

Pacific Rim Advisory Council  
**January 2017 e-Bulletin**

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**CONFERENCES & EVENTS**

Upcoming Conferences

PRAC 61st International Conference  
Hong Kong - Hosted by Hogan Lovells - April 22 - 25, 2017

PRAC 62nd International Conference  
Sao Paulo - Hosted by TozziniFreire - October 21 - 24, 2017

For more information visit [www.prac.org](http://www.prac.org)

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## ARIFA ANOUNCES FIVE PARTNER APPOINTMENTS

ARIFA IS PLEASED TO WELCOME  
FIVE NEW PARTNERS
**ARIFA**

ARIAS, FABREGA &amp; FABREGA

Arias, Fábrega & Fábrega recognizes the exceptional work and professional accomplishments of its lawyers with these well-deserved appointments to partnership.

Panama • London • Luxembourg • Geneva • Hong Kong • British Virgin Islands • Belize • Uruguay

 We congratulate our  
first-rate lawyers:

**Sofía J. Cohen**

Litigation and arbitration; antitrust, trade and competition; aviation and environmental matters.

**Andrés N. Rubinoff**

Mergers &amp; acquisitions; banking and finance; securities regulation and corporations.

**Federico Alfaro**

Corporate services and private clients.

**Claudio De Castro**

Litigation and arbitration.

**Pilar Castillo**

Shipping and ports; corporations and aviation.

## DAVIS WRIGHT TREMAINE PROMOTES 11 TO PARTNER

**SEATTLE, 10 January 2017:** Eleven lawyers at Davis Wright Tremaine have been promoted to partnership as of January 1, 2017. This is the largest class of new partners at the firm in over a decade. The new partners, along with their areas of practice are:

Samuel M. Bayard – Media/IP

Clifford A. DeGroot – Business &amp; Tax

Brian J. Hurh – Financial Services

Matthew E. Moersfelder – Intellectual Property

Andrew W. Steen – Business &amp; Tax

Maya Yamazaki – Media/IP

Michael Caughey – Financial Services

Rebecca J. Francis – Litigation

Ame Wellman Lewis – Environmental

Gillian Murphy – Employment

Sean M. Sullivan – Litigation/IP

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

## **BAKER BOTTS WELCOMES INTERNATIONAL INFRASTRUCTURE AND ENERGY PARTNER**

**LONDON, 09 January 2017:** Baker Botts L.L.P., a leading international law firm, announced today that James Douglass, who specializes in the development and financing of energy and infrastructure projects, has joined the firm's London office as a partner.

"James is an exciting addition to our Global Projects team and brings a wealth of legal expertise to our London office, including an exceptional knowledge of Asia. His appointment demonstrates our commitment to recruiting highly skilled lawyers and will help us to further strengthen our international capabilities," said Andrew M. Baker, Managing Partner of Baker Botts.

"James has excellent energy and infrastructure experience and I am delighted to welcome him. Working alongside our market leading team, he will play a key role in advising our energy and infrastructure clients on a wide range of international projects. The addition of James further highlights our dedication to hiring the best legal talent available in London and providing first class service for our clients on complex international projects and transactional work," said Mark Rowley, Partner-in-Charge of the firm's London office.

Mr. Douglass has over 24 years of experience and has been involved in ground breaking projects across the power, oil and gas, and infrastructure sectors.

"Baker Botts is a leading international firm in the energy sector and joining the dynamic London office is the perfect fit for me. There has been a strong demand for project development and financing recently in emerging markets due to increased infrastructure investments, and this trend is expected to continue. I am pleased to join such a strong global player and become part of a talented team, where I will be best placed to take advantage of these exciting new opportunities," said Mr. Douglass.

Mr. Douglass obtained a Bachelor of Laws (LLB) from the University of Queensland, Australia, and is qualified to practice in Queensland, England & Wales, and Hong Kong.

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

## **GOODSILL ANNOUNCES PARTNER APPOINTMENT AND WELCOMES NEW ASSOCIATE**

**HONOLULU, 04 January 2017:** Goodsill Anderson Quinn & Stifel LLP has promoted Walter K. Coronel from Associate to Partner. Walter grew up in Kailua-Kona on the Big Island of Hawai'i, received a B.S. degree from the University of California, Irvine, and earned his J.D. degree at the University of San Francisco. He joined Goodsill in 2012 after managing his own practice for two years; and prior to that, he practiced with a large law firm in Silicon Valley.

Currently, he concentrates his practice in the areas of technology transactions, intellectual property procurement, licensing, portfolio management, internet, ecommerce, contract drafting and negotiations.

In December, the firm welcomed Dylan J. Taschner as a Bankruptcy and Corporate associate. Dylan graduated from the William S. Richardson School of Law and concentrates his practice in the areas of bankruptcy, creditors' rights, commercial litigation and corporate law. Prior to law school he earned an undergraduate degree in Business Administration from Chapman University and also worked in the sports and entertainment marketing industry.

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

**DENTONS RODYK WELCOMES FORMER JUDICIAL COMMISSIONER**

**SINGAPORE, 03 January 2017:** Dentons Rodyk is pleased to announce that former Judicial Commissioner Edmund Leow has joined the Firm as part of its Tax practice.

Edmund brings with him 29 years of legal experience, advising multinational organisations on cross-border tax planning, transfer pricing and tax disputes. He also advises on international trade issues such as customs, WTO and free-trade agreements. In addition, Edmund also advises high net worth individuals, private banks and trust companies in personal tax, as well as in trust and estate planning matters.

Of Edmund's wealth of experience, Philip Jeyaretnam S.C., Global Vice Chair and CEO of Dentons Rodyk said, "The ability to provide complex tax advice to our clients completes the full service nature of our legal services. Our clients are now rest assured they can rely on Dentons Rodyk to provide seasoned tax advice with a top ranked lawyer like Edmund."

Edmund, who played a key role in growing the Tax practice at Baker & McKenzie. Wong & Leow, looks forward to working with the team at Dentons Rodyk. Edmund says, "With my extensive experience in the practice, I am confident of leading the team at Dentons Rodyk and ensuring that we provide our clients with the support necessary in helping them succeed in their projects. Whether it involves local or cross border matters, the team and I will provide first-rate tax advice to our clients, many of whom are multinational organisations, large local companies and government agencies who have requirements for legal advice in the area of tax."

Edmund was recognised as a Tier 1 lawyer for Tax in The Legal 500 Asia Pacific 2012, and has also been listed by Euromoney Guide as one of the world's leading tax advisers. He is a co-founder of the Singapore Trustees Association (STA) and served as President from 2004 to 2008, then as Vice-President from 2008 – 2013.

This follows the hire of John Dick in December 2016. John joined the firm as part of its Energy Practice and its South East Asia Regional Practice. John will build on Dentons Rodyk's achievements in the energy and infrastructure areas in the region. In addition, he would be able to draw on the strong capabilities of the highly ranked global Dentons Energy Practice to support clients as they venture across border.

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

**GIDE APPOINTS 6 TO PARTNER IN PARIS AND NEW YORK**

**PARIS, 01 JANUARY 2017:** GIDE is pleased to announce the appointment of 6 partners effective 01 January, 2017:



Paris  
Marie Bouvet-Guiramand  
(Projects - Finance & Infrastructure)



Paris  
Bertrand Jouanneau  
(Tax)



Paris  
Jean-Hyacinthe de Mitry  
(Intellectual Property)



Paris  
Alexandra Munoz  
(Dispute Resolution / International Arbitration)



Paris  
Jean-Philippe Pons-Henry  
(Dispute Resolution)



New York  
Vanessa Tollis  
(Tax)

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

## **HOGAN LOVELLS ANNOUNCES 29 PARTNER APPOINTMENTS; 37 PROMOTED TO COUNSEL**

**04 JANUARY, 2017:** Hogan Lovells has announced the promotion of 29 new partners globally, effective 1 January 2017. They will join more than 800 partners in offices across Africa, Asia, Australia, Europe, the Middle East, and the Americas.

Each of Hogan Lovells' five practice groups is represented in the 2017 promotion round:

Eight in Corporate (including in Corporate, Real Estate, and Tax)

Eight in Litigation & Arbitration (including in Investigations, White Collar and Fraud)

Five in Government Regulatory (including in Competition, Privacy & Cybersecurity, Health and FDA/Medical Devices)

Five in Finance (in Banking, International Debt Capital Markets and Infrastructure, Energy, Resources and Projects)

Three in Intellectual Property

The jurisdictional spread reflects the global nature of Hogan Lovells' practice:

19 in the United States & Latin America: Denver, Mexico City, Miami, New York, Northern Virginia, Washington, D.C.

Nine in Europe: Dusseldorf, London, Munich, Paris

One in Asia: Shanghai

In addition to the 29 new partners, 37 new appointments to the role of counsel have been made.

CEO Steve Immelt said:

"Supporting and growing our internal talent pipeline is a key priority for Hogan Lovells and integral to offering our clients the highest quality service. It gives me great pleasure to promote from within and recognise the hard work and dedication of these individuals, who represent the quality, breadth, and depth of Hogan Lovells around the world, which no other law firm can match. I congratulate all those who were promoted and wish them every success as they continue their career with us."

For more information, see [www.hoganlovells.com](http://www.hoganlovells.com)

**ALLENDE & BREA AND HOGAN LOVELLS**

LEAD WYNDHAM HOTEL GROUP'S ACQUISITION OF ARGENTINE HOTEL CHAIN FEN HOTELS

**BUENOS AIRES, JANUARY 2017:** Denver and Miami offices of Hogan Lovells and Allende Brea coordinated the due diligence for the acquisition in several Latin American jurisdictions. The Sellers are unidentified to public and no value for the acquisition was disclosed. The US hotel chain closed the purchase on 30 November.

Fen Hotels operates in six countries: Argentina, Costa Rica, Paraguay, Peru, Uruguay and the US.

Counsel to Wyndham Hotel Group - In-house counsel - Christopher Nowak and Jodi Campbell; Hogan Lovells LLP Partner Tim Aragon and associates Kathryn Raffensperger and Jim Fipp in Denver, and associate Pedro Coll in Miami; Allende & Brea Partners Valeriano Guevara Lynch and Nicolás Grandi, and associates Tomás Di Cío and Camila Fernández Llorente in Buenos Aires.

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

**BAKER BOTTS**

REPRESENTS VENADO OIL &amp; GAS IN THE \$800 MILLION ACQUISITION OF EAGLE FORD ASSETS FROM SM ENERGY

**HOUSTON, 06 January 2017:** Deal Description: January 3, 2017 – SM Energy Company (NYSE: SM) announced that it entered into a definitive agreement with a subsidiary of Venado Oil & Gas, LLC, an affiliate of KKR, for the sale of the company's third party operated assets in the Eagle Ford, including its ownership interest in related midstream assets, for a purchase price of \$800 million (subject to customary adjustments).

Baker Botts represented Venado Oil & Gas, LLC in the transaction.

Baker Botts Lawyers/Offices Involved: Mike Bengtson (Partner, Austin); Hugh Tucker (Partner, Houston); Erin Hopkins (Senior Associate, Houston); Lindsey Swiger (Associate, Houston); Rachel Ratcliffe (Associate, Austin); James Chenoweth (Partner, Houston).

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

**BENNETT JONES**

ASSISTS TOTAL ENERGY SERVICES COMMENCE AN OFFER TO PURCHASE SAVANNA ENERGY SERVICES CORP

- Date Announced: December 09, 2016
- Date Closed: TBD
- Deal Value: Approximately \$400 million (including indebtedness)
- Client Name: Total Energy Services Inc.

On December 9, 2016, Total Energy Services Inc. commenced an offer to purchase all of the outstanding common shares of Savanna Energy Services Corp., by way of unsolicited takeover bid.

Total Energy Services Inc. and Savanna Energy Services Corp. are both headquartered in Calgary Alberta. The offer has been made in all provinces and territories of Canada. Savanna Energy Services Corp. shareholders are located in the United States, Australia and various other foreign jurisdictions.

Involved in the transaction from Bennett Jones are Nicholas P. Fader, Jeff Kerbel, John Piasta, Juliamai Giffen, and Kris Simard (Public Markets and Mergers and Acquisitions), Greg Johnson (Tax), and Beth Riley (Competition).

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

**BRIGARD & URRUTIA**

ASSISTS IN SALE OF 50% STAKE IN 4G COLOMBIAN HIGHWAY PROJECT

Colombian firm Brigard & Urrutia in Bogota assisted Israeli construction company Shikun & Binui in sale of a 50% stake in a 4G highway project east of Bogotá.

Shikun & Binui enlisted Brigard & Urrutia Abogados in Bogotá and Herzog, Fox & Neeman in Tel Aviv. The US\$610 million road project is part of Colombia's mammoth 4G infrastructure programme, which hopes to stimulate trade by increasing national and international connectivity.

