PACIFIC RIM ADVISORY COUNCIL

Pacific Rim Advisory Council

December 2016 e-Bulletin

MEMBER NEWS

►ARIAS Announces Branding Changes, Reinforces Strategy and Commitment to Central American Region
►DAVIS WRIGHT Launches Blockchain and Distributed Technologies Initiative
►GIDE Warsaw Strengthens Labor, Banking & Finance and Energy Infrastructure Teams
►HOGAN LOVELLS Expands Antitrust Practice With Senior DOJ Official
►SyCipLaw Announces New Managing Partner
►TozziniFreire Expands White-collar Crime Practice

COUNTRY ALERTS

►AUSTRALIA and United States Diverge on Road to Legal Liability for Automated Vehicles CLAYTON UTZ
►BRAZIL Infrastructure Opportunities in Provisional Measure 752 TOZZINIFREIRE
►CANADA 2017 ISS and Glass Lewis Updates to Canadian Proxy Voting Guidelines BENNETT JONES
►CHILE New Law to Boost Productivity CAREY
►CHINA Passes Controversial Cyber Security Bill HOGAN LOVELLS
►EL SALVADOR New Requirements Related to Money Transfer Services ARIAS
►FRANCE Default Interest Under ISDA and French Master Agreements - Lessons from Lehman Waterfall II GIDE
►INDONESIA Draft Law on Drug and Food Supervision ABNR
►MALAYSIA Review of Aviation Consumer Protection Code SKRINE
►NEW ZEALAND Director Residency Requirement Under the Companies Act SIMPSON GRIERSON
►NETHERLANDS Supreme Court Narrows VAT Exemption for Management of Real Estate Investment Funds NAUTADUTILH
►PANAMA Legislation Establishes Documentation Requirements for Offshore Entities ARIFA
►TAIWAN Amendment to Regulations Governing Tender Offers LEE & LI
►UNITED STATES
►Continued Misappropriation After May 2016 Allows Cause of Action under Defend Trade Secrets Act BAKER BOTTS
►Quarterly Securities Enforcement Briefing DAVIS WRIGHT TREMAINE
►U.S. House of Representatives Passes 21st Century Cures Act, Including Numerous Device Related Provisions HOGAN LOVELLS

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

MEMBER DEALS MAKING NEWS

►ARIAS assists in financing of bank acquisition in Guatemala
►BAKER BOTTS represents MedcoEnergi in ConocoPhillips acquisition
►BENNETT JONES assists independent members of the Board of Directors of Performance Sports Group Ltd
►BRIGARD URRUTIA assists Copec with US$747 million deal with ExxonMobil
►CAREY assists Chilean biotechnology company Phage Technologies achieve major distribution agreement with Bayer
►CLAYTON UTZ advises Tox Free Solutions on successful completion of $186m strategic acquisition and $85m entitlement offer
►GIDE advises China's Bank of Communications on establishment of its Paris branch
►HOGAN LOVELLS advises Stellwagen on sale to Acasta
►MUNIZ advises private equity fund Nexus Group with majority stake acquisition of gaming company
►NAUTADUTILH assists BNG in the issuance of its first USD sustainability Bond
►SIMPSON GRIERSON advises Shanghai Maling on purchase of a 50% interest in Silver Fern Farms
►TOZZINIFREIRE Advises Kirin in sale of Rio bottling plant to Ambev

PRAC TOOLS TO USE

PRAC Contacts   PRAC Member Directory   Events
Visit us online at www.prac.org

ARIAS ANNOUNCES BRANDING CHANGES, REINFORCES STRATEGY AND COMMITMENT TO CENTRAL AMERICAN REGION

SAN SALVADOR , November 21, 2016: Following up on our communication of November 15, in which with much enthusiasm we announced the change of our brand to Arias, we wish to reiterate our commitment to our friends, clients and the region through our seven offices in the six countries of Central America (Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica and Panama).

We also inform that all of our offices remain intact with the same lawyers and regular operations, except the Costa Rican office from which the Muñoz brothers have parted, and from now on is Arias without Muñoz, operating with total normality, with a team of 20+ lawyers who are part of the 120 lawyers of Arias throughout the region, all of them with an ethical and responsible commitment of service to our clients.

Arias has not joined or merged with any international firm. We are based on the solid model of a single firm with offices in each country in Central America and Panama. Arias is convinced that its model is the one that best responds to the needs of its clients and the community and it has been demonstrated over its 75 years of practice.

On the other hand, Arias has built close and long-lasting work and friendship relationships with the world's most prestigious law firms, relationships that we value, appreciate, respect and will continue to foster, in order to keep providing clients with comprehensive and innovative legal solutions across five continents.

Additionally, we are pleased to share with you that on November 16, our firm was honored by the prestigious "Mercados & Tendencias" Magazine, in recognition of our trajectory in the Central American market. We feel honored to have been selected among the 10 recognized companies and to be the only legal firm to receive this award. With 75 years of operation in Central America and with the seven offices operating in the region, Arias strengthens its leadership as "The Firm of reference in Central America".

