit(s) to consider whether their evolving AI business processes and AI-generated works infringe third party intellectual property rights. Canadian businesses will also need to comply with applicable regulatory obligations under *AIDA*, if such legislation is





enacted. Use of any open source software or tools within AI systems should also be subject to compliance with their respective license terms and conditions, such as proper attribution where contractually required.

Copyright holders will need to be more proactive in monitoring the Internet for potential infringement of their copyrighted works. If your business is licensing use of an AI-powered technology, seek legal advice to ensure that your agreements with AI technology providers contain fulsome representations and warranties that include all legal rights to use any training data or other source materials, and strong indemnification to protect against potential third party intellectual property infringement claims.

To learn more, contact the author of this article, Sze-Mei Yeung, at [syeung@rbs.ca](mailto:syeung@rbs.ca).

<sup>[1]</sup> U.S. Copyright Office, Statement of Policy, “Works Containing Material Generated by Artificial Intelligence” (March 16, 2023)

<sup>[2]</sup> *Anderson et al. v. Stability AI Ltd., Stability AI Inc., Midjourney Inc. and Deviantart, Inc.*, No. 23-cv-00201 (N.D. Cal.), *Getty Images (US) Inc. v. Stability AI Inc., No. 23-cv-135* (D. Del.) and *DOE 1 et al v. GitHub Inc. et al*, No. 3:22-cv-06823 (N.D. Cal.)

<sup>[3]</sup> <https://www.parl.ca/legisinfo/en/bill/44-1/c-27>

<sup>[4]</sup> <https://www.parl.ca/legisinfo/en/bill/44-1/c-27>, Section 2 (Definitions)

<sup>[5]</sup> U.S. Copyright Office, Statement of Policy, “Works Containing Material Generated by Artificial Intelligence” (March 26, 2023)

<sup>[6]</sup> <https://www.bailii.org/ew/cases/EWHC/Patents/2020/2412.html>, *Stephen Thaler v. Shira Perlmutter, in her official capacity as Register of Copyrights and Director of the United States Copyright Office; and The United States Copyright Office*, No. 1:22-cv-01564 (Washington D.C.)

<sup>[7]</sup> *Authors Guild, Inc. v. Google, Inc.*, 804 F.3d 202 (2d Cir. 2015) and *Authors Guild, Inc. v. HathiTrust*, 755 F.3d 87 (2d Cir. 2014)





## News Alerts

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# Illegal commerce: Court of Appeal of Santiago orders the Municipality of Santiago to take action

On March 3, 2023, the Court of Appeal of Santiago [granted a constitutional petition for protection](#) (“*recurso de protección*”) filed by a bookstore chain against the Municipality of Santiago for not adopting adequate and effective measures to prevent the installation of street vending in Ahumada Street. This judgment is an important step in the fight against unregulated street vending and the negative consequences it causes, among others, the sale of counterfeit products that infringe the industrial property rights of trademark owners.

The claimant argued that the failure of the Municipality of Santiago to adopt specific measures that contribute to the eradication of street vending corresponds to an illegal omission that affects its constitutional guarantees. The claimant's main argument is that the street vending that has been set up on Ahumada street obstructs the visibility of its commercial premises and hinders easy access to it, as well as constituting acts of unfair competition that the defendant allows by not exercising its legal oversight powers in this matter.

The Second Chamber of the Court of Appeal of Santiago, composed of the judges Héctor Plaza Vásquez and Jessica González

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Troncoso, and the member-attorney Óscar Torres Zagal, in a split decision, granted the petition for protection filed by the claimant. The Court found that illegal street vending affects the right to "develop any economic activity," as enshrined in article 19 N° 21 of the Political Constitution of the Republic, as such vending hinders free access to the claimant's commercial premises and obstructs its visibility, thereby affecting the aforementioned constitutional guarantee. The Court further recognized that the disturbance cannot be exclusively attributed to an action or omission of the Municipality of Santiago, making it appropriate to evaluate this phenomenon from a multisystemic perspective.

According to our point of view, the Court's ruling calls for institutions such as Customs, the Internal Revenue Service, the police, the Governorship, the Intendancy, the Regional Ministry of Health, and affected private entities to work together to eradicate illegal commerce.

Considering the above, the Court of Appeal of Santiago ordered the creation of a working group with the various entities involved in the prevention and combat of illegal commerce in the area (Ministry of the Interior and Public Security, National Service for the Prevention and Rehabilitation of Drug and Alcohol Consumption, and other relevant entities) with the purpose of coordinating actions to suppress informal commercial activities that take place on the aforementioned street in the commune of Santiago.

Furthermore, the Court of Appeal of Santiago established a deadline of forty-five days from the date the judgment became final for the Municipality of Santiago to provide a detailed report on the agreements reached by the working group and the specific measures adopted to guarantee and protect the constitutional rights of the claimant.

This ruling consolidates efforts to combat illicit trade and counterfeiting. The decision issued by the Court of Appeal of Santiago is directly related to the entry into force of Law No. 21,426 on Illegal Trade of the Ministry of the Interior and Public Security, which strengthens the investigative and oversight powers of various authorities in this area, such as municipalities. In this regard, among

other things, the Law on Illegal Trade gave municipal inspectors powers to oversee street vendors, authorizing them to require those engaged in such trade to display the corresponding municipal or sanitary permits, as well as documents proving the origin of the products being sold. Additionally, it expressly regulated the duty of municipalities to establish in their respective regulations the places where street vending may be exercised.

***AUTHORS: Francisco Carey, Jorge Gatica, Carolina Baeza.***

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# Legal Commentary

May 11, 2023

## Highlights of the Draft Measures for the Administration of Generative Artificial Intelligence Services

Author: Kevin DUAN | Kemeng CAI | Yi ZOU<sup>1</sup>

Generative AI has become a worldwide sensation recently with the launch of ChatGPT, Stable Diffusion, Midjourney, and other eye-catching products. Large language models such as ChatGPT have shown their phenomenal capacity for human language comprehension, human-machine interaction, text writing, programming, reasoning, etc. by generating output that is often on a par with the level of human intelligence, if not better. Despite this, however, the use of generative AI has raised concerns about privacy violations, trade secrets leakage, misinformation, information cocoons, cybercrimes, and other potential risks, which has aroused global attention and regulatory responses in different countries and regions. For instance, Garante, Italy's data privacy watchdog, has imposed a nationwide ban on using ChatGPT due to privacy violation concerns. Following this trend, on April 11, 2023, the Cyberspace Administration of China ("CAC") issued an exposure draft of the *Measures for the Administration of Generative Artificial Intelligence Services* (the "**Draft Measures**"), which is open for public comments until May 10, 2023. The Draft Measures, consisting of 21 articles, begin by clarifying its administrative objectives of facilitating healthy development and regulated application of generative artificial intelligence services, leaving space for further policies to regulate the development and use of generative AI. In this commentary, we summarize and comment on key aspects covered by the Draft Measures, the challenges they may pose in practice, and our suggestions to address those challenges.

### Scope of application: services to "the public in the territory of the [PRC]"

The scope of application of the Draft Measures is presented in Article 2, which is: "the research, development, and utilization of generative AI products to provide services to the public in the territory of the [PRC]". For the purpose of the Draft Measures, "generative AI" refers to "technologies that build on algorithms, models, and rules and are used for producing texts, images, audio, videos, codes, and other forms of content". Therefore, the Draft Measures, once adopted, will apply to popular generative AI products such as ChatGPT, Google Bard, Stable Diffusion, and Midjourney, as well as large language models rolled out by Chinese tech giants. A question invited by this provision is how to understand the

<sup>1</sup> Han Kun intern Yuxin XIANG also contributed to this legal commentary.

part of “providing services to the public in the territory of the [PRC]”. In our opinion, considering the meaning of the provision *per se* and the overall legislative purpose, the Draft Measures should apply to all providers that offer generative AI services to customers in China, regardless of whether the providers themselves are located in or outside China, and regardless of whether they provide services directly to end users or indirectly by linking to services from other carriers.

## AIGC regulation

The Draft Measures also emphasize the regulation of AI-generated content (“**AIGC**”) and ideological security, with a focus on the following aspects.