The acquisition closed on 20 December.

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

**DAVIS WRIGHT TREMAINE**

ASSISTS FAMILY BUSINESS WITH MAJOR LAND CONSERVATION DEAL

Working in partnership with Forterra, a land conservancy nonprofit, Davis Wright Tremaine has enabled a longtime client to accomplish the sale of two environmentally significant land parcels, which will now be preserved in perpetuity.

The two parcels, comprising 376 acres, are located in the foothills of the Cascade Mountains and contain some of King County's last unprotected old-growth forest as well as habitat for two endangered species. The land was held for decades by the Cugini family, whose private company has owned, logged, and milled timber for three generations. Crissa Cugini, of counsel at Davis Wright Tremaine and the granddaughter of company founder Alex Cugini (seen below), participated in the sale on the client side.

Previous attempts to transfer the land to the public or to conservation groups had been undone by regulations that significantly depressed the appraised value. "There's nothing in the federal regulations that recognizes a value for conservation," says Davis Wright Tremaine partner Warren Koons, who has extensive experience with timberlands transactions and led this one.

Seeking a new approach, Koons turned to Forterra in 2013. DWT partner Jim Greenfield is a longtime Forterra board member. With his leadership, the firm and Forterra have jointly hosted several events on sustainable development. "They have a lot of innovative ideas and are one of the very few groups that can bridge the environmental and timber/development sides of the economy," says Koons. "They also have a strong understanding of the regulatory agencies."

Together, the team of Koons, Forterra, and the Cugini family developed some creative ways to structure the deal that allowed our client to be fairly compensated and preserved this extraordinary land under a conservation easement retained by Washington's Department of Natural Resources.

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

**CAREY**

ASSISTS CODELCO WITH CREDIT LINE REFINANCING

**SANTIAGO, 22 November 2016:** Chilean firm Carey has helped one of its regular clients, state-run copper mining company Codelco, refinance a US\$250 million loan.

Codelco refinanced a credit line granted by The Bank of Tokyo-Mitsubishi UFJ. The bank is believed to have hired Philipp Prietocarrizosa Ferrero DU & Uría (Chile), but this was not confirmed before publication.

The transaction closed on 21 October.

Counsel to Codelco In-house counsel – Manuel Díaz.

Carey Partner Diego Peralta and associates José Tomás Otero, Manuel José Garcés and Patricia Montt in Santiago.

For additional information visit [www.carey.cl](http://www.carey.cl)

**CLAYTON UTZ**

ACTS FOR FINANCIERS TO CONSORTIUM ON THE SUCCESSFUL COMPLETION OF \$16.189 BILLION AUSGRID LEASE DEAL

**MELBOURNE, 02 December 2016:** Clayton Utz has acted for the financiers to the consortium comprising IFM Investors and AustralianSuper on the successful completion of the partial lease of electricity and energy services distributor Ausgrid.

The transaction, valued at \$16.189 billion, reached financial close yesterday.

Under the terms of the Sale and Purchase Agreement, which was announced by the NSW Government on 20 October, the consortium has acquired 50.4% of the long-term lease of Ausgrid, with the NSW Government retaining a 49.6 percent stake.

The NSW Government will apply the proceeds raised towards funding critical infrastructure projects as part of its \$20 billion Rebuilding NSW plan.

Partner Dan Fitts led the Clayton Utz deal team, which included special counsel Trish Moloney and special counsel Maria Ratner.

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

**GIDE**

COUNSEL TO DCNS ON SETTING UP DCNS ENERGIES

**PARIS, 11 January 2017:** DCNS, the European leader in the naval and defence industry, and the SPI fund ("Société de Projets Industriels", or Industrial Projects Company), managed by Bpifrance for the French state as part of the Investments Programme for the Future ("Programme d'Investissements d'Avenir"), have announced the establishment of DCNS Energies, a new industrial player in the marine renewable energies sector, which is also supported by Technip Group and BNP Paribas Development.

DCNS Energies, majority owned by DCNS and 36% by the SPI fund of Bpifrance, will devote its activity to the industrial and commercial development of three technologies for the production of electricity from Marine Renewable Energies (MRE): tidal turbine power that uses the kinetic energy of sea currents, Ocean Thermal Energy Conversion (OTEC) and offshore wind energy via semi-submersible floats. DCNS Energies positions itself as a turnkey constructor of MRE plants for the French and export markets.

In addition to the contributions in terms of industrial facilities and intellectual property of DCNS, the four shareholders will provide a total of EUR 100 million in equity for DCNS Energies, which will also use financial leverage.

DCNS and DCNS Energies were advised by Gide, with partner Anne Tolila and associate Bruno Laffont on M&A aspects, partner Stéphane Hautbourg on competition law aspects, partner Stéphane Vernay and associate Alix Deffrennes on contract law aspects, and law firm Arsene Taxand with partners Denis Andres and Nicolas Jacquot on tax aspects.

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

**HOGAN LOVELLS**

REPRESENTS PLAYA HOTELS & RESORTS IN US\$1.75 BILLION BUSINESS COMBINATION

**WASHINGTON, D.C., 21 December 2016:** Hogan Lovells is representing Playa Hotels & Resorts in a definitive business combination with Pace Holdings (Pace) (NASDAQ:PACE), a special-purpose acquisition company (or SPAC) sponsored by an affiliate of TPG. The publicly traded company will have an initial estimated enterprise value of approximately US\$1.75 billion.

Playa owns and operates 13 all-inclusive resorts located on prime beachfront properties in leading destinations in the Dominican Republic, Jamaica, and Mexico.

Corporate partners Eve Howard, Mike McTiernan, and Bruce Gilchrist led the Hogan Lovells team, which included Paul Manca, Tifarah Allen, Tracy Branding, Weston Gaines, Jaebin Lee, Cat Schmierer, and Katherine Tyson. Gordon Wilson advised on banking. Nancy O'Neil, Scott Lilienthal, and Charlie Stones advised on tax. Martha Steinman and Michael Applebaum advised on executive compensation. Logan Breed and Robert Baldwin advised on antitrust matters. Jon Talotta advised on litigation. T. Clark Weymouth and Roy Liu advised on international trade and investment.

Hogan Lovells also advised Playa in its acquisition of the initial portfolio in 2006 and Playa's corporate reorganization and financing transaction in 2013.

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

**MUNIZ**

ASSISTS PRIVATE EQUITY FUND NEXUS GROUP ACQUIRE MAJORITY STAKE IN GAMING COMPANY

**LIMA, December 2016:** Peru's Muñiz Ramírez Pérez-Taiman & Olaya have helped Peruvian private equity fund Nexus Group buy a majority stake in lottery, sports betting and gaming operator Intralot de Perú. Nexus Group is a subsidiary of Peruvian conglomerate Intercorp, which operates in the banking, insurance, retail, construction and education sectors.

Nexus bought 80% of Intralot de Perú's capital stock from its former parent company, Athens-based Intralot Group. The near-US\$70 million purchase took place over the Lima Stock Exchange.

The deal closed on 25 November.

Local counsel to Nexus Group Muñiz Ramírez Pérez-Taiman & Olaya led by Partners Mauricio Olaya and Juan Carlos Vélez in Lima.

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

**TOZZINIFREIRE**

ADVISES KIRIN IN SALE OF RIO BOTTLING PLANT TO AMBEV

**SAO PAULO:** The deal was announced on 4 November. Ambev paid approximately 486 million reais (US\$149 million) in stock for the plant located northeast of Rio in Cachoeiras de Macacu.

Counsel to Brasil Kirin led by TozziniFreire Advogados Partner Jun Oyafuso Makuta and associate Roberta Graziela dos Santos Aronne; In-house counsel – Leandro Ambiel.

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

**SIMPSON GRIERSON**

ADVISES SHANGHAI MALING ON PURCHASE OF A 50% INTEREST IN SILVER FERN FARMS

**AUCKLAND, 06 December 2016:** Simpson Grierson has advised China's Shanghai Maling Aquarius Co. Ltd, on the purchase of a 50% interest in Silver Fern Farms for an investment of around \$260m.

Partner James Hawes says this is one of the most high profile deals in New Zealand in recent years.

"It is hoped that the tie up will provide a platform for Silver Fern to expand its export business in China, and bring business to New Zealand."

Silver Fern Farms is New Zealand's largest processor, marketer and exporter of lamb, beef, venison and associated products, selling to more than 60 countries.

Shanghai Maling is a related company of Bright Food, China's largest food company.

Simpson Grierson's team was led by partners Peter Hinton and James Hawes, and included Jaron McVicar and Matt Smith.

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

**NAUTADUTILH**

ASSISTED LONZA GROUP WITH ITS ACQUISITION OF CAPSUGEL SA

NautaDutilh recently assisted Swiss pharmaceutical manufacturer Lonza Group AG (LONN:VTX) with its acquisition of Capsugel SA, a Luxembourg holding company, from private equity firm KKR & Co LP for USD \$5.5 billion in cash, including the refinancing of approximately USD \$2 billion in Capsugel debt. The transaction was financed with a combination of debt and equity, and the parties signed the acquisition agreement on 15 December 2016.

Capsugel manufactures empty, two-piece hard capsules and finished dosage forms for drug delivery. With approximately 3,600 employees, it serves more than 4,000 corporate customers in over 100 countries and owns and operates 13 manufacturing sites, three of which also house R&D centres of excellence (including one in Bornem, Belgium).

NautaDutilh advised on all Belgian and Luxembourg legal aspects of the deal including due diligence, deal structure, share purchase agreement, etc.

Our team was led by Elke Janssens and Maxime Colle in Belgium and Greet Wilkenhuysen and Aline Nassoy in Luxembourg.

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



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April 22—25, 2017

Hosted by Hogan Lovells

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PRAC EVENTS



PRAC 59th INTERNATIONAL CONFERENCE 21 - 24 MAY 2016



PRAC @ Vancouver 2015





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

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22 DEC 2016

# The cost of dealing with employee information theft

BY CAMERON GASCOYNE AND ZOE GIFFARD

The SAI case highlights the importance of being vigilant and acting promptly and decisively to minimise the risk and impact of information theft.

The cost of taking prompt and decisive action to contain the impact of information theft by an employee may be significant, but the alternative could be much worse.

When SAI Global discovered that its former employee, Liam Johnstone, had taken SAI's customer list with him to a competitor, it took action in the Federal Court (SAI Global Property Division Pty Ltd v Johnstone [2016] FCA 1333).

The Court's decision focused on who should bear the cost of that action, and although it was not all good news for SAI, it was probably a cost worth bearing.

## **Confidential information goes missing**

SAI is a leading provider of integrated search, settlement and conveyancing software and services in Australia. It employed Mr Johnstone as a business development manager. When Mr Johnstone resigned to work for a competitor, he was asked to attend an exit interview at which SAI gave him a letter reminding him of his confidentiality obligations to SAI. Mr Johnstone returned the laptop that had been supplied to him by SAI, and went on gardening leave.

SAI was suspicious about Mr Johnstone's conduct and had his laptop forensically examined. SAI discovered files had been copied to a USB device three days before Mr Johnstone resigned. The files included SAI's confidential customer list.

## **A fight without much of a fight**

SAI immediately commenced legal action against Mr Johnstone in the Federal Court. The court ordered that Mr Johnstone provide an affidavit setting out details of the SAI information he had taken and used, and that he not delete any SAI information from any device in his possession. He was also ordered to deliver up these devices to the court.

Mr Johnstone realised the game was up. He promptly signed an affidavit admitting he had copied SAI's information and used it to identify which of SAI's customers were also customers of his new employer. He said he had not contacted any customers, or provided SAI's information to his new employer. He also handed up to

the court a USB device and laptop belonging to him containing SAI's information. A laptop belonging to his new employer was also delivered up. SAI, not having any particular reason to trust Mr Johnstone, had these devices forensically examined too.

### **Damages = \$5,001**

Mr Johnstone admitted all material wrongdoing and there was little dispute about the facts. The real issue was what orders the court should make, particularly relating to damages and costs.

SAI could not show it had suffered any loss or Mr Johnstone had made any profit from the wrongful use of its confidential information, so it did not pursue damages for that.

The SAI customer list was a copyright work so SAI sought, and Mr Johnstone agreed to, nominal damages of \$1 for infringement of copyright.

SAI also sought and obtained \$5,000 additional damages due to the flagrancy of the infringement.

### **SAI legal costs = \$275,459**

SAI sought a further order that Mr Johnstone pay its legal costs. Costs are calculated using a court scale and, as a rule of thumb, a successful party can expect to recover about 60% of its actual costs from the unsuccessful party.