For additional information visit www.ariaslaw.com

DAVIS WRIGHT TREMAINE LAUNCHES BLOCKCHAIN AND DISTRIBUTED TECHNOLOGIES INITIATIVE

Multidisciplinary Team of 33 Lawyers Advises Across Ten Industries

SEATTLE, 29 November 2016: Davis Wright Tremaine LLP today announced the launch of its Blockchain and Distributed Technologies Initiative, which brings together a multidisciplinary team of more than thirty lawyers focused on the application of blockchain technology to the various industries in which they specialize. Collectively, the DWT team provides clients with the combined expertise to successfully evaluate and implement blockchain and distributed technologies and guide them through regulatory and market challenges as they arise. The team advises start-ups and established companies across the gamut of industries, including corporate and consumer finance, music, media, energy, entertainment, healthcare, nonprofits, telecommunications and supply chains/food distribution. DWT is unique among law firms in its development of a multiregional, multi-industry, and multidisciplinary team focused on the emergence of this game-changing technology and how its application impacts the way business is conducted.

DWT's Blockchain and Distributed Technologies Initiative is led by partners Lance Koonce and Courtney Stout . Lance is a preeminent intellectual property and privacy/security practitioner in the fields of advertising, software, music, television, film, and consumer products. He has extensive experience advising clients on the implications of emerging technologies and is co-chair of the New York County Lawyers Association's Law & Technology Committee. Lance is the founder of DWT's CreativeBlockchain.com Blog. Courtney is a seasoned privacy and security attorney with over 20 years of experience advising clients in the technology, data security, and financial services industries. She is part of DWT's Breach Response Team and regularly advises clients on blockchain-related issues in the payment and security space.

"Blockchain technology will both disrupt and transform many industries," said Lance Koonce. "Its ability to securely and privately transfer anything of value without third-party intermediaries can affect how every company conducts business. In addition to advising clients in the financial sector, DWT works closely with those in other industries – such as entertainment/media and consumer products companies – that will soon begin to feel the effects of this technology. "

For more information, visit www.dwt.com

GIDE WARSAW STRENGTHENS LABOR, BANKING & FINANCE AND ENERGY INFRASTRUCTURE TEAMS

WARSAW, 14 November 2016: Gide Warsaw has recently strengthened its Labour Law, Banking & Finance and Energy/ Infrastructure teams.

Labour Law: Magdalena Kalinowska, advocate, specialising in labour law, social security issues, and immigration law. She brings Gide her vast experience on issues such as hiring and firing key personnel, including the employment of foreigners in Poland and Polish citizens abroad.

Energy, Infrastructure and Public Tenders: Dorota Derlicka, legal advisor, specialising in environmental protection law. She has extensive professional experience in advising on key investment projects, both at law firms and as an in-house lawyer at energy companies.

Banking & Finance and Project Finance: Paweł Wasiel, legal advisor, specialising in banking law and finance. He has acted on a great number of transactions involving project finance, real estate financing, infrastructure project financing (including airports, stadiums, sports and entertainment arenas, hospitals, acquisition of rail and bus fleets), and the issuing of debt instruments.

For additional information visit www.gide.com

TOZZINIFREIRE EXPANDS WHITE-COLLAR CRIME PRACTICE

SAO PAULO, 21 November 2016: Ludmila Leite Groch is the new partner at TozziniFreire Advogados' white-collar crimes practice.

Master in Criminal Law by the Law School of the University of São Paulo (USP), Ludmila has 15 years of experience working in Brazilian and foreign law offices.

She was also graduate course professor at the University Cruzeiro do Sul, between 2004 and 2006, and professor of tax criminal law graduate of the State University of Londrina (UEL) between 2008 and 2009.

Ludmila's hire reinforces the office's growth strategy, particularly those related to compliance, investigation and white-collar crime issues, practice areas which TozziniFreire is a pioneer in Brazil.

For additional information visit www.tozzinifreire.com.br

HOGAN LOVELLS EXPANDS ANTITRUST PRACTICE WITH SENIOR DOJ OFFICIAL CHRISTOPHER CASEY

WASHINGTON, 05 December 2016: Hogan Lovells announced today that Christopher H. Casey, former Deputy Associate Attorney General at the United States Department of Justice, will join the firm's Antitrust, Competition and Economic Regulation (ACER) practice as a partner in its Washington, D.C. office.

As Deputy Associate Attorney General, Chris was responsible for advising senior DOJ and Obama Administration officials on antitrust matters and was the primary interface between the Antitrust Division and DOJ leadership. He also oversaw DOJ's major financial fraud cases – including those involving the packaging and sale of residential mortgage-backed securities (RMBS) in the run-up to the financial crisis – as well as the Tax Division and the US Trustee Program.

Before working at the Department of Justice, Casey was a trial lawyer in private practice at a major firm in Philadelphia and an Assistant US Attorney and public defender. He also spent more than five years as an antitrust litigator at the Federal Trade Commission (FTC), primarily in the telecommunications, energy, chemical, and food industries.

"Chris will play a critical role in the expansion of our civil antitrust litigation practice in the US," said Suyong Kim, ACER co-head. "The first chair trial and litigation skills he gained through his experiences as a civil litigator, a criminal defense attorney and prosecutor, an antitrust enforcer at the FTC, and more recently as a high-ranking official at the Department of Justice are unparalleled and will greatly benefit our clients."