- **Service providers are responsible for AIGC security.** The Draft Measures stress that organizations and individuals (i.e., service providers) bear responsibility as the AIGC producer where they offer chat services and text, **image**, or audio generation or similar services by using generative AI products. In reality, however, a user may nonetheless find a means to create illegal or harmful content by using generative AI services. As such, it is debatable whether it is fair to hold a service provider responsible for AIGC outputs in all instances.
- **Generated content should be truthful and accurate.** Controversy has arisen regarding the requirement in the Draft Measures that “the content created by generative AI must be truthful and accurate, and measures shall be taken to prevent the generation of false information”. At present, it seems unavoidable that, sometimes, large language models such as ChatGPT deliver “confident nonsense”, a phenomenon known as an AI hallucination, which may derive from technological limitations such as divergences in the source content and errors in decoding by the transformer. Therefore, an overemphasis on the truthfulness and accuracy of generated content may impose onerous duties on service providers.
- **Measures to curb violative content.** Article 15 would require service providers to counteract generated content that is found to violate the Measures by means such as content screening, as well as retraining of the AI generator model for optimization within three months to prevent reproduction of such content. However, in practice, there might be hurdles to implement this provision given the existing technological bottlenecks which make it difficult to identify the origin of the violative content and to retrain the model in question to prevent such violative content.

In addition to model optimization, the Draft Measures impose more conventional, *ex post* obligations on service providers to curb violative content, which include: (1) taking measures to stop the generation of any text, image, audio, video or other content that, to their awareness or knowledge, has infringed upon others’ portrait rights, reputation rights, personal privacy, trade secrets, or that has violated any requirement of the Measures, as a way to discontinue the harm caused thereby; (2) suspending or terminating services to users who they find have violated relevant laws and regulations, business ethics or social morals in the course of using their generative AI products, namely users who have committed acts such as social media hyping, malicious posting and commenting, spam creation, malware programming, and improper business marketing.



- **Labelling requirements.** Article 16 of the Draft Measures would require service providers to label generated images, videos, and other content in accordance with the *Provisions on Administration of Deep Synthesis of Internet-based Information Services* (“**Deep Synthesis Provisions**”), though the Draft Measures would not expressly require the labelling of AI generated texts, as is prescribed in the Deep Synthesis Provisions.

## Training data compliance

The quality of training data is essential to ensure the accuracy and integrity of AIGC and to avoid AI discrimination and bias. Given that, the Draft Measures would hold service providers responsible to ensure that the data used to pre-train and retrain their generative AI models are obtained from legitimate sources, and impose detailed requirements for training data compliance in the following aspects.

- **Personal information protection.** According to the Draft Measures, where personal information is used for pre-training or retraining a generative AI model, service providers must obtain the consent of the personal information owner, or, under other circumstances, comply with requirements of applicable laws and administrative regulations. Specifically, pursuant to the Draft Measures, service providers must obtain consent from users for using their personal information to pre-train or retrain the relevant generative AI models, or, in any other circumstance, they must comply with requirements as prescribed in applicable laws and administrative regulations. In addition, service providers are prohibited from illegally retaining input data which can be used to infer users’ identities. Service providers are also banned from profiling based on users’ inputs and their use of the services, nor may they provide users’ inputs to any other party.
- **No infringement of intellectual property.** The Draft Measures would require that the data used for AI training must not contain any content that infringes upon intellectual property rights. This requirement may cause disagreements in practice. Training data used for developing and improving generative AI models are usually scraped from open sources on the internet, which inevitably involve many copyrighted works. It is currently a highly controversial issue worldwide as to whether the use of copyrighted works for algorithm training infringes the right of the copyright owner or whether it falls within the ‘fair use’ exception. Some argue that restricting the use of copyrighted works for AI training may significantly compromise the quality and diversity of training data. Therefore, striking a balance between the interests of the copyright owner and the service provider remains a question to be discussed at both theoretical and policy levels.
- **Training data must be truthful, accurate, objective, and diverse.** This requirement in the Draft Measures would also pose great challenges for service providers when selecting AI training data.

## Improvement of existing rules on recommendation algorithm-based services and deep synthesis services

The Deep Synthesis Provisions define “deep synthesis technology” as that which “employs deep learning, virtual reality, and other synthetic algorithms to produce text, images, audio, videos, virtual scenes, and other online information”, including but not limited to technologies used for text generation, text-to-speech

conversion, music creation, face generation, image generation, as well as 3D reconstruction, digital simulation and other technologies that create or edit 3D characters and virtual scenes. The *Provisions on the Administration of Algorithm-generated Recommendations for Internet Information Services* (“**Recommendation Algorithm Provisions**”) also expressly include “generative and synthetic” algorithms into its scope of application. This means that generative AI, which by definition constitutes both a “deep synthesis technology” and a “recommendation algorithm-based service”, also falls under the umbrella of the aforesaid AI regulations concerning deep synthesis technologies and recommendation algorithm-based services. Given that, the Draft Measures would incorporate and improve upon these existing rules in the following aspects.

- **Ethics and fairness of algorithm-based services.** The Draft Measures reiterate and would refine the Recommendation Algorithm Provisions and other rules that are in place to promote algorithm ethics and fairness and avoid algorithm-related discrimination. The Draft Measures stress that providers of generative AI products and services should “take measures to prevent discrimination on the basis of race, ethnicity, belief, nationality, region, gender, age, occupation, etc. in the process of algorithm design, training data selection, model generation and optimization, and service provision”, should “respect intellectual property rights and business ethics and not engage in unfair competition by using advantages such as algorithms, data, and platforms”, and should not “generate discriminatory content based on the race, nationality, gender, etc. of their users”.
- **Security assessment and registration for algorithm-based services.** Article 6 of the Draft Measures stipulates that, prior to the provision of services to the public by using generative AI products, service providers must conduct and report on security assessment to the competent cyberspace administration in accordance with the *Provisions on the Security Assessment for Internet-based Information Services with Public Opinion Attributes and Social Mobilization Capability*, and shall complete procedures for registration, change of registered particulars, and deregistration (as applicable) of services by following the Recommendation Algorithm Provisions. Based on the above provision, all generative AI products would be deemed as information services “with public opinion attributes and social mobilization capacity”, and thus be subject to security assessment and registration requirements under the applicable laws.
- **Transparency of algorithms.** According to the Draft Measures, service providers must, as required by the CAC and relevant competent authorities, provide necessary information that may affect users’ trust in and choice of the relevant services, including description of the source, scale, type and quality, etc. of pre-training and retraining data, rules for manual labelling, the scale and type of manually labelled data, basic algorithms, and technical systems, among others.
- **Disclosure requirements and measures to prevent addiction.** Article 10 of the Draft Measures would require service providers to specify and disclose the intended users, occasions, and purpose of their services and to take proper measures to prevent users from over-relying on and becoming addicted to generated content. This provision, placed in tandem with Article 8 of the Recommendation Algorithm Provisions which prohibits service providers from “setting up algorithms to induce users toward addiction or excessive consumption”, requires service providers

to ensure proper use of relevant products on various fronts from public disclosure to algorithm management.

### **Conclusion: impact and outlook**

According to Article 20 of the Draft Measures, violations of the Measures may be punished pursuant to the *Cybersecurity Law of the PRC*, *Data Security Law of the PRC*, *Personal Information Protection Law of the PRC*, and other applicable laws and regulations. Where a violation is not covered by the abovementioned laws and regulations, the service provider concerned may be given a warning, subject to public criticism, or be ordered to make rectification within a time limit; the service provider may even be ordered to suspend or terminate its use of generative AI for service provision and be subject to a fine of up to RMB 100,000. Behaviors in violation of administrative rules for public security will be subject to punishment in accordance with law, and behaviors that constitute criminal offences will be subject to criminal liability.

On the whole, by issuing the Draft Measures, Chinese regulators have directly responded to new issues posed by the recent generative AI breakthroughs under the current regulatory framework, which also conveys China's overarching AI regulatory principle of providing guidance and rules for the purpose of promoting growth of the industry. Nevertheless, the Draft Measures would impose some compliance requirements that seem to be difficult to implement in practice given current technological bottlenecks. Therefore, companies should consider responding with creative solutions by wisely integrating technology and law, so as to help assuage regulators' security concerns and create more policy space for further development of the generative AI industry.

***Important Announcement***

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## Colombian DPA launches inquiry into OpenAI's ChatGPT

15 May, 2023

Following the announcement made last week by the Ibero-American Data Protection Network (RIPD), the Colombian DPA has launched an inquiry into OpenAI's ChatGPT compliance with Colombian data protection laws. This inquiry seeks to establish if the collection and processing of personal data of Colombian residents via ChatGPT complies with Law 1581 of 2012, and further conforms to standards under the so-called Accountability Principle (Principio de Responsabilidad Demostrada).