SAI's costs came to the grand total of \$275,469, most being incurred after Mr Johnstone admitted fault. Mr Johnstone submitted that there was no need for SAI to incur further costs after he complied with the court's orders.

The court disagreed. It was reasonable for SAI to have the USB drive and laptops delivered up by Mr Johnstone forensically examined, which accounted for \$34,411. The court also said it was reasonable for SAI to pursue the matter to a final hearing, given Mr Johnstone continue to dispute some issues, which accounted for a further \$158,106. These costs, however, were out of proportion to the importance and complexity of the matter, and so ordered they be discounted by 50%.

Based on these orders, Mr Johnstone likely ended up having to pay about \$120,000 of SAI's costs, plus his own costs. That left SAI having to pay about \$155,000 of its costs, despite being successful on nearly every point.

### **Expensive, but still worth doing**

It is difficult to say what SAI could have done differently to avoid this outcome. The most robust security measures are unlikely to stop a determined employee from stealing confidential information. An employee who takes confidential information cannot be trusted, so any assurances they give once caught will hold little weight. The potential loss to SAI if the information had been misused could have been substantial. SAI no doubt decided that thorough and vigorous legal action to prevent that was justified. And it cannot be forgotten that Mr Johnstone will still have to pay a substantial amount of money.

Despite the significant cost to SAI of pursuing Mr Johnstone, businesses in a similar situation would need to weigh up the potentially greater losses that might flow from not acting. The case highlights the importance of being vigilant and acting promptly and decisively to minimise the risk and impact of information theft, and sends a strong message to other employees that information theft will be taken seriously.

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December 20, 2016

**Newsletter - Brazil - Implementation of online proceedings for software registration sent to public consultation**

The Brazilian Patent and Trademark Office (INPI) opened a public consultation on the implementation of a new electronic system for software registration. Any interested parties may send, until February 3, 2017, their inputs and suggestions to the INPI. Following the new rule, once the electronic system is launched, the paper filing will be extinguished.

According to the INPI, the new mechanism will provide greater legal certainty and efficiency to the software registration processes. If the application complies with all the formalities imposed by the legal rules, the INPI expects to publish such application within seven days from its filing.

It is worth highlighting that in the new procedure the maintenance of the software will be user's responsibility and no longer the Office. The INPI will only keep a digital summary (Hash code), created from the original software source code. If, later, the software is modified, it will give rise to a new Hash code, which will differ from that originally maintained by the INPI. This practice will ensure the protection of the specific filed program.

Anyone who is interested in submitting suggestions shall fill in the electronic form of the INPI and send it by e-mail. The implementation of the new system is scheduled for the first half of 2017.

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## Cybersecurity: United States Federal Trade Commission Strikes Again; Foreshadowing of things to come in Canada?

December 20, 2016 | Ruth Promislow and David Cassin

The United States Federal Trade Commission ("FTC") strikes again. In the action by the FTC involving the cybersecurity breach of Toronto-based AshleyMadison.com (operated by Ruby Corp. and hereafter referred to as "**Ashley Madison**"), a settlement has been reached.

The settlement concludes an investigation by the FTC, and participating states, into Ashley Madison's unfair and deceptive practices regarding misrepresentations made to its customers, which were exposed in its notorious data breach in July 2015. The settlement, which was announced by the FTC on December 14, 2016, requires Ashley Madison to pay a fine of US\$1.6 million to settle the FTC and state investigations.<sup>1</sup>

This FTC action against Ashley Madison is a recent example of the enforcement actions commenced by the FTC against U.S. companies for failing to adequately safeguard their consumers' personal information.<sup>2</sup>

Over the past 10 years, the FTC has repeatedly exercised its authority to regulate cybersecurity in the United States. Since 2014, the FTC has commenced 18 enforcement actions relating to data security.<sup>3</sup>

Penalties and fines levied by the FTC are not insignificant. In particular, in December 2015, the FTC levied fines of US\$100 million against LifeLock, in part for misrepresentations it made to customers regarding the protection of their private information.<sup>4</sup> Prior to the LifeLock fine, the FTC made headlines by imposing a US\$22.5-million fine on Google for its 2012 data breach.<sup>5</sup>

### The Complaint and Settlement

The FTC's complaint against Ashley Madison alleged that the company engaged in deceptive and unfair practices. In particular, the FTC alleged that the company had weak security practices including:

- failing to adequately train company staff and management on data security duties;
- failing to have a written security policy; and
- failing to monitor and verify the effectiveness of security measures.<sup>6</sup>

In addition, the FTC alleged that Ashley Madison made a number of misrepresentations about its data security, including:

- that it took reasonable steps to ensure the website was secure;
- that it received a 'Trusted Security Award' (which appeared to have been fabricated);
- that certain communications received by users were from actual women when in fact they were from computer bots; and
- that it deleted user profile information for users who paid for a 'Full Delete' of their profile.<sup>7</sup>

The settlement reached between the parties originally required Ashley Madison to pay US\$17.5 million.<sup>8</sup> However, as a result of the company's inability to pay the total settlement amount, the parties agreed for an immediate payment of US\$1.6 million to be divided evenly amongst the states and the FTC.<sup>9</sup> The settlement with Ashley Madison also requires the company to maintain a comprehensive information security program, and obtain biennial data security assessments.<sup>10</sup>

Despite the ultimate fine of US\$1.6 million being considerably lower than those awarded in the LifeLock and Google breaches, the settlement still sends a clear message to businesses who fail to take reasonable steps to protect consumers' data: it will come at a significant cost.

#### Foreshadowing of Canadian Regulatory Enforcement

The FTC's basic consumer protection authority is grounded in section 5 of the *Federal Trade Commission Act*.<sup>11</sup> Section 5 provides that unfair or deceptive acts or practices in or affecting commerce are unlawful.<sup>12</sup> The FTC's jurisdiction under this section with respect to data security enforcement actions has been specifically upheld by the Third Circuit Court of Appeals.<sup>13</sup>

In Canada, the Competition Bureau investigates and oversees complaints of unfair or deceptive practices and enforces the provisions of the *Competition Act*.<sup>14</sup> If the Competition Bureau finds a company non-compliant, it can initiate enforcement proceedings before the Competition Tribunal or before a civil court. Upon application by the Commissioner of Competition, the court can order a corporation with unfair or deceptive practices to pay an administrative penalty of up to \$10 million and, for each subsequent order against that corporation, an amount of up to \$15 million.<sup>15</sup>

Canada's Competition Bureau has not sought to regulate cybersecurity through its authority to oversee unfair or deceptive practices. However, as Canadian businesses continue to be exposed to cyber-attacks, the FTC's success in policing cyberspace in the United States may be influential in ushering in a new era of cyberspace regulatory enforcement by the Competition Bureau in Canada.

Businesses operating in Canada should not rule out the risk of significant administrative penalties levied by the Competition Bureau upon failure to take adequate measures to protect personal data from cybersecurity attacks.

#### Notes:

<sup>1</sup> Federal Trade Commission, "Operators of AshleyMadison.com Settle Charges", (14 December 2016).

<sup>2</sup> The Federal Trade Commission has brought over 60 enforcement actions related to data security breaches since 2000, see: Federal Trade Commission, Data Security Cases.

<sup>3</sup> See: Federal Trade Commission, Data Security Cases.

<sup>4</sup> Federal Trade Commission, "LikeLock to Pay \$100 Million", (17 December 2015).

<sup>5</sup> Federal Trade Commission, "Google Will Pay \$22.5 Million to Settle FTC Charges", (9 August 2012).

<sup>6</sup> Complaint, *Federal Trade Commission v Ruby Corp. et al*, (Case No: 16-CV-02438), at para 31 (Complaint).

<sup>7</sup> Complaint at paras 46-56.

<sup>8</sup> "A.G. Schneiderman Announces \$17.5 Million Settlement", (14 December 2016).

<sup>9</sup> "Ashley Madison Owner Reaches \$1.6 Million Settlement", New York Times (14 December 2016).

<sup>10</sup> Stipulated Order, *Federal Trade Commission v Ruby Corp. et al*, (Case No: 16-CV-02438) at p.4-7.

<sup>11</sup> 15 USC § 45.

<sup>12</sup> *Federal Trade Commission Act*, s5(a)(1).

<sup>13</sup> *Federal Trade Commission v Wyndham Worldwide Corporation*, Case No. 14-3514 (3d Cir. 2015).

<sup>14</sup> *Competition Act*, RSC 1985, c C-34, at s. 74.01.

<sup>15</sup> *Competition Act*, s 74.1(1)(c)(ii).



## Law No 20,950 – Authorizes the issuance and operation of pre-funded payment methods by non-banking entities

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Law No 20,590 (the “**Law**”), that authorizes the issuance and operation of pre-funded payment methods or any other similar system (the “**Prepaid Cards**”), by non-banking entities, when these systems involve that the issuer or the operator regularly engages in monetary obligations with the general public or to specific sectors or groups thereof, was published and came in force on October 29, 2016.

Its main provisions are the following:

### Requirements to incorporate Issuers or Operators

The non-banking Prepaid Card issuers or operators (the “**Issuers**” and the “**Operators**”, respectively) must be incorporated as special purpose corporations according to Law No 18,046, and their exclusive corporate purpose must be the issuance or operation of Prepaid Cards. The Operators may also be incorporated as bank supporting companies, according to the General Banking Act.

The Law also modifies Law No 18,772, empowering the Republic to issue and to operate pre-funded payment methods, establishing a special regulation applicable to Metro S.A. (the Santiago underground train).

### Common rules to Issuers and Operators

- Both are subject to the supervision of the Superintendence of Banks and Financial Institutions (“**SBIF**”) and both are required to report to the Financial Analysis Unit (the Chilean AML entity), when corresponds.
- The Chilean Central Bank will dictate rules to set their minimum operational requirements: paid up capital and minimum reserves, liquidity, risk management and control, among others.

- The Issuers can operate their own Prepaid Cards.
- The requirement to have an exclusive corporate purpose shall not prevent the entity from issuing or operating different types of payment methods.

#### System Operation

##### *(i) Receipt of money from the public*

The Issuers are empowered to receive money from the public, which can only be used to:

- Make payments for the use of the Prepaid Cards;
- Charge the correspondent commissions;
- Reimburse the funding received from the cardholder.

##### *(ii) Applicable regime to the deposited money*

The cardholders' money shall be accounted for and kept segregated from any other operations performed by the Issuer. It will not accrue interests or indexations in favor of the cardholder.

These funds shall not be confiscated nor can be subjected to injunction or any other ownership limitations arising from obligations assumed by the Issuer different from those described in (i) above.

The funds must be kept in the Issuer's account or be invested in financial instruments authorized by the Chilean Central Bank.

The cardholder may redeem the funds at any time.

##### *(iii) Prepaid Cards Issuance*

The Issuers may issue Prepaid Cards either in a nominative form or to the bearer, according to the following:

a) Nominative Prepaid Cards: They can be issued without a determined term of validity. The funds that the cardholder delivers to the Issuer are subject to expiration, under Article 156 of the General Banking Act, which broadly states that such sums must be transferred to the national treasury after 5 years of inactivity.

b) Prepaid Cards to the bearer: They must always be issued with a term of validity. When this term expires, the cardholder has a 6 month term to redeem the funds, and if this does not occur, the Issuer must transfer the funds to the Regional or Provincial Treasury of its main primary domicile.

*(iv) Use of Prepaid Cards*

The Law does not regulate the businesses in which the Prepaid Cards can be used, or its national or international character, so we expect that the Chilean Central Bank and the SBIF will clarify this matter at a later date.

Despite these changes to the law, passengers' access to the public transportation system shall continue to be regulated by the Chilean Transport and Telecommunications Ministry.

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## China passes controversial Cyber Security Law

November 2016

# China passes controversial Cyber Security Law

China's Cyber Security Law, which will take effect from 1 June, 2017 was finally adopted on 7 November. The third draft of the law adopted by the Standing Committee of the National People's Congress, China's highest legislative authority, contained few changes from the second draft put forward for comment in July, 2016 (see our [briefing](#)). The net result is ongoing controversy coupled with uncertainty, with multi-national businesses in particular questioning the intent behind the law and criticising its vagueness. The final draft contains a number of broadly-framed defined terms that are critical to its interpretation which continue to leave much to be resolved through detailed measures that may or may not follow. All in all, the direction of travel is towards a much more heavily regulated Chinese internet and technology sector, with an open question as to whether China's cyber space will be truly integrated with the rest of the world in the coming years.