"As the new Trump administration's positions on antitrust enforcement become clearer, it will be important prepare our clients to be ready for the new administration's antitrust enforcement actions, and we do expect civil antitrust litigation to continue to grow. Chris' experience will be extremely valuable to our clients," added Janet McDavid, ACER co-head. "We welcome him to the firm."

"I look forward to bringing my trial skills, and antitrust and government agency experience, to a firm that has a broad domestic and international base," said Casey. "Hogan Lovells offers an ideal platform for me to take my practice to the next level."

Casey earned his J.D. from the George Washington University Law School, and B.A. in Mathematics from the College of the Holy Cross.

Hogan Lovells' antitrust team includes more than 135 lawyers in 17 countries who operate as an integrated team handling all aspects of antitrust law, including mergers, government investigations and cartel cases, civil litigation, and counseling.

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

SYCIP LAW ANNOUNCES NEW MANAGING PARTNER

Hector M. de Leon, Jr. is new SyCipLaw Managing Partner

MANILA, 24 November 2016: SyCip Salazar Hernandez & Gatmaitan (SyCipLaw) is pleased to announce that Hector M. de Leon, Jr. has been elected as the firm's managing partner. Mr. de Leon joined SyCipLaw in 1988 and has been a member of the firm's Executive Committee since 2014.

Mr. de Leon's practice focuses on corporate and commercial matters, with emphasis on equity investments, mergers and acquisitions, project development and finance, and similar commercial transactions. Together with the other lawyers of the firm, he worked on some of the biggest M&A transactions in the Philippines, several of which were awarded or nominated as "Deal of the Year" by international publications.

Mr. de Leon has authored or co-authored books and articles on, among others, commercial law and civil law. He is a fellow of the Institute of Corporate Directors and a member of the Tax Management Association of the Philippines.

He is a professorial lecturer at the University of the Philippines College of Law. He also worked as a legal officer at the United Nations Compensation Commission in Geneva, Switzerland. He obtained his A.B. (cum laude) and LL.B. from the University of the Philippines and his LL.M. from the University of Michigan.

Chambers Global Guide 2016 named Mr. de Leon as one of the leading lawyers in the Philippines in "Projects, Infrastructure and Energy" (Band 1). He also belongs to Asialaw's 2016 Leading Lawyers in the Philippines. For the past several years, he is mentioned in Chambers Asia-Pacific's Leading Lawyers for Business and in The Legal 500: Asia Pacific Guide to Asia's Commercial Law Firms.

Mr. de Leon succeeds Rafael A. Morales who retired as a partner of the firm in March 2016.

For additional information visit www.syciplaw.com

ARIAS

ASSISTS IN FINANCING OF BANK ACQUISITION IN GUATEMALA

GUATEMALA, November, 2016: Three Arias offices have acted as legal local counsel for Bladex, Credit Suisse and Deutsche Bank in connection with a syndicated credit facility of up to US$223,000,000.00 for Promerica Financial Corporation, destined to finance the acquisition of Citibank's credit card business and consumer banking in Guatemala. As stated in its press release, with this acquisition, Grupo Promerica strengthens its position in Guatemala, reaching total assets of US $ 1.6 billion and becoming the 7th bank (by asset size) in the country (from the current 10th position). The combined assets of Promerica Group amount to date to $ 12.3 billion.

Jorge Luis Arenales, Partner in Arias Guatemala was the lead counsel and coordinated the deal which included El Salvador and Honduras offices as well. "The importance of the transaction is that we worked together with the M&A team of both parties in order to secure local guarantees of Grupo Promerica and the target companies in all the pertinent jurisdictions prior and post-closing, depending on the authorization of the Guatemalan banking authority. The timing and guarantees structures were a significant challenge to overcome in transaction", stated Jorge Luis Arenales.

The firm provided assistance in the analysis of the local structures, due diligence, of the local entities involved; as well as the review, draft and negotiation of all relevant documents/agreements, which included, review of master credit agreement, draft local guarantees, PoAs, trust agreement, corporate resolutions, legal opinions and other documents requested by Bladex Credit Suisse and Deutsche Bank, and necessary by law.

The closing took place on October 31st, 2016.

Arias team involved: Arias Guatemala (Coordinating office) Jorge Luis Arenales, Lead Partner; Ximena Tercero, Partner; Juan José Del Pino, Senior Associate; Arias El Salvador Zygmunt Brett, Partner; Mariana Nóchez, Senior Associate; Arias Honduras Evangelina Lardizábal, Partner; Bertha Argüello, Partner in Nicaragua.

For additional information visit www.ariaslaw.com

BAKER BOTTS

REPRESENTS MEDCOENERGI IN CONOCO PHILLIPS ACQUISITION

22 November 2016: PT Medco Energi Internasional Tbk ("MedcoEnergi") today announced that MedcoEnergi has completed its purchase of ConocoPhillips Indonesia Inc. Ltd. ("CIIL") and ConocoPhillips Singapore Operations Pte. Ltd. ("CSOP"). CIIL and CSOP are subsidiaries of ConocoPhillips.

CIIL has a 40% working interest in the South Natuna Sea Block B PSC offshore Indonesia and operates that block and the 640km sub-sea West Natuna Transportation System offshore Indonesia through which gas from several blocks is delivered to Singapore. CSOP operates an onshore receiving facility in Singapore.