In a public statement the Colombian DPA announced that its inquiry is part of a broader, coordinated effort endorsed by the RIPD, a coalition of 12 countries (Portugal, Uruguay, Brazil, Peru, Panama, Costa Rica, Colombia, Chile, Argentina, Spain, Andorra, and Mexico), and of 16 local data protection authorities, which have set out to monitor and oversee ChatGPT, to protect and ensure personal data and data privacy rights.

While the investigation is ongoing, the Colombian DPA has advised users of ChatGPT to review the applicable privacy policy, to carefully consider the appropriateness of providing personal data, and to exercise caution with responses provided by ChatGPT.

The Colombian DPA has a history of actively enforcing compliance with Colombian data protection laws, and this new inquiry follows a trend involving global tech companies against which the Colombian DPA has asserted jurisdiction.

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## COSTA RICA

### RENEWAL OF CHEMICAL PRODUCTS REGULATION

May/2023

The Central American Technical Regulation "RTCR 478:2015 Chemical Products. Hazardous Chemical Products, Registration, Importation and Control" Decree No. 40705-S, entered into force on May 03, 2018, abrogating the "Regulation for the Registration of Chemical Products" Decree No. 28113-S. This approved regulation established new hazard classification criteria for chemicals based on the Globally Harmonized System of Classification, which obliges holders of chemicals registered with the Ministry of Health prior to 2018 to apply for a new sanitary registration.

Decree 40705-S included a transitional provision which obliges holders of raw materials or chemicals registered or notified before the Ministry of Health to apply for renewal no later than May 3, 2023, five years after the entry into force of the decree, completing the requirements established by this same regulation in numeral 7.2.

If you would like more information about the decree and its application, please do not hesitate to contact us.

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# IA and IP: the impossible reconciliation?

20 April 2023

The success of Chat GPT since its launch on 30 November 2022 has put generative Artificial Intelligence (AI) in the spotlight. These AIs can autonomously generate content: text for Chatgpt, images for Dall- E or Midjourney. Human intervention is limited to giving instructions to the AIs.

The legal status of this content and its protection under a copyright or patent law is under debate. Moreover, the functioning of these AIs is based on a learning process, called "machine learning" or "deep learning", which requires the analysis of existing data which are themselves potentially protected. This raises the question of the infringement of third party rights by AIs.

## Can an AI be a creator or inventor?

Under French law, to be original, and therefore protectable by "droits d'auteur", a work must bear the stamp of its author's personality.

The Court of Justice of the European Union (CJEU) also has a subjective definition of originality, an original work being "*the expression of the author's own intellectual creation*" (16 July 2009, C-5/08). The Court stated in Painer that a work must "*reflect the personality of its author, manifesting the latter's free and creative choices*" (1er December 2011, -C145/10). This is not the case '*where the realisation of an object has been determined by technical considerations, rules or other constraints*' (Football Dataco and Others, 1er March 2012, -C604/10).

Since Rousseau, we know that, philosophically, "*Freedom consists less in doing one's own will than in not being subject to the will of others*". It is this freedom of the author that is enshrined in law.

Yet, an AI produces a result according to the instructions it receives and the data it has analysed.



This result, conditioned by its programming, is therefore not free and cannot express its personality, which an IA is moreover by nature devoid of. The subjective definition of originality therefore excludes an AI from being the author of a copyrightable work.

However, there is a temptation to ignore this subjective definition and consider only the result obtained by AI. AI-generated "works" can be as beautiful or even more aesthetically beautiful than works created by a human artist. For example, in February 2023, an AI-generated image won a photography competition in Australia, deceiving all the participants and the professional jury. The company responsible for this deception claimed that the machine was "*now the superior artist to man*". Why shouldn't these "works", whose aesthetic value is recognised, be entitled to protection?

There are at least two objections to this reasoning.

First of all, pursuant to "droit d'auteur" law the merit of the work is not a criterion. An object may be beautiful and yet not be protected, and vice versa. The CJEU thus recalled in the Cofemel case that "*the fact that a model generates an aesthetic effect does not, in itself, make it possible to determine whether that model constitutes an intellectual creation reflecting the freedom of choice and the personality of its author, and thus satisfying the requirement of originality*" (Cofemel, 12 September 2019, C-683/17).

Moreover, recognising AI-generated content as a protectable work would imply a profound change in the objective of "droit d'auteur": to encourage creation by ensuring an income for authors. However, an AI does not need to be encouraged to generate content, nor does it need an income. Copyright would then be used to reward the investments of AI companies or AI users.

The European courts that will be called upon to rule on this issue will probably be influenced by American precedents. The US Copyright Office has twice refused to protect an image generated by an AI. In the first case, Dr Thaler sought to register in 2016 an image created "*autonomously by a computer algorithm*", an AI named DABUS. The Copyright Office refused on the grounds that "*the requirement of a human author is a long-standing requirement of copyright law*". An appeal is pending. More recently, on 21 February 2023, the Copyright Office partially revoked the copyright protection of a graphic novel "Zarya of the Dawn". While the text was written by an individual author, the images were generated by the AI Midjourney.

Patent law does not seem to offer more prospects for protection even though AIs can also be used to solve technical problems, i.e. to develop inventions.

Although apparently more objective than copyright, patent law is nevertheless built around the postulate that an invention is the result of the work of an individual inventor.

Thus, in the United States, only natural persons may file a patent, to the exclusion of legal persons who may only be assignees.

Dr. Thaler, who was already behind the first decision of the US Copyright Office, filed applications before several patent offices naming the AI Dabus as the inventor. The US, UK, Taiwanese have rejected these applications. In Australia and South Africa, however, the fact that an AI is an inventor has been accepted.

The European Patent Offices (EPO) has refused to grant these patents but only on the grounds that the inventor, within the meaning of the European Patent Convention, must be a person with legal capacity, which is not the case for an AI. Conferring legal personality on the AI, as suggested by a

resolution of the European Parliament on 16 February 2017, would therefore a priori overcome this difficulty, as the EPO does not require the inventor to be a natural person.

Such a development could lead to significant collateral legal damage, in particular with regard to the assessment of the criterion of inventive step currently based on the obviousness of the claimed solution from the point of view of the person skilled in the art. Indeed, if an AI can be an inventor, why can't it also be a "person skilled in the art"? The average skills of this "artificial person skilled in the art" could be so enhanced that access to patent protection would necessarily be more difficult, which would risk penalising research and innovative companies.

## Is AI an infringer by nature?

AI is based on a learning process that requires the analysis of a great deal of pre-existing data. AIs thus access content available on the Internet most often by means of the "web scraping" technique. This technique enables content to be extracted from websites automatically so that it can be reused in another context. However, this content may be protected by copyright or the sui generis right of database producers.

If the content subsequently generated by AI reproduces in whole or in part a content protected by copyright/"droits d'auteur", the infringement will be characterised in application of the classic rules of copyright/"droits d'auteur".

However, the question of whether there is an infringement by virtue of the mere fact of accessing and reproducing protected images to train AIs, in particular by web scraping, is a matter of debate.

In the United States, several infringement actions have been brought on this basis against companies specialising in AI, notably Midjourney. Getty, the famous online image database, took action in the United States, and in the United Kingdom before the High Court of Justice in London against Stability AI, which markets the AI Stable Diffusion, which also generates images.

In Europe, Directive (EU) 2019/790 of 17 April 2019 provides a framework for the practice of web scraping by authorising text and data mining, including for commercial purposes, provided that the rights holder has not expressed his refusal (opt-out). This directive has been transposed in France, in particular by adding Article L.122-5-3 of the Intellectual Property Code. The opt-out may be materialised by machine-readable processes (in particular metadata) or by a mention in the general terms of use of a website or service.

While most online content sharing platforms have put in place such opt-out, this constraint is cumbersome and complex for authors who share their works on their own platforms. In addition, there is the issue of remuneration for authors whose works have already been used by AIs without their consent before the opt-out measures were put in place.

Ethical AI that respects the intellectual property rights of authors has yet to be imagined. Several companies, notably Adobe, seem to have embarked on this path. They have announced that they are setting up AIs trained exclusively on royalty-free images or images for which they have acquired the rights. Shutterstock, which markets the Dall-e image-generating AI, has also indicated that it is creating a fund to pay creators whose photos are used to train it.