## A Quick Recap

The Cyber Security Law's seventy-nine articles address a wide range of issues, but as previously noted we see particular focus on three main aspects:

- **Technology regulation:** The Cyber Security Law seeks to regulate what technology can or cannot be used in China's cyber space, including by: (i) imposing requirements for pre-market certification of "critical network equipment" and "specialised security products"; and (ii) designating certain systems as "critical information infrastructure" that will be subject to national security reviews and detailed measures to be issued by the State Council. The concern here is whether there will be a protectionist slant to these measures that will make it difficult for foreign players to compete.
- **Co-operation with authorities:** The Cyber Security Law imposes duties on "network operators" to provide technical support and assistance in national security

and criminal investigations and to retain weblogs for at least 6 months.

- **Data Localisation:** The Cyber Security Law requires operators of "critical information infrastructure" to store personal information and "important data" within China, save where it is truly necessary to send this data offshore and the offshoring arrangements have cleared a security assessment process that is yet to be defined. Revisions in the final draft broaden the scope of personal data from "citizen's person data" to "personal data", suggesting that personal information of foreigners in China will also be subject to the localisation requirement, which does little to reassure foreign residents who may need to move data across borders for any number of good reasons.

## Continuing Uncertainty as to Scope

Obligations under the Cyber Security Law attach to two main classes of business: "network operators" and operators of "critical information infrastructure." Neither of these terms are defined in any detail under the new law, leaving much room for speculation and interpretation.

"Network operators" are defined as an "owner or manager of any cyber network and network service providers," casting a potentially very wide net for the obligations to maintain weblogs and co-operate with authorities noted above. "Critical information infrastructure" is ultimately left to be defined by the State Council, but is stated in the Cyber Security Law to be critical infrastructure relating to critical industries, being public communications and information services, energy, transportation, water conservancy, finance, public services, e-government affairs and other significant industries and sectors, as well as any other infrastructure that may jeopardise national security, the national economy, people's livelihoods or the public interest were it to be destroyed, experience a loss of functionality or data leakage. Ultimately it is a subjective test.

Following the recent inspection of critical information infrastructure carried out by the

Office of the Central Leading Group for Cyberspace Affairs, (often referred to as the Cyberspace Administration of China (the "CAC")) (the "Cyberspace Inspection"), the CAC moved to define "critical information infrastructure" by reference to a three step process, beginning with the identification of critical businesses, then identifying information systems and industrial control systems that ensure the functioning of those businesses and then finally identifying the degree to which these businesses are vulnerable to attack in relation to specific items of infrastructure forming part of their systems.

In its press release on the Cyberspace Inspection, the CAC set out a non-exhaustive list of critical businesses within each of the critical industries identified. In relation to telecommunications and internet sector, a wide swathe of facilities and non-facilities-based services are identified, from voice, data, basic internet networks and hubs, through to domain name resolution systems and data centre and cloud services. A section headed "business platforms" refers to instant messaging, online shopping, online payments, search engines, e-mail, BBS, maps and audio/video services. To give context to the degree of materiality envisaged in the wake of the Cyberspace Inspection if, for example, they have over one million average daily visitors or if a cybersecurity breach would affect the life and work of over one million people, web sites are considered to be critical information infrastructure for critical businesses. Corresponding examples applicable to online platforms are RMB10 million in direct economic loss due to a cyber security breach or the loss of personal data of one million people.

In addition to key definitions such as "network operator" and "critical information infrastructure", the scope of certain obligations under the Cyber Security Law lacks precision in many areas. It is not clear, for example, the extent of technical assistance that "network operators" will be obliged to provide in support of national security and criminal law investigations. Does this encompass, for

example, directions to install "back doors" in technology that would enable uninterrupted access by law enforcement to data and communications? Similarly, what security assessment will need to be applied to proposals to offshore personal information and important business data collected or created by critical information infrastructure? These are fundamental issues for many of the foreign investors in this area.

### **Changes in the Third Draft**

The final version of the Cyber Security Law passed on 7 November contains few changes from the second draft presented in July, but there are nonetheless some important points to note. The first two drafts of the law defined "personal information" by reference to Chinese citizens. The version of the law adopted by the Standing Committee eliminates this reference, meaning that provisions in the Cyber Security Law addressing personal data will apply to citizens and foreign nationals alike. In some respects this amendment is non-controversial. For example, obligations on network operators to keep personal data secure and a general prohibition on the unlawful sale of personal data, both of which now provide assurances to foreign nationals. The data localisation requirement applying to the personal data of foreign nationals as well as Chinese citizens is, conversely, more controversial. Amendments to Article 12 expand on the previously tabled requirement that cyber networks not be used to threaten national security by including a prohibition against using such networks to pose threats to the reputation or interests of the state.

An amendment to Article 21 clarifies that specific regulations will be issued prescribing how weblogs are meant to be maintained by "network operators" for at least 6 months. In several cases there have been increases to the level of fines applicable to offences under the Cyber Security Law. A notable amendment to Article 64 extends the liability of "network operators" infringing privacy rights to personal liability for individuals directly in charge of the operator and other directly responsible persons,

a formulation more often seen in the criminal law context.

## Implications

China's Cyber Security Law has drawn significant criticism since the first draft was tabled. Multi-national businesses have expressed grave concerns over the potential for discriminatory application of the law to foreign technologies and equipment, as well as over data localisation requirements that hamper efficiencies and may be counter-productive to information security. Human rights and free speech advocates see in the Cyber Security Law a further tightening of state control of China's media and communications infrastructure, especially against the broader background of new restrictions on internet publishing (see our [briefing](#)).

It is difficult to reconcile the Cyber Security Law with China's move to integrate with the global economy and gradually open the technology services sector to wider foreign participation. It is not clear, for example, whether or not foreign technologies will continue to meet the requirements for use in critical information infrastructure in China, and to what extent there will be official or unwritten requirements for "back doors" that may ultimately compromise security and intellectual property rights. There are also worrying parallels between the requirements under the Cyber Security Law and requirements for the use of state-approved "secure and controllable" technologies in the financial services sector (see our [briefing](#)), the concern here being that foreign technologies may be deemed incapable by their nature of being "secure and controllable" or that achieving certifications against such standards may involve the disclosure of source code and other trade secrets or standards that only domestic players can meet.

More broadly, the Cyber Security Law escalates concerns that China is pursuing a course where its domestic internet becomes something isolated and detached from the global internet. This is already true to a degree in relation to internet content, which is heavily censored in China. The thrust of the Cyber Security Law is

to expand the monitoring to the infrastructure level, with implications for technical standards and interoperability. If the result is that businesses in China are required to operate using technologies that meet China's security standards but do not meet international standards, there is a threat that networks in the rest of the world will be even more reluctant to interconnect due to security concerns. What this could mean for the international growth of China's fast-growing technology sector remains to be seen.

There is some evidence that China is alive to the need to react to the widespread international criticism. Chinese Premier Li Keqiang remarked during his August 2016 visit to the US that China will communicate with foreign companies to seek to find effective approaches to co-operation in cyber security matters. Some progress on this front may be seen in the CAC's opening of its Technical Committee 260 to participation by foreign technology businesses. Amongst other responsibilities, Technical Committee 260 is tasked with developing standards that will be applied under the Cyber Security Law.

## Practical Next Steps

It is clear that businesses operating in China must review their technology and data arrangements in the light of the implications of the Cyber Security Law coming into effect on 1 June 2017. Technology businesses will need to review their Chinese business strategies and evaluate whether or not their products and services fall within the scope of the new requirements and if so, for example, will be subject to some form of certification or worse still, face exclusion from the market. They also need to consider matters such as the nature of personal data collected in China and how and where this data is stored.

Businesses in other sectors will need to evaluate their technology use in China across a range of fronts, including:

- the impact of the Cyber Security Law on the available options for technology procurement in China and what the range of options means in terms of performance,

functionality, cyber security and other matters;

- the interoperability of onshore systems with offshore networked systems;
- options for data server locations; and
- potential knock-on effects of the Cyber Security Law for related areas of regulation, such as the encryption regulations and telecommunications licensing.

Businesses in the financial services sector, in particular, will need to consider the Cyber Security Law in the context of their specific technology risk management regulations, with an eye in particular to the move towards "secure and controllable" technology requirements, which to those in the know, have set something of a worrying precedent.

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## Colombian Central Bank Issues Opinion on Close-out-netting registration

On November 10, 2016 the Colombian Central Bank (“CCB”) issued Opinion JDS-24326 regarding registration of derivatives transactions (the “Opinion”). The opinion was issued in the context of commodities derivatives.

The Opinion established the position of the CCB on the correct way to carry out registration of derivatives transactions for the enforceability of close-out-netting of derivatives transactions with Colombian counterparties, under Article 74 of Law 1328 of 2009.

The CCB stated that derivatives transactions may not be reported on a consolidated basis as a single purchase operation and a corresponding sale operation covering all the corresponding transactions; on the contrary, registration must be made on an individual basis for each transaction entered into. According to the CCB, this is intended to ensure the correct tracing of each individual operation, as well as any modifications thereto, and it also enables the close-out-netting under the law.

The Opinion is also important because it helps to reiterate the possibility to register commodities derivatives under Colombian law, with a view to ensuring the correct application of close-out-netting for this type of derivatives.

It is worth mentioning that in March, 2016, the CCB had already modified External Regulation DODM-144 to include an explicit reference to commodities derivatives over prices of the following underlying products (among others): climate and greenhouse gas emissions.

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## client alert

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21 DECEMBER 2016

### SAPIN II ACT'S IMPACTS ON COMMERCIAL RELATIONSHIPS

The Act No. 2016-1691 of 9 December 2016 on transparency, anti-corruption and economic modernisation (known as "Sapin II Act") was published in the Official Journal on 10 December 2016 and entered into force on 11 December 2016.

The main innovations in economic law are the following.

#### **MULTIANNUAL FRAMEWORK AGREEMENT**

From 1 January 2017, the Sapin II Act introduces the opportunity for professionals to conclude a framework agreement for a period longer than one year (for two or three years maximum).

The multiannual framework agreement shall specify the conditions for the review of the agreed price<sup>1</sup> as determined by the parties. Article L.441-7 of the French Commercial Code indicates that "*these conditions can provide for the taking into account of one or more public indices reflecting changes in the production factors price*".

The deadline for concluding the framework agreement (whether annual or multiannual) remains 1 March 2017 (or within two months of the start of the marketing period for products or services subject to a particular marketing cycle).

#### **FRAMEWORK AGREEMENT IN THE AGRICULTURAL SECTOR**

The transparency of negotiations on the purchase or sale of unprocessed agricultural products for which a written contract<sup>2</sup> is required (i.e. sheep, milk, and fresh fruits and vegetables<sup>3</sup>) has been reinforced as follows:

- suppliers (and agricultural cooperatives) must include in their general terms of sale the average provisional price offered to the producer of the agricultural products. The criteria and methods for determining the provisional price may refer to one or more public indices of cost-of-production in agriculture, and one or more public indices of food product retail prices<sup>4</sup>.
- contracts of less than one year entered into by a supplier (or an agricultural cooperative) and a distributor for the design and production of food products in accordance with the particular needs of the purchaser shall include the price or the criteria and detailed rules for determining the purchase price of the products used in such food products<sup>5</sup>.

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<sup>1</sup> Article L.441-7, I, paragraph 5 of the French Commercial Code

<sup>2</sup> Article L.631-24 of the French Rural and Maritime Fishing Code

<sup>3</sup> Articles R.631-8 and R.631-12 of the French Rural and Maritime Fishing Code

<sup>4</sup> Articles L.441-6, I, paragraph 6 of the French Commercial Code

<sup>5</sup> Article L.441-10 of the French Commercial Code.

The Sapin II Act also limits the amount of promotional benefits for certain agricultural products to 30% of the value of the unit price scale, including management fees. The products concerned are milk, dairy products, fruit and vegetables (with the exception of ware potatoes) intended to be sold fresh to consumers, fresh meats, frozen poultry or rabbit meat, eggs and honey<sup>6</sup>.

## PAYMENT PERIOD

The Sapin II Act introduces a new maximum 90-day payment period from the date of issuance of the invoice for the VAT-free<sup>7</sup> payment of goods intended for delivery outside the EU, unless they are carried out by large companies<sup>8</sup>. This payment period must be expressly stipulated by contract and must not constitute manifest abuse towards the creditor<sup>9</sup>.

As a reminder, the maximum contractual payment period in principle remains at 60 days from the date of issuance of the invoice. By way of derogation, the parties may also agree to a period of 45 days end-of-month (45 days + end of month, or end of month + 45 days)<sup>10</sup> from the issuance of the invoice, provided that this period is expressly stipulated by contract and does not constitute manifest abuse towards the creditor<sup>11</sup>.

The Sapin II Act also increases the amount of the administrative fine applicable to legal persons in the event of non-compliance with the payment terms from EUR 375,000 to EUR 2 million<sup>12</sup>, and provides for automatic publication<sup>13</sup>. This fine no longer represents an upper limit when several administrative fines are imposed on the same author in the event of simultaneous infringements<sup>14</sup>.