For additional information visit www.bakerbotts.com

BENNETT JONES

ASSISTS INDEPENDENT MEMBERS OF THE BOARD OF DIRECTORS OF PERFORMANCE SPORTS GROUP LTD IN CONNECTION WITH PROCEEDINGS UNDER THE COMPANIES' CREDITORS ARRANGEMENT ACT

- Date Announced: October 31, 2016
- Date Closed: TBD
- Deal Value: USD575,000,000
- Client Name: Performance Sports Group Ltd.

Performance Sports Group Ltd. (the "Company"), a leading developer and manufacturer of high performance sports equipment and apparel, filed voluntary petitions under Chapter 11 of the United States Bankruptcy Code in the District of Delaware and commenced proceedings under the Companies' Creditors Arrangement Act (the "CCAA") in the Ontario Superior Court of Justice in order to facilitate a financial and corporate restructuring through a going-concern sale of substantially all of the Company's assets (the "Restructuring Process").

In connection with the Restructuring Process, the Company has entered into an asset purchase agreement with an acquisition vehicle to be co-owned by an affiliate of Sagard Capital Partners, L.P. and Fairfax Financial Holdings Limited (collectively, the "Purchaser"), pursuant to which the Purchaser has agreed to acquire substantially all of the assets of the Company and its North American subsidiaries for U.S.$575 million in aggregate, assume related operating liabilities and serve as a "stalking horse" bidder through the Restructuring Process. The Purchase Agreement sets the floor, or minimum acceptable bid, for an auction under the supervision of the Courts, which is designed to achieve the highest available or otherwise best offer.

For additional information visit www.bennettjones.com

CLAYTON UTZ

ADVISES TOX FREE SOLUTIONS ON SUCCESSFUL COMPLETION OF $186M STRATETIC ACQUISITION OF $85 MILLION ENTITLEMENT OFFER

PERTH, 02 December 2016: Clayton Utz has advised ASX-listed environment, waste management and industrial services provider Tox Free Solutions Ltd (ASX: TOX) in respect of its successful acquisition of 100% of the shares and related assets of Daniels Health Pty Ltd and Daniels Manufacturing Pty Ltd, a leading provider of medical waste solutions, collection and treatment in the Australian healthcare sector.

Clayton Utz partner Mark Paganin and senior associate Stephen Neale led the firm's team, which includes partner Stuart Byrne, special counsel David Benson, senior associate Sam Fiddian and lawyers Kaley Ohariw, Thomas Parker and Annella Cox.

The acquisition, which was announced on 26 October, was completed yesterday. The total consideration for the acquisition was $186 million (subject to adjustments).

Clayton Utz also advised Tox Free in relation to its successfully completed $85 million fully underwritten 1 for 3.9 pro-rata accelerated non-renounceable entitlement offer, undertaken to partly fund the acquisition.

For additional information visit www.claytonutz.com

CAREY

ASSISTS CHILEAN BIOTECHNOLOGY COMPANY PHAGE TECHNOLOGIES ACHIEVE MAJOR DISTRIBUTION AGREEMENT WITH BAYER

SANTIAGO, November 2016: Three young Chilean biotechnologists managed to draw the attention of the German pharmaceutical giant Bayer Health Animal with its Milkeeper S product, which prevents or eradicates bacteria in animals and has been successfully used in the bovine industry.

Phage Technologies is a Chilean biotechnology company founded in 2009 by the Biotech engineers, Hans Pieringer, Diego Belmar and Nicolás Ferreira. The company has been incubated in the Science and Life Foundation of Dr. Pablo Valenzuela and supported by its Business Director, Cristián Hernández-Cuevas.

The negotiation of the distribution contract between Bayer and Phage Technologies lasted more than a year. During this time, the Chilean company was subjected to intense tests and controls run by Bayer, in order to certify the quality of its product.

Advised by Carey's partners Guillermo Carey, Cristián Eyzaguirre and Francisco Guzmán, Phage reached this important global distribution agreement, which is already being recognized as a successful case in the current Venture Capital ecosystem in Chile.

Phage creates biotechnologies to add new functions to animal and human food, developing solutions for important industry and production problems.

For additional information visit www.carey.cl

BRIGARD URRUTIA

ASSISTS COPEC WITH US$747 MILLION DEAL WITH EXXONMOBIL

BOGOTA, December 2016: Colombia's Brigard & Urrutia Abogados have helped Chilean energy conglomerate Empresas Copec reach a US$747 million deal to buy oil major ExxonMobil's lubricants and fuels business in Colombia, Ecuador and Peru. The transaction is subject to approval from Chilean, Ecuadorean and Colombian authorities.

Copec has operated an alliance with ExxonMobil in Chile since 1957. The latest agreement aims to expand the distribution of Mobil lubricants in the rest of the Andean region.

The deal is expected to close in the second half of 2017.

Colombia counsel to Empresas Copec was led by Brigard & Urrutia Abogados Partner Sergio Michelsen and associates Fernando Castillo, Tomás Holguin, Andrea Camila Cruz and Catalina Manga in Bogotá.