The debates on the draft European regulation on artificial intelligence could be an opportunity to clarify the legal status of content created by AI and, above all, as called for by the League of Professional Authors and many creators, particularly illustrators, to provide a stricter framework for the practice of web scraping.

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## 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."**

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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](#)).

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### 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 *Lamos* 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".

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### 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 EJs 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 EJs 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.

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## 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 EJC's in bankruptcy proceedings, much time and effort can be saved by issuing proceedings in line with the parties' agreement, especially where it concerns forum.

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## Unconventional trademark - Sound mark

By [Aparna Venkat](#)

February 2023

A trademark is a brand or logo that represents one's business. In simple words, it is an identity. The conventional and traditional trademarks such as plain words, devices, logos, designs, labels and packages have been used since long for distinguishing goods and services. Over time, other elements besides words, logos, colour combinations and graphic designs have come to serve as identifiers of the source of goods/services, thus serving the function of trademarks. The concept of trademark function can be examined based on the rudimentary essentials a mark needs to satisfy such as being inherently distinctive, indicating commercial origin of products/ services, creating a nexus serving as a source identifier thereby holding an exclusive identity.

Unconventional marks go beyond the traditional trademarks in nature, characteristics, scope and economic potentials. The following are the main categories of non-traditional trademarks that can be registered.

- i. Sound/aural marks/audio signature,
- ii. Smell/scent/olfactory marks,
- iii. Tactile/touch/texture/haptic marks,
- iv. Single colour marks,
- v. Shape marks/three dimensional/3D marks,
- vi. Taste/gustatory marks,
- vii. Holograms; and
- viii. Moving images/motion/animated marks.

Each kind of unconventional trademark presents challenges in terms of meeting one of the basic criteria of a trademark i.e., 'a mark must be capable of being represented graphically'. Over the course of time, measures are undertaken in such a manner either to accommodate the requirement or amend the procedures to make way for the new emerging trends.

### Sound Mark

This write up will focus on the registrability of a Sound Mark under the Trade Marks Act, 1999. (Act). The definition of the term "mark" and "trademark" under Sections 2(1)(m) and 2(1)(zg) respectively is inclusive and not exhaustive of accommodating registration of a sound mark within the existing framework of the Act. Sound/ Music is one of the best channels to be employed for marketing a product/ service, as it

is etched in the minds of the public more rapidly than any other type of a source identifier. It acts as an audio signature.

The whole idea is to recognize and protect varied untapped potential elements in the market that serves as the origin of a source and links the public to a commercial business, sound mark being one of them. The art of launching products into the market by organizations along with a song, jingle, tune, chimes, etc., has been in practice for the longest time and subconsciously it seeks indefinite refuge in our head making it memorable and immortal which provides an edge to the organization, thereby providing exclusivity. Also, there exists a persuasive ability to embed messages in the minds of the consumers.

### **Procedure to file a Sound Mark**

There was no mention of registering a sound mark under the Trade Marks Rules, 2002 (Rules), yet few proprietors registered their sound mark. On August 18, 2008, a sound mark registration was granted to Sunnyvale, California-based Internet firm Yahoo Inc.'s three-note Yahoo yodel by the Delhi branch of the Trademark Registry. It was registered in classes 35, 38 and 42 for a series of goods including email, advertising and business services and managing websites.

Post the amendment of the Rules in 2017, Rule 26(5) provides provisions to file and register a sound as a trademark. Requirements for filing:

- a. Submit recording in MP3 format not exceeding 30 seconds,
- b. Clearly audible and capable of replaying, and
- c. Graphical representation of its musical notations.

The procedure to assess the registrability of a sound mark thereafter is same as that of any other mark filed before the Office of the Trade Marks Registry relating to preliminary objections, examination reports, evidentiary documents, acceptance and advertising a mark, opposition and registration.

Few other registered sound marks are, Tarzans yell (TM# 1748778 [2015]), National Stock Exchange (theme song) ( TM# 2152244 [2016]), ICICI Bank (Corporate jingle) (TM# 1807772 [2018]), Britannia Industries (four note bell sound) (TM# 1904243 [2011]), Eicher Motors (TM# 3044834 [2017]), Reliance Industries, (TM# 3838573 [2018]) Tata Coffee ( TM# 4211214 [2021]), Netflix (TM# 5236448 [2023]), etc.

### **Copyright and Sound mark overlap**

As per Rule 26(5) of the Rules, only a 30 second segment of a musical work is subjected to sound mark protection under the Act. The remaining music will continue to be protected under the Copyright Act, 1957. Also, Section 11(3)(b) of the Act prohibits registration of a trademark if its use in India is prevented by the law of copyright. While this being so, the circumstances surrounding each sound mark application will determine the proper course of action with respect to adducing relevant documents of evidentiary value, that includes no objection certificate, agreements between parties with respect to transfer of rights or any other form of arrangements, to ensure proper and clean title to the sound mark.



## Conclusion

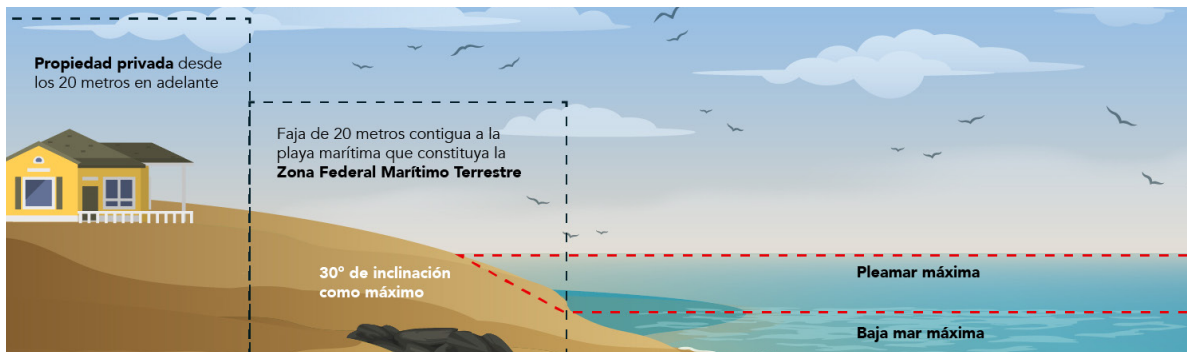
The amendment of the Rules in 2017 has streamlined the process of registering a sound mark by making it fairly simple. Like any other subject matter, over a period of time, many nuances will unfold and as the unconventional nature of the mark itself, the measures to tackle them will likely differ from the conventional manner of adjudging and enforcing the rights vested in such marks.

-§-

**The Federal Maritime Terrestrial Zone (ZOFEMAT, for its acronym in Spanish) is relevant for specific projects since it is usually the main attraction of some hotels and real estate developments in coastal areas, given that it is linked to what is commonly known as the beach.**

The ZOFEMAT is the portion of land contiguous to the sea, established by the Ministry of Environment and Natural Resources (SEMARNAT, for its acronym in Spanish), with a width of 20 meters from its upper and highest level without extraordinary circumstances (this level is known as pleamar). This portion of the land shall be accessible and with a slope of no more than 30°. In this regard, where the ZOFEMAT ends, private property can be found.

An example of the abovementioned is shown below:



Source: [SEMARNAT](#)

Notwithstanding, anyone with a concession title issued by SEMARNAT may access and use the ZOFEMAT if the intention is to offer some particular touristic facilities, such as swimming pools, beach club, or lounge chairs, among others.

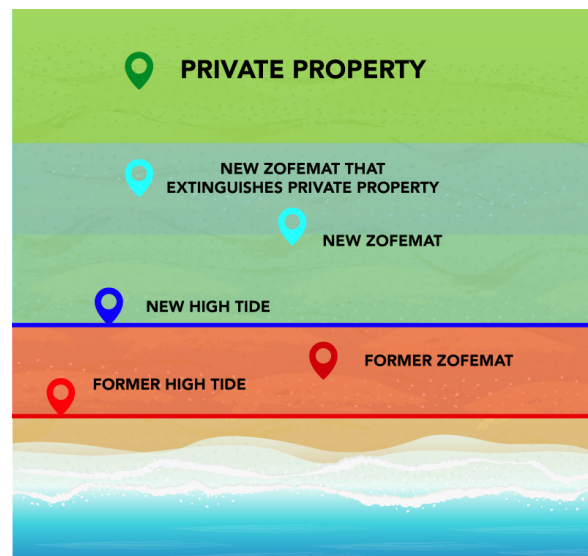
Please note that obtaining said concession title and complying with the terms and conditions set forth therein might be a complicated task to carry out. However, based on our experience in this matter, we offer the following recommendations:

### 1. THE ZOFEMAT'S LIMIT CHANGES ACCORDING TO THE LEVEL OF THE HIGH TIDE.

The maximum sea level is not permanent, so the delimitation of the ZOFEMAT will depend on the delimitation made by SEMARNAT based on the high tide.