## LATE PENALTIES IN CASE OF FORCE MAJEURE

The list of restrictive practices is increased in order to oversee, in line with Article L.442-6 of the French Commercial Code, professionals subjecting, or attempting to subject, a trading partner to late penalties in the event of force majeure<sup>15</sup>.

As a reminder, "*there is a case of force majeure pertaining to contracts when an event beyond the control of the debtor, which could not be reasonably foreseen upon entering the contract and whose effects cannot be avoided by appropriate measures, prevents the performance of the debtor's obligations*"<sup>16</sup>.

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<sup>6</sup> Article L.441-7, I, paragraph 9 of the French Commercial Code and Article D.441-2 of the French Commercial Code.

<sup>7</sup> Article 275 of the French General Tax Code.

<sup>8</sup> For the definition of "large company", see Decree No. 2008-1354 dated 18 December 2008 on the criteria used to determine a company's category for purposes of statistical and economic analysis.

<sup>9</sup> Articles L.441-6, I, paragraph 15 and L.443-1 paragraph 8 of the French Commercial Code.

<sup>10</sup> See background note of the DGGCRF dated 22 October 2014.

<sup>11</sup> Article L.441-6, I, paragraph 9 of the French Commercial Code.

<sup>12</sup> Articles L.441-6, VI and L.443-1 of the French Commercial Code.

<sup>13</sup> Article L.465-2, V of the French Commercial Code.

<sup>14</sup> Article L.465-2, VII of the French Commercial Code.

<sup>15</sup> Article L.442-6, I, 13° of the French Commercial Code.

<sup>16</sup> Article 1218 paragraph 1 of the French Civil Code.

## PRICE REVISION OR RENEGOTIATION CLAUSES

The restrictive practices of Article L.442-6 of the French Commercial Code now also cover a professional's decision to enforce a price review or renegotiation clause in reference to one or more public indices that are not directly related to the products or services that are the subject to the agreement.

This prohibition applies to all types of commercial relations<sup>17</sup>, including those pertaining to certain agricultural products (perishable or resulting from short production cycles, live animals, carcasses, aquaculture products and staple food products resulting from the first processing of such products)<sup>18</sup>.

## INTERNATIONAL PURCHASING ORGANISATIONS

The Sapin II Act adds to the list of abuses provided under article L.442-6, I of the French Commercial Code, as regards advantages that may not apply to any commercial service actually provided or that are patently disproportionate to the value of the service provided, the remuneration for services rendered by an international purchasing organisation<sup>19</sup>.

## INCREASED PENALTIES

The Sapin II Act reinforces the sanction mechanisms applicable to restrictive practices by increasing the civil fine from EUR 2 million to EUR 5 million<sup>20</sup> and by providing for the automatic publication of fine decisions<sup>21</sup>.

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<sup>17</sup> Article L.442-6, I, 7° of the French Commercial Code.

<sup>18</sup> Article L.441-8 of the French Commercial Code.

<sup>19</sup> Article L.442-6, I, 1° of the French Commercial Code.

<sup>20</sup> Article L.442-6, III of the French Commercial Code.

<sup>21</sup> Article L.442-6, III of the French Commercial Code.

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## **COMPETITION REGULATIONS MAKE THEIR WAY INTO GUATEMALA**

“Competition Regulations” also referred to as “Antitrust Regulations” aim to ensure that fair competition exists in open market economies. They prevent “anti-competitive” behavior of traders that offer goods and services in specific markets. Said branch of Law has been implemented in some legal systems with the execution of rules of public nature, and in some others, with the execution of rules of private nature. The objective of regulating this matter is for the competition between agents to be developed in accordance with the principles of good faith on commercial practices.

The impact of signing international treaties has led to the execution of legal reforms in Guatemala. Competition regulations are included in such reforms; therefore, Guatemala is internationally committed to adopt regulations to promote the defense of free competition.

Guatemala must implement a new and complete legal regime for Competition; otherwise, the breach of international treaties may lead to international claims of non-compliance. There are also economic reasons for said implementation. Most of Guatemalan trade relations with its most important sources of exchange depend on the execution of such regulations.

Thus, several legal proposals have been presented recently by different governmental authorities in Guatemala. The most analyzed proposals in the Guatemalan practice have distinctive features; however, they have the following common notes: (a) they create a governmental authority to supervise the Competition in Guatemala; (b) they implement administrative procedures for its strict control; and (c) they establish violations, administrative sanctions, fines, penalties and prescription terms.

Legislative proposal number 5074, which was approved by the Congress of the Republic of Guatemala on November 29, fulfills these common characteristics. Such proposal states the following fundamental objectives: a) an increase of the country's economic efficiency through competition by vigorous competition among suppliers operating in domestic markets for goods and services, and b) an improvement of the consumer welfare through an adequate supply of goods and services that become more competitive in quality and price.

The Congress approved the proposal with the reserve of reviewing and discussing the articles one more time. They also will have a final review of the whole project. The above mentioned legislative proposal has been criticized by opponents with the following arguments: a) the governmental authority that the law creates is “independent” and it “should depend” on the Ministry of Economy. B) The law states an obligation for judges to apply the principles of Competition law in their judgments and “such obligation should not exist” because this branch of law is “specialized” and cases on this matter should remain on the jurisdiction of the governmental authority created by the same law. C) And third,

sanctions may be “confiscatory” because of the vagueness of the regulation, opponents state that such articles must be reviewed and clarified for the law to be in accordance with the Constitution.

Guatemala's commitment is to have the law drafted and implemented in its legal system by the end of 2016, so we are waiting for the Congress of the Republic of Guatemala to discuss and review the approved proposal for it to come in force as soon as possible.

Please do not hesitate to contact us for more information.



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21/10/2016

**DRAFT LAW ON DRUG AND FOOD SUPERVISION**

The Government has submitted a draft law on Drug and Food Supervision ("Bill") to the House of Representatives, just in time following the recent uncovering of the counterfeit vaccine and drugs scandal. The Bill has been included in the 2015-2019 National Legislative Program, even though it is not placed in the priority category for the year 2016.

Serving as an umbrella for regulations on supervision of foods and drugs, the Bill covers a wide range of aspects of the supervision, among others:

- a. Production;
- b. Distribution;
- c. Export and Import;
- d. Promotion and Advertising;
- e. Laboratory Testing, Recalls and Disposal;
- f. Liabilities; and
- g. Criminal Sanction.

The following is noteworthy:

- a. Pursuant to its definition, "Drugs and Foods" includes: (i) Drugs, (ii) Drug Raw Materials, (iii) Herbal Drugs, (iv) Herbal Extracts, (v) Cosmetics, (vi) Health Supplements, and (vi) Processed Foods (including packaged foods and ready-to-serve foods).
- b. The Bill shows the government's intention to expand and strengthen the role and authority of the National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan or "BPOM"). Under the Bill, BPOM replaces the role of the Ministry of Health in granting Pharmaceutical Manufacturing Licenses (Izin Industri Farmasi), Pharmaceutical Wholesaler Licenses (Izin Pedagang Besar Farmasi), and Cosmetic Manufacturing Licenses (Izin Industri Kosmetik). Processed foods manufacturing licenses are still granted by referring to the Industrial Business License issued by the Ministry of Industry.
- c. The BPOM will maintain its current role as issuer of Drugs and Foods marketing authorization (izin edar).
- d. The Bill emphasizes the previous BPOM requirement that the information stated on drug and food product labels be objective, comprehensive, correct and not misleading.
- e. The Bill stipulates the following drug distribution channeling:

Pharmaceutical industries		<ul style="list-style-type: none"> <li>a. Pharmaceutical wholesalers; and</li> <li>b. Governmental pharmaceutical stock storage facilities.</li> </ul>
Pharmaceutical wholesalers		<ul style="list-style-type: none"> <li>a. Other pharmaceutical wholesalers;</li> <li>b. Pharmacies;</li> <li>c. Governmental pharmaceutical stock storage</li> </ul>

		facilities; d. Hospital pharmaceutical facilities; e. Clinic pharmaceutical facilities; f. Drugstore, except for prescribed drugs; and g. Scientific institutes
Governmental pharmaceutical stock storage facilities		a. Other governmental pharmaceutical stock storage facilities; b. Government-hospital pharmaceutical facilities; c. Public Health Centers (Puskesmas); and d. Clinic pharmaceutical facilities.

- f. The Bill allows online distribution of Drugs and Foods, provided that the licensing, manufacturing and labeling standards and requirements are complied with. However, it is still unclear as to whether there are restrictions on the online distribution, given the restrictive nature of prescribed drugs.
- g. In addition to the usual import licenses (API), Drugs and Foods exporters and importers are required to obtain an export/import certificate (Surat Keterangan Impor) from the BPOM.
- h. The promotion and advertising of Drugs and Foods products require the approval of BPOM. The scope of BPOM's authority in this is still unclear.
- i. Marketing authorization holders are obliged to recall Drugs and Foods products (i) which do not meet the standards and/or (ii) which marketing authorization is revoked. The Head of BPOM has the authority to announce Drugs and Foods products which are being recalled from circulation.
- j. Drugs and Foods manufacturers must ensure the safety, quality and efficacy of their products. Failing to do so may cause the manufacturer to face a tort claim.
- k. The sanctions imposed on corporations for violations of certain responsibilities, obligations or requirements under this draft law are 3 (three) times heavier than the sanctions for the same violations imposed on individuals.

The Bill is currently being deliberated between the Government and the House of Representatives. When it has become a law, its implementing regulations will still need to be issued by the BPOM. (By: *Adri Yudistira Dharma*)

## NOW EVERYONE CAN FLY ... WITH LESS HEADACHES! \*

A review of the Malaysian Aviation Consumer Protection Code 2016

### INTRODUCTION

The aviation industry today is increasingly diverse and competitive, with airlines of different business models offering a wide range of fare structures and service levels to suit the different travel needs of consumers. Generally, the market place consists of low cost carriers (“LCCs”), which provide basic, no frills-service at competitive prices and full service carriers (“FSCs”), which offer a comprehensive array of services at premium prices. However, it is increasingly difficult to pigeon-hole airlines into the traditional categories of LCCs or FSCs as airlines of one category have adopted some practices of the other category and evolved their business models over time.

As air travel becomes more accessible to the public, especially with the proliferation of low cost travel options, the issue of safeguarding consumers’ interests has attracted increasing attention. The Malaysian Government has chosen to specifically regulate airline service standards by introducing the Malaysian Aviation Consumer Protection Code 2016 (“Code”) under the Malaysian Aviation Commission Act 2015, and removing it from the purview of the Consumer Protection Act 1999. The Code, which came into operation on 1 July 2016, aims to strike a right balance between protecting passengers and industry competitiveness.

### FRAMEWORK OF THE CODE

The Code consists of six Parts, with Parts II to IV containing the core provisions of the Code. The main thrust of these provisions is further examined below.

Part II consists of paragraphs 3 to 9 of the Code, which deal with the minimum service levels and the standards of performance for airlines and aerodrome operators.

#### *Paragraph 3 – Full disclosure of air fare*

An airline shall indicate the final price of the air fares to be paid and shall clearly itemise at least the following: (a) government taxes and fees; (b) fees and charges imposed by the Malaysian Aviation Commission (“Mavcom”); (c) passenger service charges; (d) security charges; (e) baggage fees; and (f) fuel charges.

#### *Paragraph 4 - Prohibition on post-purchase price increase*

An airline is prohibited from increasing the price of an air fare after it has been sold, unless the increase is due to taxes or fees imposed by the government or fees imposed by Mavcom and the consumer is notified of the potential price increase and has consented to it before completing the purchase.

#### *Paragraph 5 - Prohibition on automatically adding on services*

Automatic adding of any optional services to a consumer’s purchase is strictly prohibited. Any optional services, such as flight insurance, must be communicated in a clear, transparent and unambiguous way at the start of any reservation process and acceptance must be on an opt-in basis only.

#### *Paragraph 6 - Identity of operating airline*

A contracting airline must inform its consumers of the identity of the operating airline during reservations and specify such obligation in its general terms of sale. If there is a change of an operating airline after the reservation for any reason, the contracting airline must take immediate steps to ensure the passenger is informed of the change as soon as practicable.

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\* This article was first published in LEGAL INSIGHTS 3/16.

## *Paragraph 7 - Disclosure of terms and conditions*

An airline is to disclose all terms and conditions of the contract of carriage to the consumer prior to the purchase of the ticket. These terms and conditions must also be printed or attached to the ticket, boarding pass or incorporated by reference.

## *Paragraph 8 – Communication of change in flight status*

An operating airline shall inform the passengers and the public of any change in the status of a flight (i.e. cancellation of flight, delay of 30 minutes or more or a diversion) as soon as practicable after it becomes aware of the same.