For additional information visit www.bu.com.com

GIDE

ADVISES CHINA'S BANK OF COMMUNICATIONS ON ESTABLISHMENT OF ITS PARISH BRANCH

PARIS, December 2016: Gide has advised Bank of Communications, China's fifth-largest commercial bank and the largest based in Shanghai, on the establishment of a branch in France of its
Luxembourg subsidiary.

Located in Paris, the new branch will offer more support to the growing number of Chinese investments in Europe. Bank of Communications currently operates in four other European countries.

Gide's advice covered all aspects of the project, including banking regulatory, corporate, tax, real estate and labour matters.

The team was led by partners Jean-Guillaume de Tocqueville in Paris and Fan Jiannian in Shanghai, with assistance from Emilie Rogey, Guillaume Jeannet, Lisa Chézé-Dartencet, Romain d'Innocente, Léonore Ville, Bai Yiran and Tang Jiale.

For additional information visit www.gide.com

HOGAN LOVELLS

ADVISES STELLWAGEN ON SALE TO ACASTA

23 November 2016: Hogan Lovells has advised new client Stellwagen group on the sale of its corporate group to Acasta Enterprises Inc. ("Acasta"), in a deal worth approximately US$270million plus contingent consideration, as part of an overall transaction for Acasta worth approximately US$900million.

Acasta has also committed to invest US$100million into Stellwagen's investment vehicles as part of the deal. Stellwagen is headquartered in Dublin and provides best-in-class asset management, financial and technology solutions to the global aviation industry.

The deal is subject to certain conditions, including regulatory approval from the Ontario Securities Commission and the Toronto Stock Exchange and the approval of Acasta's shareholders.

The cross-practice team was led by London Corporate head, Ben Higson, supported by London-based partners Don McGown and Derek Meilman, senior associate Catherine Lah, associates Nothando Malaba and Ben Coleman and trainee Nagham Al-Turaihi; antitrust and competition partner, Mark Jones and associate Aniko Adam; tax partner, Karen Hughes, and counsel, Aaron Burchell; and New York debt capital markets partner, Lewis Cohen, and counsel, Edgard Alvarez.

For additional information visit 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

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

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

NAUTADUTILH

ASSISTED BNG IN THE ISSUANCE OF ITS FIRST USD SUSTAINABILITY BOND

AMSTERDAM, 25 November 2016: NautaDutilh assisted Bank Nederlandse Gemeenten (BNG) in the issuance of its first USD Sustainability Bond. BNG's Sustainability Bonds are innovative in that the proceeds will be used to support the best-in-class sustainable municipalities in the Netherlands.

Selection of the most sustainable municipalities is based on a methodology developed in partnership with the Tilburg Sustainability Center of Tilburg University. This methodology ranks the municipalities according to their sustainability performance.

Sustainability Bonds enable investors to invest in sustainable Dutch cities via bonds whose risk level and liquidity are on a par with other bonds issued by BNG.

The NautaDutilh team consisted of Petra Zijp, Arjan Pors, Nico Blom, Antonia Netiv, Nina Kielman, Wouter Wehmeijer and Gwenn Korteweg.

For additional information visit www.nautadutilh.com

PRAC @ Hong Kong 2017
Island Shangri-La Hotel

April 22—25, 2017

Hosted by Hogan Lovells

Registration Now Open
Visit www.prac.org

PRAC EVENTS


PRAC2016
Barcelona
PRAC 59th
INTERNATIONAL
CONFERENCE
21 - 24 MAY 2016
RCD
ROUSAUD
COSTAS
DURAN S.L.P.
PACIFIC RIM


PRAC @ Vancouver 2015


PRAC @ Brisbane 2015


PRAC @ Taipei 2014


PACIFIC RIM
ADVISORY COUNCIL


PRAC @ INTA San Diego


PRAC @ IPBA Hong Kong

PACIFIC RIM ADVISORY COUNCIL

The Pacific Rim Advisory Council is an international law firm association with a unique strategic alliance within the global legal community providing for the exchange of professional information among its 28 top tier independent member law firms.

Since 1984, Pacific Rim Advisory Council (PRAC) member firms have provided their respective clients with the resources of our organization and their individual unparalleled expertise on the legal and business issues facing not only Asia but the broader Pacific Rim region.

www.prac.org

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

ABNR Counsellors at Law

Davis Wright Tremaine LLP — Defining Success Together

Estudio Muñiz — Muñiz Ramirez Perez-Taiman & Olaya Abogados

Allende & Brea Abogados

Gide — Gide Loyrette Nouel

NautaDutilh

Arias

Goodsill Anderson Quinn & Stifel — 1878 — A Limited Liability Law Partnership

Hoet Pelaez Castillo & Duque

r | b | s — richards buell sutton LLP

ARIFA — Arias, Fabrega & Fabrega

Hogan Lovells

RCD — Rousaud Costas Duran SLP

Dentons Rodyk

Baker Botts LLP

Kim, Chang & Lee

Santamarina y Steta — law solutions

Bennett Jones

Kochhar & Co. — Advocates & Legal Consultants

Simpson Grierson

Skrine

Brigard & Urrutia

理律法律事務所 — Lee and Li — Attorneys-at-Law

SyCip Salazar Hernandez & Gatmaitan

/Carey

Clayton Utz

Mulla & Mulla & Craigie Blunt & Caroe — Advocates, Solicitors and Notaries

TozziniFreire Advogados

CLAYTON UTZ

18 NOV 2016

Australia and US diverge on road to legal liability for automated vehicles

Sydney, 18 November 2016: Australia's Transport Ministers are proposing a different road to the US in allocating legal responsibility for the next generation of automated vehicles - with the Australian position favouring manufacturers over drivers, according to a new Clayton Utz report.