In this regard, if the high tide enters the land, SEMARNAT will establish a new delimitation of the ZOFEMAT inland. However, if the new delimited strip overlaps the property of third parties, these lands and their buildings will cease to be private property and will become part of ZOFEMAT, leaving the prior owners without the right to compensation.

For a better exemplification, the following map is shown:





Derived from the abovementioned, we recommend that properties neighboring the ZOFEMAT are aware of the delimitations that may be established by SEMARNAT regarding the high tide, especially if they have built any construction directly in or near the ZOFEMAT.

In the event that ZOFEMAT's limit overlaps with private property, we suggest requesting SEMARNAT for the studies that led it to establish the new delimitation. In case of any inaccuracy and/or miscalculation found therein, legal action may be initiated, requesting the authority to recognize the validity of the previous limit.

### **2. ONLY ONE CONCESSION TITLE MAY BE ISSUED FOR EACH ZOFEMAT STRIP.**

This is one of the most common reasons that SEMARNAT can not grant a concession title since some concession applications have partial or total overlaps with previous concession titles.

### **3. TO OBTAIN THE CONCESSION TITLE FOR THIS STRIP, IT IS NOT NECESSARY TO BE THE OWNER OF THE PROPERTY NEIGHBORING THE ZOFEMAT.**

Anyone may request a concession title for a ZOFEMAT strip and carry out any economic activity in this area, for example, the provision of tourism services.

### **4. THERE ARE NO PRIVATE BEACHES. THE HOLDER OF A CONCESSION TITLE IS ONLY ENTITLED TO CARRY OUT CERTAIN ECONOMIC ACTIVITIES IN THE ZOFEMAT.**

Furthermore, the property built and/or located in this area may only be used by those authorized by the concession holder, such as bedding areas or tourist facilities. However, prohibiting the access or use of the ZOFEMAT to people not involved in tourism development could lead to SEMARNAT's revoking the concession title and the imposition of fines.

### **5. CARRYING OUT AN ECONOMIC ACTIVITY IN THE ZOFEMAT ENTAILS THE OBLIGATION TO OBTAIN A CONCESSION TITLE AND PAY FEES.**

Therefore, compliance with these payments is important since failing to fulfill this obligation could lead to fines, updates, and surcharges.

### **6. IT IS ESSENTIAL TO ENSURE THAT THE USE OF THE ZOFEMAT SPECIFIED IN THE CONCESSION TITLE IS FOLLOWED.**

The applicable environmental regulations establish three possible uses for this area: (i) protection or ornamentation, which is recommended for environmental preservation activities, therefore an area where economic activities cannot be carried out; (ii) some productive activities, such as fishing and agriculture, among others; and (iii) general use, which allows the development of all economic activities, including the construction of some projects.

The payment of fees corresponds to the type of use for which the ZOFEMAT is intended. Accordingly, duties in the protection and ornamental area can be up to MXN\$ 45.57 per square meter, while for general use, they can be up to MXN\$ 163.31 per square meter of ZOFEMAT.

### **7. IF THE ZOFEMAT IS USED WITHOUT A CONCESSION TITLE OR WITH AN EXPIRED CONCESSION TITLE, ADMINISTRATIVE, FISCAL, AND CRIMINAL LIABILITIES COULD BE GENERATED.**

In this regard, we recommend paying attention to the delimitations of the high tide and the ZOFEMAT established by SEMARNAT and the term of the concession title, which may be extended if it is about to expire. In addition, it is important to mention that the loss of a concession title entails the loss of rights for specific use in the ZOFEMAT.





Due to the abovementioned, it is advisable that the owners of properties neighboring the ZOFEMAT obtain the corresponding concession title. In addition, proper planning and legal advice are essential to use this area, protect private property from neighboring projects, and preserve one of the main attractions of this type of development: the beach.



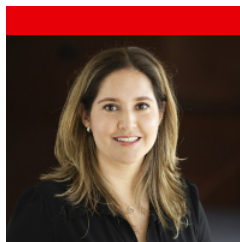
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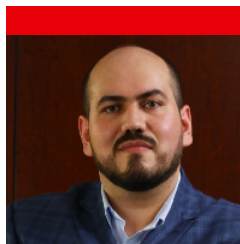
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## The Dutch Hydrogen Roadmap: a map in transition – three key insights

15-03-2023

The Netherlands wants to play an important role in the global hydrogen market. The November 2022 Dutch Hydrogen Roadmap, which was prepared at the request of the Dutch Ministry of Economic Affairs and Climate Policy, describes how a broad group of stakeholders aims to make this happen. The text starts by stating that the map will be outdated at the moment of publication, as developments in this field are moving at a rapid pace. This prompted us to research the latest developments, by initiating a roundtable discussion with academic and industry experts, among others. By doing so, we identified three key transition insights.

### 1. Scaling up electrolysis capacity: important, but not easy

The Roadmap urges the government to increase its ambition of having 3-4 GW electrolysis capacity by 2030 to 6-8 GW. In a recent debate with the Minister for Climate and Energy Policy Rob Jetten, several Members of Parliament shared this view on raising the level of ambition. Minister Jetten emphasised that electrolysis capacity has to be scaled up in sync with the development of wind and solar farms in order to achieve current targets. This statement underlines the Dutch government's focus on green hydrogen. Besides the availability of (green) electrons, the road to scaling up is paved with several other hurdles. These include: protracted permitting procedures, the need for a stable hydrogen market, the question of whether blue hydrogen will help kickstart the low-carbon hydrogen economy, insufficient manufacturing capacity for electrolyser components and general concerns about health and safety risks.

### 2. Hydrogen market regulation: perfect is the enemy of good

The Roadmap states that scaling up renewable and low-carbon hydrogen production requires mature production technologies, proper market functioning and availability of (preferably green) energy resources. At EU level, hydrogen market regulation is envisaged to take the form of a revised Gas Directive and Gas Regulation. This entails applying the traditional gas market principles of third-party access and unbundling of transmission and distribution system operators. This presents a challenge as the gas market is a fully developed market, whereas the hydrogen market is still maturing. Several market parties consider the regulatory proposal too rigid, as it leaves little flexibility to react to the new technical and market developments that will undoubtedly occur. A transition period is needed to enable the market to develop. Some experts fear that implementing a 2050-proof regulation from the start will prevent a healthy development of a stable and reliable green hydrogen market. Perhaps perfect is the enemy of good in this case.

### 3. Unlocking the potential of hydrogen: overcoming import challenges

Importing green hydrogen carriers from parts of the world that have the necessary wind and solar hours seems an inevitable step for the Netherlands, since it cannot generate sufficient green electricity within its own territory. According to the Roadmap, no concrete import goals have as yet been set. Imports can only flourish with clear import and transport conditions and a functioning and reliable certification system.

Although challenges remain, the first necessary steps have been taken. EU legislation envisages that hydrogen imported into the EU may be qualified as green provided it meets certain eligibility criteria. In relation to green hydrogen for use in the European transport sector, the long-awaited publication of the revised EU Renewable Energy Directive (RED II) delegated acts on [renewable electricity used in hydrogen production and the methodology to assess greenhouse gas emissions savings](#) [https://energy.ec.europa.eu/system/files/2023-02/C\\_2023\\_1087\\_1\\_EN\\_ACT\\_part1\\_v8.pdf](https://energy.ec.europa.eu/system/files/2023-02/C_2023_1087_1_EN_ACT_part1_v8.pdf) brought much-needed clarity. The delegated act on renewable electricity also reiterates that green hydrogen (for the purpose of the transport sector) may be produced both within and outside EU territory.