## *Paragraph 9 – Non-discrimination of person with disability*

An airline shall not refuse to: (a) accept a reservation for a flight departing from an aerodrome which is subject to the Code; or (b) embark a person with disability at such aerodrome, if that person has a valid reservation.

However, an airline may refuse to accept the reservation or embark a person with disability if such refusal is to meet safety requirements or the size of the aircraft's doors makes it physically impossible to do so. In such event, the airline is obliged to immediately inform the person concerned of the reasons for the refusal and if requested, provide the reasons in writing within five working days from the request.

An airline which refuses to accept a reservation or embark a person with disability on one of the permitted grounds stated above must make reasonable efforts to propose an acceptable alternative to the person concerned, failing which that person is to be offered, *inter alia*, compensation and care as prescribed under the First Schedule of the Code.

The Code also sets out specific procedures and timelines on the airlines when they are notified of the need for assistance by a person with disability and places an obligation on the airlines to provide assistance to such person upon arrival or transit at the aerodrome. The Code also requires an aerodrome operator to provide structural amenities and facilities to enable a person with disability to take the flight.

Part III consists of paragraphs 10 to 16 of the Code, which deal with passengers' rights.

## *Paragraph 10 – Entitlement to claims*

The Code defines a person who is entitled to claim compensation and care as a passenger who has a confirmed reservation on the flight and presents himself for check-in at the stipulated time by the airline or has been transferred to another flight by an airline from the flight for which he held a reservation.

The instances where a passenger can make a claim for compensation and care are set out below:

- (a) *Paragraph 12* – A passenger is entitled to claim compensation and care in certain instances of flight delay or cancellation.

For a flight delay of two hours or more, a passenger is to be offered, free of charge, meals, refreshments, limited telephone calls and internet access. If a flight is delayed for five hours or more, the passenger must be offered, free of charge, hotel accommodation where stay becomes necessary and transport between the airport and the place of accommodation.

Where a flight is cancelled, a passenger is to be offered a choice between: (i) reimbursement, within 30 days, of the full amount of the ticket price (including taxes and fees) for the part of the journey not made and for the part already made, if the latter serves no purpose in relation to the passenger's travel plans; or (ii) re-routing under comparable conditions to his final destination, subject to the availability of seats at no extra cost. Alternatively, if the passenger agrees, the operating airline may provide a flight to an airport alternative to that for which reservation was made, at no extra cost.

- (b) *Paragraph 11* - When a passenger has been denied boarding (except on grounds such as health, safety or security, or inadequate travel documentation), he is entitled to claim all of the compensation and care applicable to a flight that has been delayed or cancelled.
- (c) *Paragraphs 13 and 16* - Where baggage does not arrive on the same flight as the passenger arrived in, or is destroyed or lost, the liability of the operating airline is limited to 1,131 Special Drawing Rights (a form of monetary currency created by the International Monetary Fund based on a basket of major currencies) for each passenger unless the passenger has made, at the latest at check-in, a special declaration of interest in delivery at destination and has paid a supplementary fee. In such event, the carrier will be liable to pay a higher liability limit. These provisions largely codify the requirements under Article 22 of the Montreal Convention.
- (d) *Paragraph 14* - Where mobility equipment or assistive devices of the passenger are lost or damaged, the passenger is to be compensated based on the prevailing market price of the device.

Part IV consists of paragraphs 17 and 18 of the Code, which deal with consumer complaints.

#### *Paragraph 17 – Complaints to airline and aerodrome operator*

An airline or aerodrome operator must make available the contact details of the department where a consumer may lodge a complaint pertaining to their services. The airline or aerodrome operator is required to acknowledge receipt of a complaint within 24 hours and to send a substantive written response and provide resolution to the complainant within 30 days from receipt of the complaint.

#### *Paragraph 18 – Complaints to Mavcom*

Consumers may lodge a complaint to Mavcom pertaining to any aviation service within one year from the date of the accrual of the cause of complaint.

Mavcom may, within seven days of receipt of the complaint, reject or accept the complaint. Mavcom may reject a complaint which: (i) it finds to be frivolous or vexatious; or (ii) does not relate to the civil aviation industry; or (iii) is subject to court proceedings which was commenced before the complaint was lodged with Mavcom; or (iv) has been decided by the court.

If Mavcom accepts a complaint, it will forward the same to the aviation service provider, with instructions to provide a substantive written response to the complainant which sets out a resolution within 30 days from the receipt of the forwarded complaint by the aviation service provider. Mavcom may order the aviation service provider to provide a remedy to the complainant if the aviation service provider does not respond to the complaint or its written response is inadequate or insufficient to address the complaint.

A decision by Mavcom is registerable and enforceable as a decision of the High Court pursuant to section 73 of the Malaysian Aviation Commission Act 2015.

## **CONCLUSION**

The provisions of the Code are in line with the core principles formulated by the International Air Transport Association (IATA), which include the following: (a) that regulations should be clear; (b) that passengers are always kept informed; (c) that efficient complaint handling procedures are to be established; and (d) that a passenger's entitlements are to be proportional in a situation of service breakdown.

The Code is a welcomed addition to consumer protection in Malaysia. It has been reported that consumers are unhappy that Mavcom is considering charging up to RM1 per passenger to fund its operations in the near future ("Mavcom Decisions Legally Binding but Consumer Groups Aren't Happy", *The Star*, 19 July 2017). While it is understandable that consumers would prefer not to pay, the proposed sum may be a small price to pay for the additional protection under the Code. True to AirAsia's iconic tagline, "Now Everyone Can Fly" with less headaches.

Shannon is a Partner in the Construction and Engineering Practice Group of SKRINE. He is also an accredited mediator on the panels of the Malaysian/Singapore Mediation Centres.



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## LEGAL UPDATE

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### MINIMUM WAGE INCREASE

On December 19<sup>th</sup>, 2016, the Council of Representatives of the National Commission of Minimum Wages (“CONSAMI”) published in the Federal Official Gazette (“DOF”) the resolution fixing the general and professional minimum wages effective as of January 1<sup>st</sup>, 2017, same which had been announced by the media earlier this month.

CONASAMI determined the following:

- To grant an extraordinary increase of \$4.00 pesos to the general minimum wage, known as **Independent Recovery Amount** (“MIR”), to reach \$77.04 pesos per day, with the objective of gradually and steadily recovering the purchasing power of workers earning minimum wage.
- To grant an increase of 3.9% to the general and professional minimum wages, resulting in \$80.04 pesos per day.

The above mentioned increases will become effective as from January 1<sup>st</sup>, 2017.

It should be noted that CONASAMI has reiterated in several occasions, including the resolution at issue, that the referred increases are not cumulative and, therefore, under NO circumstances, but especially in salary revision bargaining processes to be held during the following year, employers and unions must consider a 9.58% increase to the minimum wage. The increase should be limited to 3.9% only. CONASAMI also recommends that contractual wage negotiations be carried out within the specific conditions of each company, taking into account their productivity, competitiveness and the need to generate decent jobs.

Finally, CONASAMI resolved that the List of Professions, Trades and Special Works in force during 2016 will remain unchanged with respect to the definitions and descriptions of said activities and professions.

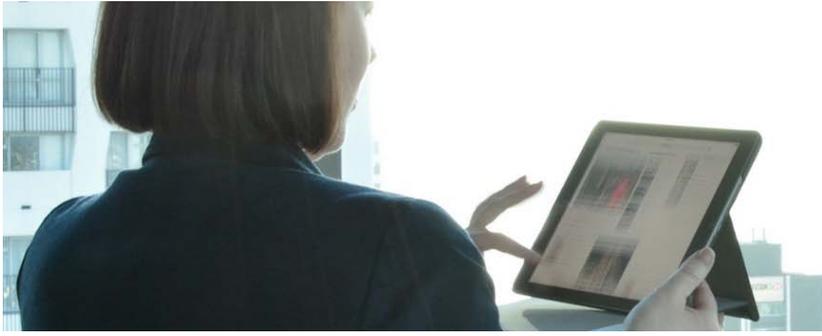
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## **Takeovers Panel expands exemption for small code companies**

December 16, 2016

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**The Takeovers Panel has expanded its class exemption from the Takeovers Code for small unlisted companies. This means that a wider range of share transactions may be undertaken without incurring the costs of full compliance with the Code.**

The class exemption applies to a "small Code company", which is a company that has:

- a. fifty or more shareholders and fifty or more share parcels on issue; and
- b. total assets not exceeding \$20 million (which, for most companies, is calculated as at the end of the most recently completed accounting period for the company).

Under the Takeovers Code, a person must not increase the percentage of voting rights they hold or control in a Code company beyond 20%, except in a manner permitted by the Code. The permitted transactions include full or partial takeover offers, or acquisitions, or allotments of shares that are approved by the Code company's shareholders. A special meeting of the company must be convened if the transaction requires shareholder approval, and the company must commission an independent adviser's report for the shareholders. This process involves significant compliance costs for the company.

Under the new class exemption, the directors of a small Code company may, on behalf of the company, opt out of the approval requirements, if they consider it to be in the best interests of the company to do so. The company must notify its shareholders of the opt out, and must provide certain details of the transaction that will take place under the opt out. Shareholders then have the opportunity to object, and to require the company to undertake full compliance with the Code. This occurs if shareholders representing 5% or more of the voting shares in the company (excluding the parties to the proposed transaction and their associates) notify the company of their objection.

The Panel had previously limited the class exemption to allotments of shares. The expanded exemption now includes acquisitions, and buybacks of shares.

"It's great to see the Panel taking further steps to reduce compliance costs for unlisted SMEs", corporate partner Andrew Matthews says. "The expanded class exemption is likely to be of particular interest to large shareholders who wish to exit from their holding in a small Code company or those who wish to facilitate a small shareholder exiting by buying their shares."

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## ECJ Ruling on the requirement of control for FCA's

Thursday 15 December 2016

### Introduction

*On 10 November 2016, the European Court of Justice (the "ECJ") rendered a judgement on the interpretation of the requirement of 'possession or control' for financial collateral arrangements ("FCA's") (C-156/15ECLI:EU:C:2016:851, Private Equity Insurance Group/Swedbank). This ruling is important because it could be argued that the ECJ's interpretation of the requirement of possession or control differs from the interpretation given to it in Netherlands legal practice and literature. In this newsletter, we will discuss the ruling and its consequences for the Netherlands practice. Firstly, we will describe what FCA's are and what the requirement of possession or control entails.*

### FCA's and the requirement of possession or control

Under an FCA, certain financial assets, such as cash and securities, are provided as collateral by means of (i) the creation of a right of pledge or (ii) a title transfer. Title 7.2 of the Netherlands Civil Code ("NCC") contains certain provisions on FCA's. This title implements Directive 2002/47/EC on financial collateral arrangements (the "Directive").

The Directive is only applicable if the collateral is brought "in the possession or under the control of the collateral taker". However, the Directive does not specify when the requirement of possession or control is satisfied. The Directive does provide that a right of substitution (the replacement of collateral with other collateral, for instance to replace cash for securities) and a right to withdraw excess collateral (the release of collateral when the value of the collateral is higher than the value of the secured obligation) for the collateral provider shall not prejudice "possession or control".

The requirement of possession or control has not been included in the Netherlands legislation implementing the Directive. Based on the parliamentary documents, it was assumed in practice and literature that it would be sufficient for obtaining "possession or control" that the collateral taker could, in case of default of the collateral provider, deprive the collateral provider of the right to dispose of the collateral. Such clauses are therefore commonly included in FCA's governed by Netherlands law.

### ECJ ruling on the requirement of possession or control and its interpretation

In the case that was brought before the ECJ, it concerned a right of pledge created on cash held in a current account for the benefit of the bank where that account was held. The ECJ assessed whether, in this case, the requirement of possession or control was met. The ECJ indicated what is required for "possession or control":

*"It follows that the taker of collateral, such as the collateral at issue in the main proceedings, in the form of monies lodged in an ordinary bank account may be regarded as having acquired 'possession or control' of the monies only if the collateral provider is prevented from disposing of them."*

The ECJ does not elaborate on how the collateral provider can be "prevented from disposing" over the cash.

In our view, a distinction can be made between two scenarios: (i) the collateral taker is granted a contractual right to (whether or not in the event of default of the collateral provider) prevent the collateral provider from disposing over the cash and (ii) the collateral provider is prevented from disposing over the cash as a matter of fact.

In light of the opinion of the Advocate General Szpunar of 21 July (ECLI:EU:C:2016:586) it could be argued that it follows from the ruling that the requirement of possession or control (merely) requires that the collateral taker should have the contractual right to prevent the collateral provider from disposing over the monies (scenario (i) above).