'*Steering the course for future driverless vehicles regulation in Australia*' critiques the regulatory reform pathway[1] approved by Australia's Transport and Infrastructure Council earlier this month. The next generation of automated vehicles is expected to be commercially available around 2020 and will allow the human driver to take his or her eyes off the road for extended periods of time.

Clayton Utz partner Owen Hayford, one of the report's key authors, said the United States' Federal Department of Transportation had gone down the road of making the entity responsible for the automated driving system - most likely, the manufacturer - legally responsible for road rule infringements caused by the vehicle once the automated system assumes responsibility for watching the road. The Australian Transport Ministers, however, think legal responsibility should lie with the human driver.

"By making the driver responsible for the vehicle, regardless of the fact the underlying driving system is automated, the driver rather than the manufacturer is more likely to be held liable for any property damage or personal injury the vehicle causes. However this may not be the case where a failure of the automated driving system, for example, is a significant contributing factor. It is highly likely that a number of factors will be relevant to the ultimate determination of liability, which means questions of liability and access to compensation for victims won't be clear cut, " said Owen.

Owen said under the current proposals, the position for manufacturers was "mixed". "While manufacturers will take less responsibility for the actions of the vehicle, they will still have to submit a safety case for the vehicle to the Australian regulator, even though the vehicle can only operate with a human driver. However manufacturers will probably consider this a small price to pay for the Australian position on liability."

Owen said the initial rationale for the Transport and Infrastructure Council's proposal of a new national safety assurance regime for automated vehicles was the absence of a licensed driver with demonstrated minimum driving competencies. However, the Council is now proposing that such a regime focus on vehicles that will still require a licensed human driver to take back control of the vehicle when requested.

"This change in position perhaps reflects an sense of unease with the idea that an automated vehicle driving system should be wholly responsible for watching the road until such systems prove themselves to be safe," said Owen, adding that creating a new legal framework for automated vehicles was not an easy exercise.

"The regulatory environment for the use of motor vehicles in Australia is complex. The National Transport Commission[2] has already undertaken some valuable work in identifying regulatory barriers for automated vehicles and options to address these. Our latest report and our 'Driving into the future: Regulating driverless vehicles in Australia' (PDF 11.8MB) report seek to build on that work and identify some of the key areas that legislators and regulators can start looking at now to ensure a clear and consistent approach to issues such as liability, access to data, cybersecurity and, at a Federal level, minimum safety standards."

[1] National Transport Commission policy paper, "Regulatory reforms for automated road vehicles", November 2016 Back to article

[2] National Transport Commission discussion paper 'Regulatory Options for Automated Vehicles', May 2016 Back to article

CONTACT US

Sydney	+61 2 9353 4000	**Melbourne**	+61 3 9286 6000
Brisbane	+61 7 3292 7000	**Perth**	+61 8 9426 8000
Canberra	+61 2 6279 4000	**Darwin**	+61 8 8943 2555

November 29, 2016

NEWSLETTER - OPPORTUNITIES IN INFRASTRUCTURE IN BRAZIL: PROVISIONAL MEASURE NO. 752

After months of discussion, the Brazilian Federal Government published last Friday (November 25) a Provisional Measure ("PM 752") establishing alternative solutions for ongoing concessions. These solutions are basically two: (i) contract term extension followed by a commitment of new investments by the concessionaire (applicable to toll-roads and railways), and (ii) the re-tendering of concession projects - including public private partnerships – PPP (applicable to toll road, railway and airports).

The main innovation brought by PM 752 is the possibility of the contracting public entity and the interested concessionaire agreeing upon the early termination of the concession agreement in force. As a consequence, the project can be re-tendered and granted to a new operator.

Only concession contracts currently under default or whose concessionaires do not have the capacity to comply with contractual obligations are eligible for early termination. Terms and conditions of the termination and of the re-tender process will be regulated on a case-by-case basis.

PM 752 also regulates the conditions under which a concession may have its term extended. The term extension can apply either at the original contractual term or during the life of the original agreement. In both cases, the concessionaire has to comply with certain conditions and request the extension at least 24 months prior to the original expiration date, unless otherwise regulated on a specific provision.

The extension on concession terms will be submitted to public consultation and to the analysis of the Federal Court of Audits prior to the Grantor's approval.
Only concessions whose current terms ranges between 50% to 90% of their original term and whose concessionaires undertake the commitment to make new investments are eligible for the early term extension set forth in PM 752. Eligibility may also depend on additional conditions, such as the commitment to new KPI levels for railway concessions; and the performance of, at least, 80% of the works initially set forth in the contract for highway concessions.