In terms of realising a functioning and reliable certification system, a [certification pilot](#) <https://www.rvo.nl/sites/default/files/2022-12/Report-RFNBO-pilot-RVO.pdf> for domestic production has proven successful. Certification of green hydrogen is now possible in the Netherlands in the form of guarantees of origin. At this stage, imported green hydrogen is not yet supported by the certification system, which covers the well-to-gate aspects of green hydrogen, i.e. the origin of the hydrogen and the greenhouse gas intensity, including upstream emissions up to the point of production, but not the gate-to-wheel aspects, including transportation from the production site to the dispensing point and the dispensing itself. Certification of these aspects is necessary for the hydrogen to count towards the renewable transport targets under RED II. In addition, RED II relies on a mass balancing system that allows hydrogen to be mixed with differing sustainability and greenhouse gas emissions saving characteristics. The challenge, therefore, lies in ensuring compatibility between guarantee of origin certification and mass balancing certification, thereby allowing for full "well-to-wheel" certification.

### Hydrogen-related matters to discuss?

Our multidisciplinary hydrogen team will gladly assist you with the challenges and opportunities in this field, whether these concern the regulated transport and import of hydrogen carriers, the development and financing of infrastructure and storage capacity, or the conclusion of contracts. Are you interested in discussing any hydrogen-related matter?

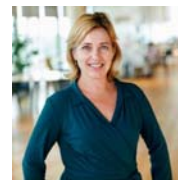
Do not hesitate to contact Gaike Dalenoord, Iris Kieft or Shirley Justice.



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## NICARAGUA

### CREATION OF THE SINGLE WINDOW FOR FOREIGN TRADE IN NICARAGUA

Apr/2023

Foreign trade is becoming more important every day, Nicaragua through Law No. 1147 "Law Creation of the Single Window for Foreign Trade of Nicaragua (VUCEN)", published in La Gaceta Official Newspaper No. 59 (hereinafter "Law No. 1147"), intends to facilitate and simplify the management of procedures through a technological platform.

The Single Window for Foreign Trade of Nicaragua (hereinafter "VUCEN") will manage a technological platform through which all procedures related to foreign trade will be managed, such as pre-customs import permits, VUCEN export documents, port procedures and other documents required for the export or import by a legal or natural person, national or foreign.

Presidential Decree No. 02-2023 "Regulation of Law No. 1147, Law Creating the Single Window for Foreign Trade of Nicaragua (VUCEN)", published on March 31, 2023 (hereinafter the "Regulation"), established the corresponding rules for the VUCEN to carry out the inter-institutional coordination with public entities related to its scope of application, for example the General Directorate of Customs Services (DGA) and the National Port Company (EPN) and other public entities that are responsible for issuing foreign trade documents. Pursuant to the Regulations, administrative agreements will be signed with the institutions to establish their coordination and responsibilities.

As a consultative body, the VUCEN will have the National Trade Facilitation Committee, which in turn is responsible for managing compliance with the commitments assumed by Nicaragua under the Trade Facilitation Agreement (TFA) of the World Trade Organization (WTO).

It is worth mentioning that VUCEN is the successor of the Export Processing Center (hereinafter "CETREX"), and that Law No. 1147 ratified the validity of export documents authorized by CETREX prior to its entry into force.

If you would like to obtain more information about this news, please do not hesitate to contact us.

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# Organisations may be held vicariously liable for their employees' acts of copyright infringement

April 11, 2023

## Introduction

1. In the case of *Siemens Industry Software Inc. (formerly known as Siemens Product Lifecycle Management Software Inc) v Inzign Pte Ltd* [2023] SGHC 50 (*Siemens v Inzign*), Singapore's General Division of the High Court (GDHC) ruled that an organisation may be vicariously liable for its employees' acts of copyright infringement.
2. This decision concerned the unauthorised download and use of a computer software by an Inzign's employee (the Employee). The Employee had downloaded an unlicensed version of Siemens' software onto an unused laptop found at the workplace with no administrative controls. The Employee had wanted to use the software to obtain practice and become more skillful in using the software.
3. The Employee's acts were subsequently discovered by Siemens through an automatic reporting function built into the software. Siemens then brought a claim of copyright infringement against Inzign.
4. The GDHC had to decide whether Inzign was liable for copyright infringement. In this regard, Inzign could be either primarily liable or vicariously liable:
  - a. Inzign could be primarily liable under section 31(1) of the Copyright Act 1987 (the equivalent of section 146(1) of the current Copyright Act 2021) if it had carried out, or authorised, the infringing acts.
  - b. Alternatively, Inzign could be vicariously liable for the infringing acts of the Employee. The issue of whether vicarious liability extended to copyright infringement had not previously been considered by the Singapore courts.

## Whether Inzign was primarily liable for the Employee's actions

5. The GDHC found that Inzign was not primarily liable for copyright infringement on the basis that it did not carry out the infringing acts, or authorise the infringing acts. This decision was made in view of the following factors:
  - a. the acts were carried out by the Employee, and could not be attributed to Inzign as they did not fall within the scope of any authority that Inzign had conferred on the Employee. Inzign also did not authorise or sanction the acts of the Employee;
  - b. Inzign did not have power to prevent the Employee's acts. Inzign may have facilitated the acts by failing to account for the laptop, or install administrative controls on the laptop. However, these were insufficient to demonstrate that Inzign had control over the Employee's acts especially where the acts were carried out without its knowledge; and
  - c. Inzign did not have actual or constructive knowledge of the copyright infringement, or the likelihood of such infringement occurring.
6. Notably, the GDHC concluded that Inzign had no primary liability for copyright infringement, despite finding that Inzign had failed to take reasonable steps in preventing the Employee's acts. While Inzign had an anti-software piracy policy, its implementation of this policy had fallen short in preventing the Employee's acts.

## Whether Inzign was vicariously liable for the Employee's actions

7. Although the GDHC did not find Inzign primarily liable for the Employee's acts, it found that Inzign was vicariously liable. This is because of the contractual employment relationship between Inzign and the Employee. Additionally, there was a sufficient connection between this relationship and the infringing acts, supported by the following factors:
  - a. Inzign's mismanagement of the laptop created and enhanced the risk that the Employee could commit the acts; and
  - b. the acts were committed in the context of the Employee's employment for Inzign's benefit as the purpose of his acts was to improve his performance at work.
8. The GDHC also noted that its finding of vicarious liability was supported by two policy considerations. First, Inzign was best placed and able to provide compensation to Siemens, especially since the Employee was unlikely to possess sufficient financial resources. Second, imposing vicarious liability on Inzign would incentivise other employers to take steps in reducing the incidence of copyright infringement by their employees.

## Key takeaways

### **Organisations may be vicariously liable for their employees' acts of copyright infringement**

9. The GDHC has made it clear from this decision that organisations may be held vicariously liable for the infringing acts of its employees. Organisations should be aware that copyright holders are fully entitled to seek relief from an organisation for its employees' acts of copyright infringement. Therefore, it is important for organisations to put in place appropriate intellectual property policies, in particular, an anti-software piracy policy.

### **Importance of operationalising intellectual property policies**

10. From a risk perspective, organisations should note the importance of not only having strong intellectual property policies (in particular, anti-software piracy policy), but also ensuring that such policies are operationalised well. For example:
  - a. Organisations ought to regularly communicate the importance of respective intellectual properties, and draw

- employees' attention to such intellectual property policies (including anti-piracy software policies);
- b. Organisations should regularly review the IT assets that they possess, including laptops and mobile devices. This ensures that organisations are kept apprised of the software or applications that may be installed on such IT assets; and
- c. Organisations will need to ensure adequate supervision of their employees in the course of their work. In *Inzign*, the Employee was found not to have been given adequate supervision in the course of his work, even though the Employee had access to company's resources.

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Dentons Rodyk acknowledges and thanks Practice Trainee Chieng Hui Jie for her contributions to this article.

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## Promotion Plan of Taiwan's FSC as the Competent Authority of Platforms of Virtual Assets with Financial Investment or Payment Nature

04/28/2023

Eddie Hsiung/Crystal Lee

Taiwan's enterprises related to virtual currency have been required to follow the "Regulations Governing Anti-Money Laundering and Countering the Financing of Terrorism for Enterprises Handling Virtual Currency Platform or Transaction" to be AML/CFT compliant since 2021. For this purpose, the Financial Supervisory Commission ("FSC") has been designated by the Executive Yuan (the cabinet) as the competent authority of enterprises of virtual currency platforms or transactions under the Money Laundering Control Act, Taiwan's anti-money laundering law ("Taiwan AML Law").