It cannot however not be excluded, and the wording of the ruling seems to support this view, that the requirement of possession or control should be interpreted so as to entail that the collateral provider is deprived of the right to dispose over the cash (scenario (ii) above) and that the ECJ's interpretation is therefore stricter than that of the Advocate General. In this scenario, a clause pursuant to which the collateral taker can only deprive the collateral provider of its right of disposal in case of default – a clause common in FCA's governed by Netherlands law - would not be sufficient to constitute "possession or control". A possibility to conform to scenario (ii) is to block the account in which the collateral is deposited.

For the avoidance of doubt, parties could agree that the collateral provider does have a right of substitution or right to withdraw excess collateral (see above under "FCA's and the requirement of possession or control"). According to the Directive, such rights do not prejudice "possession or control" and the ruling does not impact this.

Finally, we note that in our view the interpretation given by the ECJ on the requirement of possession or control applies mutatis mutandis to scenarios in which (i) the collateral does not consist of cash, but of securities and (ii) the account is held with a third party instead of with the bank which is also the collateral taker.

## **Impact**

The question arises what the impact of the ruling for collateral arrangements governed by Netherlands law is that do not satisfy the requirement of possession or control.

The requirements for creating a right of pledge over collateral are laid down in Book 3 NCC. In legal practice and literature, it is assumed that, in the context of a so-called disclosed pledge over cash and securities, the collateral provider can be granted a right to dispose over the collateral. This means that, under Netherlands law, even when parties intend to create a FCA-pledge, but the requirement of possession or control has not been satisfied, generally, a valid right of pledge will nonetheless have come into existence.

Although the collateral arrangement will usually be valid, not satisfying the requirement of possession or control does have consequences for the collateral taker:

- Firstly, in the event of insolvency of the collateral provider, it cannot invoke certain safeguards for FCA's, such as the inapplicability of (i) the retroactive effect of insolvency to 00.00 hours and (ii) a possible freeze.
- Secondly, it is not possible for the parties concerned to agree that the collateral taker will be granted certain powers, such as (i) a right of use (the right of the collateral taker to dispose over the collateral as if it were legally entitled to the collateral) and (ii) a right to appropriate securities provided as collateral in case of default of the collateral provider. Such clauses are invalid if the collateral arrangement does not constitute an FCA.

## **Final remarks**

As described above, the ECJ ruling on the requirement of possession or control may have implications for both existing FCA's and FCA's that will be concluded in the future. In light thereof, it is advisable to check whether these FCA's satisfy the requirement of possession or control under the stricter interpretation of scenario (ii), what the impact is when the requirement is not met and whether measures should be implemented with respect to existing collateral arrangements in order to satisfy the aforementioned requirement.

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## Foreign E-commerce Operators to File Tax Registration and Pay VAT in Taiwan Soon

12/29/2016

Josephine Peng/Dennis Yu

Under Taiwanese business tax laws, sellers are in general the payer of business tax (also known as value-added tax or VAT). However, in a case where the seller is a foreign entity without a fixed place of business (FPB) within Taiwan and sells services in Taiwan, the Taiwanese service purchaser becomes the payer of the VAT payable on such services; if the service fee is less than NT\$3,000 or the purchaser is a VAT operator, the 5%VAT is exempt.

With the fast growing digital economy, while many foreign e-commerce operators (FEOs) provide electronic services to Taiwanese individuals, most, if not all, do not establish any FPB in Taiwan; instead, they either engage an affiliate or a third party to provide the so-called auxiliary or soliciting services. Technically, the VAT on the service fees generated by these FEOs should be paid by the Taiwanese individuals; however, in practice, individuals rarely pay 5% VAT on the service fees that they pay to the FEOs. Such non-payment of VAT not only means a loss to the national coffers but is also unfair to Taiwanese e-commerce operators as they are required to pay 5% VAT on their sales revenue while FEOs without FPB in Taiwan are not.

In response, the Ministry of Finance (MOF) proposed amendments to the Business Tax Act, most of which are based on the recommendations made by the Organization for Economic Co-operation and Development and the approaches adopted by EU members, Korea and Japan. The Executive Yuan (Cabinet) approved the amendments on 14 September 2016 and forwarded them to the Legislative Yuan (Legislature) for review and approval.

The Legislative Yuan passed the amendments to the Business Tax Act ("Amendments") on December 9, 2016, and authorized the Executive Yuan to set a date for implementation. The Amendments are expected to take effect in mid 2017.

The Amendments include the addition of three provisions and revision to nine provisions. The key points of the Amendments are as follows:

- I. Those FEOs without FPB in Taiwan that are selling electronic services to Taiwanese individuals are deemed business operators and VAT taxpayers in Taiwan (Articles 2-1 and 6 of the Business Tax Act);
- II. The replacement of the term "Business Registration" with "Tax Registration" (Article 28 of the Business Tax Act).
- III. FEOs must file a tax registration with the Taiwan tax authorities [like Taiwanese business operators], file VAT returns and pay the VAT payable in due course, if their annual sales meet the threshold [to be set by the MOF], or engage a tax agent to do so on their behalf (Article 28-1 of the Business Tax Act);
- IV. The abolishment of the VAT exemption for service fees of under NT\$3,000 ((Article 36 of the Business Tax Act); and
- V. A penalty will be imposed on a FEO's tax agent if the tax agent fails to, on behalf of the FEO, file a tax registration or VAT return or pay VAT (Article 49-1 of the Business Tax Act).

The Amendments do not cover certain issues; for example, what constitutes electronic services and whether FEOs are required to issue government uniform invoices for the service fees received from Taiwanese individuals. We expect that the MOF will clarify these issues when it amends the Enforcement Rules of the Business Tax Act.



# Ideas

## IRS Clarifies Earlier Guidance on Production Tax Credit Safe Harbors

05 January 2017

### Updates

On December 15, 2016, the Internal Revenue Service (the “[IRS](#)”) issued Notice 2017-04 (the “[Notice](#)”), which clarifies earlier guidance with respect to safe harbors available for determining when construction of a facility has begun such that the taxpayer is eligible for the renewable electricity production tax credit (“[PTC](#)”) or to elect the investment tax credit (“[ITC](#)”) in lieu of the PTC.

### 1. Background

In December 2015, Congress extended the PTC under Section 45 of the Internal Revenue Code of 1986, as amended (the “[Code](#)”), for two years with respect to certain facilities (e.g., biomass facilities, geothermal facilities and certain hydropower facilities) the construction of which begins before January 1, 2017, and wind facilities the construction of which begins before January 1, 2020. The same legislation also instituted a phase-out of the PTC for wind facilities. Under this phase-out, for wind facilities that commence construction during 2017, the amount of the PTC will be reduced by 20%. For wind facilities that commence construction during 2018, the amount of the PTC will be reduced by 40%. For wind facilities that commence construction during 2019, the amount of the PTC will be reduced by 60%. We discussed these extensions and limitations along with other impacts of the legislation on renewable energy tax credits in a prior client update, which can be found [here](#).

Under Section 48 of the Code, a taxpayer may elect the ITC in lieu of the PTC with respect to these facilities. To be eligible for the PTC (or the ITC), construction of the qualifying facility must begin before the appropriate date (the “[Commencement of Construction Requirement](#)”). In Notice 2013-29, the IRS provided two alternative tests under which a taxpayer may meet the Commencement of Construction Requirement: the “[Physical Work Test](#)” and the “[Five Percent Safe Harbor](#).” In either case, the taxpayer must make continuous progress towards completion of the facility (the “[Continuity Requirement](#)”). Notice 2013-29 was the subject of a prior client update we issued on April 17, 2013, which can be found [here](#).

In Notice 2013-60, the IRS provided a safe harbor (the “[Continuity Safe Harbor](#)”) under which a taxpayer is deemed to meet the Continuity Requirement if the facility was placed into service before January 1, 2016. If the taxpayer does not qualify for the Continuity Safe Harbor, whether the taxpayer meets the Continuity Requirement will be based on the relevant facts and circumstances. Notice 2013-60 was the subject of a prior client update we issued on October 2, 2013, which can be found [here](#).

In Notice 2015-25 and as a result of the Congressional extension of the PTC, the IRS extended the Continuity Safe Harbor by one year to include facilities placed into service before January 1, 2017 if construction began before January 1, 2015.

In May 2016, the IRS released Notice 2016-31, which extended the Continuity Safe Harbor to four years from the end of the year in which construction began. Under Notice 2016-31, a taxpayer who begins construction, as measured under either the Physical Work Test or the Five Percent Safe Harbor, will be deemed to meet the Continuity Requirement if the facility is placed into service by the later of (1) a calendar year that is no more than four calendar years after the year during which construction began or (2) December 31, 2016. Notice 2016-31 also prohibited a taxpayer from effectively extending the Continuity Safe Harbor period by using the Physical Work Test in one year then using the Five Percent Safe Harbor in a following year with respect to the same facility. In addition, Notice 2016-31 provided guidance as to when facilities containing used property were qualified facilities and how the Five Percent Safe Harbor applied to such facilities. Under that guidance, a facility may be a qualified facility if the fair market value of such used property is not more than 20 percent of the facility's total value, which is the cost of the new property plus the value of the old property (the "80/20 Rule"). However, only the expenditures paid or incurred with respect to new construction used to retrofit the facility count towards satisfying the Five Percent Safe Harbor. A more complete discussion of Notice 2016-31 can be found in our June 16, 2016 client update, which is available [here](#).

## **2. Notice 2017-4 Extends the Continuity Safe Harbor**

The Notice extends the Continuity Safe Harbor to allow a taxpayer to satisfy the Continuity Safe Harbor if the taxpayer places the facility into service by the later of (1) four years from the end of the year in which construction began and (2) December 31, 2018. Under this rule, taxpayers have two more years to complete projects unlike the earlier guidance in Notice 2016-31, which set the latter deadline at December 31, 2016. While this extension has little impact on projects begun recently, it may help taxpayers who began construction on a qualifying facility several years ago but with respect to which the construction had been interrupted or delayed. For example, under Notice 2016-31, qualifying facilities construction of which began in 2012 or earlier would not qualify for the Continuity Safe Harbor unless completed on or before December 31, 2016. Now, projects begun in 2013 or earlier years can qualify for the Continuity Safe Harbor if placed in service before December 31, 2018.

## **3. Notice 2017-4 Permits Use of the Different Safe Harbors in Alternating Years in Certain Cases**

Notice 2016-31 prohibited taxpayers from relying on the Physical Work Test in one year and the Five Percent Safe Harbor in the following year to satisfy the Continuity Requirement. After issuing Notice 2016-31, IRS officials publicly indicated that the IRS may reconsider this rule. Rather than reconsider the rule in full, the Notice applies this prohibition prospectively only as of June 6, 2016, the date on which Notice 2016-31 was published in the Internal Revenue Bulletin. The prospective application of this rule implies that taxpayers that satisfied the Physical Work Test prior to 2016 and then subsequently satisfied the Five Percent Safe Harbor before June 6, 2016 (or vice versa) could benefit from the Notice by using the latter date to start the four-year period to satisfy the Continuity Safe Harbor. For example, if a taxpayer began construction January 1, 2015 under the Physical Work Test but cannot place the facility into service until after December 31, 2019, then the taxpayer cannot meet the Continuity Safe Harbor (i.e., because the placed-in-service date is more than four years since commencing construction and after December 31, 2018). However, if under the Five Percent Safe Harbor, the taxpayer

began construction on January 1, 2016, then the taxpayer may qualify for the Continuity Safe Harbor because the placed-in-service date is within four years of commencing construction.

#### **4. Notice 2017-4 Clarifies the Treatment of Retrofitted Facilities & the 80/20 Rule**

Under Notice 2013-29, the Five Percent Safe Harbor is applied by taking into account all costs properly included in the depreciable basis of the facility. The Notice clarifies that, with respect to determining whether a retrofitted facility can meet the 80/20 Rule, the costs of the new property to be taken into account includes all costs properly included in the depreciable basis of the new property, thereby including indirect costs that may be capitalized into the tax basis of the facility. This clarification aligns the application of the 80/20 Rule with the calculation of costs to determine whether the Five Percent Safe Harbor has been met.

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## California Employment Law Update: What's New for 2017

11.03.16

By William David and Judith Droz Keyes

This is our year-end assessment of the most important developments for California employers. All of the new laws are effective on Jan. 1, 2017, unless otherwise noted.

The California legislature once again had a busy session. Of the 898 bills Gov. Brown signed into law, there are few that significantly impact most California employers. However, there are important new regulations under federal law and new city ordinances that affect many California employers, as well as a California Supreme Court decision to watch for.