Bennett Jones

2017 ISS and Glass Lewis Updates to Canadian Proxy Voting Guidelines

November 24, 2016 | Jon Truswell, Karen Keck, Brad Markel and Kismat Nijjar

Institutional Shareholder Services (ISS) and Glass, Lewis & Co (Glass Lewis) have both released their updates to their respective Canadian proxy voting guidelines for the upcoming 2017 proxy season. The ISS updates apply to shareholder meetings of publicly traded Canadian companies occurring on or after February 1, 2017, while Glass Lewis updates apply to meetings that are held in 2017.

Recommendations from proxy advisory firms such as ISS and Glass Lewis can have a significant impact on the outcome of business conducted at shareholder meetings, especially if institutional investors comprise a significant component of the company's shareholder base. Canadian public companies should review the updates with their legal counsel to determine the likely impact and take steps to mitigate any potential adverse voting recommendations from ISS or Glass Lewis.

A. Director Overboarding Policy (ISS/GL – TSX Listed Issuers)

As we noted in our 2016 update, ISS and Glass Lewis announced tighter rules for director overboarding, which will be implemented in 2017. ISS and Glass Lewis have each adopted thresholds in which they will consider directors to be overboarded and define these thresholds for CEO's and non-CEO directors as follows:

- **CEO:** If the CEO sits on the board of more than two (>2) public companies (including the board of the company where they are CEO) for ISS and this applies to all executives for Glass Lewis.[1]
- **Non-CEO directors:** If the director sits on more than four (>4) public company boards for ISS and more than five (>5) public company boards for Glass Lewis.

ISS and Glass Lewis will make the following voting recommendations for overboarded directors:

- **ISS:** In the absence of a valid reason, ISS will issue a negative voting recommendation if an overboarded director attends less than 75% of his or her board and committee meetings.
- **Glass Lewis:** In making a voting recommendation against a specific director, Glass Lewis will consider a number of factors, including the size and location of the other public companies that the director serves as a board member, the director's role on such other boards and the attendance record of the director at each board meeting.

The Director Overboarding Policies do not apply to Reporting Issuers listed on the TSX Venture Exchange.

B. Shareholder Rights Plan Policy (ISS/GL – TSX and TSXV)

ISS and Glass Lewis have each revised their position on shareholder rights plans in light of the 2016 amendments to the take-over bid regime in National Instrument 62-104 – *Take-Over Bids and Issuer Bids* and National Policy 62-203 – *Take-Over Bids and Issuer Bids*. Among other changes, these amendments now require all non-exempt take-over bids to remain open for a minimum of 105 days (as opposed to 35 days under the old regime).

Under their updated policies, each of ISS and Glass Lewis will not support shareholder rights plans that require take-over bids to remain open for a minimum period of greater than 105 days.[2]

C. Director Compensation Practices (ISS/GL – TSX)

ISS will now recommend that shareholders withhold votes for members of the compensation committee (or potentially, the board chair or full board) if director compensation practices threaten a non-employee director's independence or are generally "problematic". Problematic director compensation practices include:

- excessive inducement grants to new directors (*i.e.*, grants that are greater than standard market practice), which could compromise such director's judgment; and
- performance-based equity grants to independent directors (*i.e.*, performance share units), which may result in the misalignment of the interests of independent directors and the interests of shareholders.

ISS has not provided guidance on what inducement grants they would consider to be "excessive" nor what performance-based equity grants may result in a "misalignment of interests."

Glass Lewis did not make changes to director compensation practices, but has previously stated that non-employee directors should receive "reasonable and appropriate" compensation and that equity grants to non-employee directors should not be tied to performance conditions.

D. Excessive Non-Audit Fees (ISS – TSX and TSXV)

ISS reviews all non-audit related fees of public companies to ensure that auditor independence is not compromised. Previously, ISS recommended withholding votes for individual directors that are members of the audit committee if the sum of non-audit fees paid to the external audit firm exceeded the sum of audit and audit-related fees. Under the new ISS updates, ISS will now issue negative recommendations against proposals to ratify auditors, and the election of individual audit committee members, if the sum of non-audit ("other") fees exceeds the sum of the audit fees, audit-related fees and tax compliance/preparation fees.

The new recommendations are rooted in a recognition by ISS that tax compliance and preparation services (two examples being the preparation of tax returns and refund claims) are most efficiently provided by a company's auditor and, consequently, such fees should not be included under "non-audit" fees for the purpose of the above calculation, while fees for tax advice, planning or consulting will continue to be included in "non-audit" fees. The ISS guidelines also note that in order for ISS to analyze whether a company's tax fees fall within its definition of "tax compliance and preparation services", companies should provide a sufficiently detailed breakdown for its tax fees.

Glass Lewis did not make any changes to its policy on non-audit fees from its 2016 policy. In its 2016 guidelines, Glass Lewis stated that it may recommend a withhold vote appointing the auditor when the sum of audit fees and audit-related fees total less than 50% of the company's overall fees to its auditor (excluding fees resulting from one-time transactions).

E. Board Responsiveness To Failed Advisory Role / Say-on-Pay (GL)

Glass Lewis is of the view that if more than 50% of the votes cast by shareholders opposed a say-on-pay proposal, shareholder concerns to such proposal should be addressed. Glass Lewis may recommend a vote against members of the compensation committees if the committee fails to address shareholder concerns.