In light of the recent insolvencies of overseas virtual asset exchanges and the trend of international supervisory organizations and regulators continuing to deepen the supervision of virtual asset service providers ("VASPs"), the FSC issued a press release on March 30, 2023, stating that the FSC will enhance customer protection for customers of domestic virtual asset platforms gradually by establishing VASP Guidelines (defined below), promoting self-regulation of VASP associations, and cooperating with other related government authorities. Certain major points of the press release are listed below:

### 1. Establishing VASP Guidelines:

The FSC will establish the "Virtual Asset Service Provider (VASP) Guidelines" ("VASP Guidelines") in accordance with the Taiwan AML Law, to be supplemented by enhancing industry self-regulation and the principles of information disclosure and transparency. The VASP Guidelines should provide principles regarding information disclosure, review procedures of product launch and withdrawal, segregation of assets between customers and platform operators, fairness and transparency of transactions, AML, protection of customer (consumer) rights, information security, management of operating systems and cold and hot wallets, and audits, so as to strengthen customer protection, improve transaction transparency, and continue to implement money laundering prevention.

### 2. Promoting self-regulation of VASP associations:

After establishing the VASP Guidelines, the FSC will invite VASPs to promote self-regulation. The VASP associations will establish self-regulatory rules in accordance with the VASP Guidelines to guide VASPs to enhance internal controls and improve the protection of customer rights.

### 3. Cooperating with other related government authorities in the future:

As virtual assets involve the affairs of various ministries within the government, it is necessary to cooperate with each government authority to enhance self-regulation and accumulate administrative and management experiences of the domestic VASPs, and continue observing the supervisory developments of international organizations and regulators to propose appropriate directions for establishing regulations.

If you have any questions regarding the above-mentioned development of regulatory approaches to virtual currency/ virtual assets, please do not hesitate to contact us.

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**BLOG POST / ARTIFICIAL INTELLIGENCE LAW ADVISOR**

Employment Litigation

# California Proposed Employment AI Regulations and Legislation

Proposals from Civil Rights Council and  
Legislature Concerning the Use of Artificial  
Intelligence in Employment

By

Jeffrey S. Bosley, Julie M. Capell,  
Patricia Kinaga, and John P. LeCrone

05.02.23

As widespread use of artificial intelligence (AI) in the employment

sector has surged throughout the country, federal and state lawmakers have been playing catch-up with their efforts to regulate this new technology. In California, the Civil Rights Council (CRC) (formerly the Fair Employment and Housing Council) first proposed modifications over one year ago to the state's employment regulations to incorporate the use of AI in connection with employment decision-making. The CRC updated its draft AI regulation in February 2023 and expects to soon issue a notice of proposed rulemaking and start the 45-day comment period. California lawmakers have also introduced multiple bills on AI-related topics, including a bill that will require audits of use of these tools by employers and developers. Given the scope and number of these initiatives, and the commitment of the CRC to move its rule forward, employers deploying this technology are advised to continue to monitor developments concerning use of AI and to consider these potential developments as they determine when and how to use this technology.

## CRC's Proposed Modifications to Employment Regulations Regarding Automated-Decision Systems (ADS)[\[1\]](#)

On February 10, 2023, the CRC published [Proposed Modifications to Employment Regulations Regarding Automated-Decision Systems](#).

This document is a revision of the CRC's draft modifications initially issued in March 2022 which proposed sweeping changes to existing rules regulating employment and hiring practices in California to incorporate the use of automated-decision systems (ADS). (Previously reported by DWT [here](#).) An [additional revision](#) to the original modifications previously was published by the CRC in July 2022.

In general, the CRC's proposed regulations state it is unlawful for an

employer to use selection criteria (including qualification standards, employment tests, ADS or its "proxy" (defined in the next paragraph)), if such use has an adverse impact on, or constitutes disparate treatment of, an applicant or employee (or classes of applicants or employees) on the basis of a protected characteristic (as traditionally listed in the Fair Employment & Housing Act<sup>[2]</sup>), unless the employer can show the selection criteria to be job-related and consistent with business necessity.

### **New and Revised Definition Regarding Automated-Decision**

**Systems:** The latest modifications contain a separate section on ADS. That section provides an expanded list of tasks, including those to be excluded ("word processing software, spreadsheet software, and map navigation systems") in its definition of ADS. What had previously been named as "machine-learning data" is now referred to as "automated-decision system data." The new definitions include "adverse impact" which is defined as being synonymous with disparate impact; "artificial intelligence" which is defined as "[a] machine-learning system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions;" and "proxy" which is defined as "[a] technically neutral characteristic or category correlated with a basis protected by the Act."

**Recordkeeping:** The initial rule had already increased the applicable time period for retention of records from two to four years; the revised regulation expands both the scope of who must retain these records and what records must be maintained. The latest version of the regulations expands the scope of entities that must retain documents to "[a]ny person who sells or provides an automated-decision system or other selection criteria to an employer or other covered entity, *or who uses an automated-decision system or other selection criteria on behalf*

*of an employer or other covered entity."* (Emphasis added.) The scope of the documents to be preserved for four years has been expanded to include "[a]ny personnel or other employment records *created or received* by any employer or other covered entity dealing with any employment practice and affecting any employment benefit of any applicant or employee (including all applications, personnel, membership or employment referral records or files *and all automated-decision system data*)."

**Employer Defense:** The CRC's latest version of the modifications provides employers with additional and clarifying language regarding potential defenses that would be available against a claim of unlawful use of selection criteria. In addition to defending themselves by showing that the selection criteria "is job-related for the position in question and consistent with business necessity," employers could also defend themselves by showing that "there is no less discriminatory policy or practice that serves the employer's goals as effectively as the challenged policy or practice." The CRC further provides that "[r]elevant to this inquiry is evidence of anti-bias testing or similar proactive efforts to avoid unlawful discrimination, including the quality, recency, and scope of such efforts, the results of such testing or other effort, and the response to the results." While an impact assessment, or outcome audit, is not specifically required by the initial or revised regulation, a bill working through the California Legislature, AB 331, would specifically require impact assessments for use of automated decision tools.

## Assembly Bill 331: Employer Use of Automated Decision Tools

Introduced on January 30, 2023, Assembly Bill 331 proposes certain

requirements and restrictions upon employer use of what it refers to as "automated decision tools" (ADT). ADT is defined in the proposed legislation as "a system or service that uses artificial intelligence and has been specifically developed and marketed to, or specifically modified to, make, or be a controlling factor in making, consequential decisions." AB 331's proposed requirements include the following:

- Deployers<sup>[3]</sup> and developers<sup>[4]</sup> of ADT would be required to perform an impact assessment by January 1, 2025, and annually thereafter. An impact assessment is defined as "a documented risk-based evaluation of an automated decision tool" that includes, among other things, a statement of purpose of the ADT and its benefits, a summary of the data collected, an analysis of the potential adverse impacts on protected characteristics, and a description of how the ADT would be used by a person. The impact assessments would be required to be provided to the Civil Rights Department within 60 days of completion with a potential administrative fine not to exceed \$10,000.
- Deployers would be required to provide notice to persons who are the subject of the consequential decisions that ADT is being used to make, at the time the ADT is used. Additionally, if technically feasible, deployers would be required to accommodate a person's request to not be subject to the ADT and to be subject to an alternative selection process or accommodation.
- Developers would be required to provide deployers with a statement regarding the intended uses of the ADT and documentation regarding any known limitations, a description

of the type of data used to program or train the ADT and a description of how the ADT was evaluated for validity.

- Prohibits the use by deployers of ADT that contributes to algorithmic discrimination.[\[5\]](#)
- Deployer and developers would be required to establish, document, implement and maintain a governance program that contains safeguards against algorithmic discrimination associated with the use of ADT.

## Additional ADS and AI-Related Legislation

In addition to the ADS and AI-related proposed legislative changes discussed above, additional bills worth tracking by employers have also been recently introduced in the California Legislature:

- **AB 302.** Introduced on January 26, 2023, AB 302 would require the Department of Technology to conduct, by September 1, 2024, a comprehensive inventory of all high-risk ADS that have been proposed for use or are being used by state agencies.
- **SB 313.** Introduced on February 6, 2023, SB 313 proposes the creation of an Office of Artificial Intelligence within the Department of Technology that would oversee the use of artificial intelligence by state agencies and ensure compliance with state and federal laws and regulations.
- **SB 721.** Introduced on February 16, 2023, SB 721 proposes the creation of a California Interagency AI Working Group to study the implications of the usage of AI and provide the Legislature with a comprehensive report by January 1, 2025 (and every two years thereafter until 2030) regarding AI.