### ***Expansion of the Equal Pay Act***

Last year, California substantially expanded the state Equal Pay Act by creating the Fair Pay Act. It was designed to assure pay equity across gender lines for employees performing substantially similar work. This groundbreaking law has now been amended in two significant ways: AB 1676 prohibits employers from justifying a wage disparity between the sexes by relying on prior salary; and SB 1063 expands the protection beyond gender, to include wage disparities involving race and ethnicity. A more complete analysis of this law will be the subject of a DWT advisory to be issued soon.

### ***Minimum Wage and Minimum Salary Increase***

Although many California cities now have ordinances providing for a higher minimum wage than state law requires (and many of these minimums will increase in 2017), California's state-wide minimum hourly wage was set to hold steady at \$10.00 for several years. Now, SB 3 establishes incremental minimum wage increases over the next three years. Beginning Jan. 1, 2017, employers with 26 or more employees must pay non-exempt employees a minimum wage of \$10.50 per hour, with the rate reaching \$15.00 per hour in 2022. Smaller businesses are not required to begin the scheduled increases until 2018.

A significant impact of this change involves the minimum salary required to be paid to exempt employees. The California requirement has long been, and remains, two times the minimum hourly wage based on a 40 hour workweek (regardless of how many hours the exempt employee actually works). Thus, for larger employers, beginning Jan. 1, 2017, the California minimum salary for exempt employees is \$840 per week, or \$43,680 per year. By 2022, the amount will increase to \$62,400 per year.

Because the federal salary threshold for exempt employees will be higher than the California minimum salary for the next few years, most employers will need to adhere to the federal minimum. Effective Dec. 1, 2016, under the federal Fair Labor Standards Act, the minimum salary required for exempt status will jump to \$47,476. This minimum will set the floor for employers covered under the FLSA until the California minimum again exceeds it.

Another wrinkle is this: federal law includes the option of allowing up to 10% of the salary (\$4,747.60 of the minimum salary) to come from bonuses or incentive pay as long as these payments are not discretionary and are paid quarterly or more frequently. Since California has no comparable provision for bonuses and incentive pay, the most a California employer can allocate to these sources in 2017 to satisfy the federal threshold will be \$3,796, because the California minimum salary requirement will be \$43,680 in 2017.

### ***Notice to Employees of Rights Concerning Domestic Violence/Stalking***

Existing law prohibits an employer with 25 or more employees from discharging, discriminating, or retaliating

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against an employee who is a victim of domestic violence, sexual assault, or stalking because he or she takes time off from work to address the situation. AB 2337 requires that employers provide written notice of these rights to new employees upon hire, and to current employees upon request. The law obligates the Labor Commissioner, by July 1, 2017, to develop and post on its website a form notice that employers can use to satisfy this requirement. The employer's obligation commences at the time the Labor Commissioner posts the form, but no later than July 1, 2017.

### ***Expansion of Protection against Use of Prior Convictions***

California has long prohibited consideration of arrests that do not lead to conviction (except for health facility employers, who are entitled to consider arrests for certain crimes), and of certain marijuana-related convictions. AB 1843 adds a prohibition against inquiring about, or using as a factor in determining any condition of employment, an arrest, detention, or conviction that occurred while the applicant or employee was under the jurisdiction of a juvenile court. There remains an exception for health facilities, which have a right to inquire about certain juvenile offenses unless the record has been sealed by a juvenile court.

### ***Remedy for Unlawful Verification of Right to Work***

SB 1001 prohibits an employer, in the course of verifying authorization to work, from: (1) requesting more or different documents than are required under federal law; (2) refusing to honor documents that on their face appear reasonably genuine; (3) refusing to honor documents or work authorization based upon the specific status or term of status that accompanies the authorization; and (4) attempting to re-investigate or re-verify an employee's authorization using an unfair immigration-related practice.

### ***Restriction on Choice of Law in Employment-Related Agreements***

SB 1241 prohibits employers from requiring employees who primarily reside and work in California, as a condition of employment, to enter into a contract that would mandate resolving a claim (a) in a forum outside of California or (b) according to the laws of a state other than California if such a requirement would deny the employee a substantive protection of California law. Any contractual provision that is inconsistent with this law is voidable by the employee, and the employee is entitled to recover attorney's fees incurred to enforce his or her rights. This new law applies only to contracts entered into, modified, or extended on or after Jan. 1, 2017, and does not apply to contracts where the employee is individually represented by legal counsel during negotiations. This law is likely to have the greatest impact on employers headquartered outside of California, who may wish to have disputes resolved in and according to the law of the state where the home office is located.

### ***Mandatory Retirement Savings***

SB 1234, the "California Secure Choice Retirement Savings Trust Act," will require employers to do the following:

1. Either offer an employer-sponsored retirement plan or enable their employees to make a direct payroll contribution to the employee's personal state-sponsored Secure Choice Retirement account;
2. provide state-developed information about the program to their employees; and
3. transmit a payroll contribution to a state-selected third-party administrator.

The California Secure Choice Retirement Savings Investment Board will administer the program. Employers will not be required to enroll their employees in the program automatically. However, employers will be required to provide employees with information about the program. Before they are enrolled, employees must acknowledge, in a manner to be determined by the Board, that they understand that an automatic payroll contribution will be made unless they choose to opt-out.

In creating the program, the Board conducted a market analysis and feasibility study to determine that the program would be self-sustaining, qualified for favorable federal tax treatment, and would not be considered an employee benefit plan under the federal Employee Retirement Income Security Act (ERISA). Before the program goes into effect, regulations must be written and the Board must contract with a third-party

administrator. At the earliest, this will be accomplished by late 2018. Until then, employers need do nothing.

### ***Sick Leave Ordinances***

In addition to the California state-wide sick leave law that became effective on Jan. 1, 2015 (with accrual beginning on July 1, 2015), the following California cities now have sick leave ordinances applicable to some or all of the employees working within their boundaries: Berkeley, Emeryville, Oakland, Long Beach, the City of Los Angeles, the County of Los Angeles, San Diego, San Francisco, and Santa Monica. Often the ordinances are passed in conjunction with a higher local minimum wage. No two ordinances are exactly the same and San Francisco's was recently revised. Employers with employees in some or all of those cities or counties must comply with both state law and the applicable city/county ordinance.

Less impactful but still noteworthy are these new laws:

***Labor Commissioner Proceedings.*** AB 2899 requires an employer contesting a Labor Commissioner citation for paying less than minimum wage to post a bond in an amount totaling the allegedly unpaid wages and liquidated damages. The proceeds of the bond, sufficient to cover the amount owed, will be forfeited to the employee if the employer fails to pay the amount determined to be owed within 10 days from the conclusion of the proceedings.

***Wage Statements.*** Under AB 2535, exempt employees are expressly excluded from the requirement to include on itemized wage statements total hours worked.

***Overtime Pay/Meal & Rest Periods for Agricultural Workers.*** AB 1066 eliminates the exemption from wage and hour, and meal and rest break requirements for agricultural workers. It phases in overtime compensation requirements for these workers over a four-year schedule that varies with the employer's size.

***Gender-Neutral Bathrooms.*** Effective March 1, 2017, AB 1732 requires all single-user restrooms in any business establishment, place of accommodation, or government agency in California to be branded as all gender, and bars any single-user bathroom to be designated as male or female only.

### **Vetoed Bill**

It is noteworthy that Governor Brown vetoed SB 654, which would have required employers with 20 or more employees to provide employees meeting certain tenure requirements with 6 weeks of unpaid parental leave. Currently, this requirement pertains only to employers having 50 or more employees (and the amount of mandated leave is 12 weeks). In his veto message, Gov. Brown cited the potentially significant cost to small businesses, but stated that he was open to revisiting a revised version of the bill in the future.

### **Case to Watch**

The California Supreme Court will soon decide a case that is as important to understanding the state rest break requirement as was the Brinker case to understanding meal periods: *Augustus v. ABM Security Services Inc.* The primary issue in the Augustus case is whether or not an employee can be "on call" during a rest break, or whether the possibility of being interrupted negates the break. The Court recently heard oral argument, so a decision is expected soon.

### **Need Additional Information?**

These capsule summaries are intended to inform employers about the most significant of the new statutes and do not fully explore any of the details. For more information on about any of the new California laws relating to the workplace, please contact any of Davis Wright Tremaine's California employment lawyers.

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# On the Heels of 21st Century Cures Enactment, FDA Finalizes Medical Device Accessories Guidance

04 January 2017

*Medical Device Alert*

On December 30, 2016, the Food and Drug Administration (FDA or the Agency) issued a final guidance document entitled *Medical Device Accessories – Describing Accessories and Classification Pathways for New Accessory Types*. This guidance generally affirms the framework set forth in the Agency's January 2015 draft version, which was intended to explain that accessories may be differently classified compared to their "parent" devices and to encourage use of the de novo process to obtain Class I or Class II classification for low-to-moderate risk accessories of a new type. The final guidance provides some additional examples, as well as nuanced clarifications, but the key messages are the same and remain in line with current FDA thinking. Of note, the final policy also represents FDA implementation of the accessories provision of the recently enacted 21st Century Cures Act.

The final guidance adopts the same definition of "accessory" set forth in the 2015 draft: accessories are products that meet the definition of a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FDC Act) and are intended specifically to support, supplement, and/or augment the performance of one or more parent devices. FDA maintains that whether a product meets this definition will generally be determined by its labeling and promotional materials, rather than those of the parent device. The final guidance also maintains the scope of eligible accessories by explicitly carving out accessories of a type previously classified under the FDC Act, approved in a premarket approval order, or cleared via 510(k) premarket notification, with the latter more explicitly delineated throughout the guidance.

Consistent with the draft guidance, the final version notes that accessories may actually pose different risks than their parent device and, therefore, should be eligible for separate classification. Historically, FDA has treated accessories, unless already separately classified, as automatically falling into the same classification as the parent device. The draft, and now final, guidance documents shift this policy to allow manufacturers to more readily seek reclassification for

accessories if the risk they pose is different from that of the parent device(s). As explained in the final guidance, this means that the risks of a parent device should not be automatically imputed to the accessory; rather, FDA should evaluate the risks imposed by the accessory's impact on the parent device when used as intended and any unique risk of the accessory as an independent device. This policy change, first announced in the draft guidance, and then endorsed and required by the recently enacted 21st Century Cures Act, provides more flexibility to accessory manufacturers. It is also consistent with FDA's overall risk-based regulatory framework for medical devices generally.

Of interest, the final guidance clarifies the scope of the policy delineated therein. Specifically, the guidance in several places emphasizes the distinction between medical devices that are specifically intended for use with another device to supplement, support, or augment its performance and are therefore subject to FDA regulation as accessories, and other products that may be used in conjunction with a medical device but are not designed for that purpose. Providing some additional clarity, FDA specifically notes that products in the latter category include off-the-shelf replacement parts such as batteries which would not themselves meet the definition of a medical device, much less an accessory. The guidance also notes that device components cannot be accessories, because an accessory is a finished device and a component, by definition, is not.

While FDA's policy is not restricted to any particular type(s) of medical devices/accessories, it focuses in part on mobile health and software as an area where what satisfies the definition of accessory may be more ambiguous. For instance, the final guidance addresses *Software as a Medical Device (SaMD)*, namely "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." While SaMD that meets the definition of a medical device is subject to FDA regulation, not all such products would be considered accessories for purposes of this guidance. For example, stand-alone software programs that analyze radiological images or heart rate data may not support, supplement, and/or augment the performance of the device that generated the data, in which case they would not constitute accessories. They would likely be actively regulated by FDA, but not as accessories. However, where SaMD does meet the definition of an accessory, FDA indicates it will be subject to the same risk-based classification framework as applies for other accessories.

Finally, the guidance addresses how to obtain classification of a new accessory type via the *de novo* process. This follows the same overall approach as set forth in the draft, with an additional requirement to include an explanation for why the subject accessory does not fit within any identified classification for the parent device(s). If the *de novo* request is granted, the accessory (and its type) will be placed in Class I or Class II and FDA will publish the required Special Controls for the device type. The accessory may be marketed immediately and serve as a predicate device for future 510(k) premarket notifications. If the *de novo* request is declined, however, the accessory remains in Class III and may be lawfully marketed only pursuant to an approved PMA. The guidance appendix provides more detailed instructions on the information to be provided to FDA in this type of *de novo* request. It remains to be seen whether the *de novo* process will be an efficient regulatory tool for clearing novel accessories.

Ultimately, the final guidance does not make significant changes to the accessories classification policy proposed in the draft released nearly two years ago and now made legally binding per the recently-enacted 21st Century Cures Act. Instead, the guidance further elucidates how FDA intends to apply this regulatory framework in

practice, including discussion of some particular device types that could be affected. In the face of continuing technological innovation, particularly in the digital health space, the finalized policy should facilitate the marketing of certain accessories that, while used with high-risk devices, may themselves present a lower risk profile.

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