## Current Status

While the proposed regulatory changes and bills described above are not yet law, they are part of a national and state enforcement trend concerning these tools, and California seems poised to continue to assert a leadership role concerning regulating these tools. Because the requirements of these California laws may also vary from laws in other states and cities, [including New York City](#), national employers will likely be faced with complex decisions on how to comply effectively with conflicting laws. In addition to continually monitoring developments in California and elsewhere, employers may also want to be thinking now about how to effectively comply with these potential requirements, whether and how AI or ADS are used in sourcing candidates or making other employment decisions, how they select vendors, and the terms of any agreements between the employer and their vendors.

As always, DWT will continue to monitor these issues and provide updates on ADS and AI regulations as needed. In the meantime, if you have any questions about your company's compliance, please contact a member of [DWT Employment Services group](#).

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[1] The February 10, 2023, Proposed Modifications to Employment Regulations Regarding Automated-Decision Systems defines ADS as "[a] computational process that screens, evaluates, categorizes, recommends, or otherwise makes a decision or facilitates human decision making that impacts applicants or employees. An Automated-Decision System may be derived from an/or use machine-learning, algorithms, statistics, and/or other data processing or artificial intelligence techniques."

[2] FEHA protects the following characteristics from discrimination:

race, color, ancestry, national origin, religion, creed, age, disability (mental or physical), sex, gender (including childbirth, breastfeeding or related medical conditions), sexual orientation, gender identity, gender expression, medical condition, genetic information, marital status and military or veteran status.

[3] AB 331 defines deployer as "a person, partnership, state or local government agency, or corporation that uses an automated decision tool to make a consequential decision."

[4] AB 331 defines developer as "a person, partnership, state or local government agency, or corporation that designs, codes, or produces an automated decision tool, or substantially modifies an artificial intelligence system or service for the intended purpose of making, or being a controlling factor in making, consequential decisions, whether for its own use or for the use by a third party."

[5] AB 331 defines "algorithmic discrimination" as "the condition in which an automated decision tool contributes to unjustified differential treatment or impacts disfavoring people based on their actual or perceived race, color, ethnicity, sex, religion, age, national origin, limited English proficiency, disability, veteran status, genetic information, reproductive health, or any other classification protected by state law."

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# The next era of digital therapeutics

16 May 2023

**Products incorporating artificial intelligence/machine learning (AI/ML) algorithms have enormous potential for health care. The power of AI can enhance the capabilities of software that has the potential to benefit more patients. However, the introduction of AI to the health care landscape raises unique regulatory questions, such as whether and how an AI product should be regulated as a medical device and what sort of data will be necessary to demonstrate that the product performs as intended. Digital therapeutics (DTx), which often incorporate AI algorithms, have incredible promise, but because they are in many ways revolutionary – especially if they are “continually learning” – they have struggled to fit within existing frameworks for delivering and regulating care.**

**On Thursday, 18 May, Hogan Lovells is hosting its annual Health Care AI Law and Policy Summit, an informative and interactive program where our thought leaders and industry guests will address a variety of topics including new and emerging health care AI policies and regulatory considerations, implications for ethics and consumer safety, developments in the U.S., UK, and EU, and more. You can register for the Summit online [here](#).**

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## Promise and pitfalls of the current DTx framework

A subset of digital health, DTx are software-driven therapeutic applications that are by themselves the therapy or are coupled with other therapeutic modalities to increase the therapeutic effect. The promise of DTx is the breadth of their possible applications. For example, they can provide individualized therapies for the treatment of conditions as varied as mental health, palliative care, substance use disorders, and chronic conditions such as irritable bowel syndrome (IBS) and diabetes. This merging of technologies, however, can also create tricky issues in their implementation and commercialization. While the COVID-19 pandemic accelerated the interest in these technologies, many challenges to their adoption remain, not the least of which is a clear path to commercialization and payment.

Although the U.S. Food and Drug Administration’s (FDA) approach continues to evolve, most DTx receive their first FDA market authorization (MA) as prescription software-as-a-medical device (SaMD). Obtaining this premarket authorization typically requires the submission of both nonclinical and clinical data to validate the algorithm and demonstrate that the device achieves its claimed intended use, in a manner that ensures that benefits to patients outweigh potential risks. Where the DTx was developed using AI or ML or seeks to incorporate AI itself, FDA requires that the sponsor provide detailed data and information about the source of the data, the methods by which the algorithm was trained, and how the resulting algorithms were validated. The Agency not infrequently engages in detailed inquiries about the source data (on issues including bias, potential confounding

factors, demographic representation, and others) and the sponsor's methods. For that reason, it is advisable to begin discussions with FDA early (through the pre-submission process) in order to obtain input on proposed study plans and related details before completing product validation.

Once they have received FDA authorization at the federal levels, prescription medical devices are subject to complex and varied state licensing requirements that can attach to the activities of manufacturers and their distribution partners, most of which are set up for the distribution of traditional medicinal products. Licensing rules vary by state as well as between prescription and over the counter (OTC) drug or device types, recipient, and facility/entity type. Adding to the complexity, most state licensing paradigms were developed to handle prescription drugs and controlled substances and, consequently, are not always well suited for the distribution models used for prescription medical devices and even less so for DTx. Further still, while distribution models are well developed for distributing tangible things, they are often not well suited for DTx for which there is no physical product, merely software downloads of applications and provision of access codes. While some states do not have any licensure requirements for prescription medical devices, many states do and those requirements apply equally to DTx and may extend from manufacturers to their distributors and third party logistics providers.

Prescription DTx (PDTx) require a health care provider to issue a prescription or medical order before a patient can access the product. Often, companies will rely on partnerships with telehealth providers who can evaluate the patients, and if appropriate, issue a prescription for the product. This raises important considerations around the agreements between these parties, in order to avoid pitfalls with issues such as state regulation of telehealth, requirements for prescriptions provided via telehealth, applicability of state pharmacy and medical device regulations, possible Sunshine disclosure obligations, and also the corporate practice of medicine. While it is possible to set up these arrangements in a way that avoids triggering issues, it requires careful consideration of the various law and issues at play.

As a practical matter, lack of payer coverage for DTx also provides a key barrier to adoption. DTx do not readily fall under any Medicare or other payer benefit category. While some DTx companies seek to fit them into existing drug or device paradigms, others liken them more to durable medical equipment (DME). While this approach may allow new devices to access the market faster, it may also result in lower reimbursement. At the moment, most DTx companies are negotiating with payers and pharmacy benefit managers one at a time and in the meantime bearing much of the costs or adopting a cash pay model in favor of market adoption.

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## Regulating AI

FDA and other regulators continue to refine their approach to regulatory requirements and also the data burden that is needed for DTx devices for marketing. In late 2022, FDA announced its greatly anticipated Clinical Decision Support (CDS) Software guidance. Notably, this updated approach appears to position more software products and AI tools within the realm of FDA regulatory authority than was previously the case, as software tools which issue a singular output or one that is tied to time-critical decision-making are now considered to generally be subject to active FDA regulation as a medical device. The final guidance also reinforces FDA's position that CDS tools based on AI algorithms are unlikely to qualify for the non-device category, because it is nearly impossible to enable the user to independently review the inputs, outputs, and methods to get from one to the other for a "black box" algorithm.

To date, FDA has not approved any SaMD with evolving AI, which means that manufacturers need to think carefully about how they plan to evolve their algorithms as new data and real world experience is gathered. Many such iterations under normal circumstances may well require a new pre-market authorization. As one option, manufacturers can consider submitting for FDA review a Predetermined Change Control Plan (PCCP), which allows them to obtain pre-approval for changes to AI devices by pre-defining for FDA how specific types of changes can be adequately validated in-house without the need for further FDA review. This approach has been accepted on a case-by-case basis to date and we have assisted clients in working through the process with the Agency. As we have described [here](#), FDA recently published long-awaited draft guidance outlining its views on PCCPs. We expect the guidance, once finalized, to further encourage innovation and delivery of AI/ML-enabled medical devices by promoting a general approach that enables manufacturers to make certain updates to their devices without re-engaging FDA