ISS does not address say-on-pay proposals in its 2017 updates. However, in its 2016 Proxy Voting Guidelines for TSX-listed companies, ISS states that it will take into account a company's response to a say-on-pay vote that received less than 70% support.

F. Equity Compensation Plans (GL)

Glass Lewis previously opposed using the 10% rolling maximum limit typically set for Canadian stock option plans for full-value award plans (*i.e.*, restricted share plans), given the greater costs to the company of issuing such full-value awards. Under the new guidelines, Glass Lewis specifies that full-value award plans with rolling limits above 5% are excessive, and may result in a Glass Lewis recommendation to vote against such plans.

G. 2017 Pay-For-Performance Evaluation and Peer Submission (ISS)

In a separate press release, ISS announced several changes to the methodology for its 2017 pay-for-performance evaluation. For 2017, ISS will use six financial metrics (return on invested capital (ROIC), return on assets (ROA), return on equity (ROE), revenue growth, EBITDA growth and growth in cash flow from operations), along with Total Shareholder Return, to evaluate a company's performance over a three-year period. Although ISS has previously evaluated the financial performance of a company relative to its peers, this update will allow the results of the evaluation to be compiled into a standardized table, which will be helpful in determining a company's relative financial performance.

ISS also announced that a peer submission group window will run from November 28, 2016 to December 9, 2016 to allow companies to submit their self-determined peer groups to ISS. This will allow ISS to take this information into account when determining the ISS peer group.

Notes

1. The thresholds adopted by ISS and Glass Lewis for director overboarding in the context of a CEO are similar, but have been phrased differently.
2. The bid period length adopted by ISS and Glass Lewis in relation to a shareholder rights plan are similar, but have been phrased differently.

NEWSALERT

Law No. 20,956: "Law to Boost Productivity"

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Carey contact.

Moro, Felipe
Partner
+56 2 2928 2231
fmoro@carey.cl

Loyola, Juan Pablo
Associate
+56 2 2928 2231
jployola@carey.cl

Bucchi, Pablo
Associate
+56 2 2928 2226
pbucchi@carey.cl

Acuña, Gabriel
Associate
+56 2 2928 2231
gacunac@carey.cl

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

On October 26th, 2016, Law No. 20,950, otherwise known as the **"Law to Boost Productivity"** (the "Law"), was published in the Official Gazette, introducing various modifications to different laws and regulations in order **to enhance the country's productivity through the expansion of the financial system and the promotion of the exportation of services.**

Main measures for the expansion of the financial system:

- **Several legal provisions of Law Decree No. 824 (Income Tax Law – "ITL")** are modified, eliminating a number of operative obstacles with the purpose of facilitating the settlement of foreign custodians in Chile and promoting the participation of foreign investors in the financial market. To these ends:
  - The methodology for calculating interest accrued by publicly offered debt instruments referred to in Article 104 ("Article 104 Instruments") is modified in order to adjust their computation method to the particular terms of each instrument's issuance;
  - A new withholding rule is established for issuers of Article 104 Instruments, under which they are obligated by default to make a general 4% withholding over the amount of interest accrued to the date of each payment or redemption with respect to the holders, allowing local holders to use the withheld amount as an anticipated payment towards any First Category Tax or Global Complementary Tax due[1].
  - It is established that for the application of the new withholding rule, the withheld amount must be paid within five business days following the withholding date, including several legal changes to ensure that the issuer has the necessary cash flows to cover the withholding tax.
  - It is established that certain Article 104 Instruments issued by the Central Bank and the General Treasury of the Republic are exempted from the obligation of recognizing the difference over the principal balance due on redemptions or prepayments as interest.
  - Finally, issuers and other agents that act as withholding agents must inform the Chilean Tax Authority as to which withholding mode has been chosen.
- **Law No.19,983 (Governs the Transference of the Assignable Copy of an Invoice and Makes it Directly Enforceable)** is modified establishing two new scenarios in which the invoice is understood to be irrevocably accepted: a) not claiming the lack of delivery of the merchandise or the provision of the service within eight calendar days from the receipt of the invoice; and b) to expressly accept the invoice within the same term. In addition, the parties are no longer allowed to agree on a term to reject the invoice and it is stated that if the receipt has not been made within eight calendar days following its reception and there is no claim made regarding the content of the invoice or non-delivery of merchandise or provision of services, it will be presumed that the services have been provided and the merchandise delivered, leaving the bill suitable for assignment and directly enforceable, with no need for the receipt to be evidenced in the invoice. With this, a higher certainty is assured regarding the terms for the acknowledgment of receipt, thus enabling higher liquidity and lower financial costs for companies via factoring.
- **Article 45 of Law Decree No. 3,500 (Establishes the new Pensions System – "DL 3,500")**, which establishes the instruments in which Pension Fund Managers ("AFP") may invest the funds of the Pension Funds, is modified, incorporating (a) instruments, transactions and agreements representative of real estate assets, private equity, private debt, infrastructure and other types of assets that the Investment Regime might determine; and (b) bonds issued by investment funds governed by Law No. 20,712. In both cases, the Investment Regime of the Pension Funds will determine the conditions to be met by these instruments.
- **Article 58 A of Law No. 19,728 (Establishes an Unemployment Insurance)**, which governs the investments of the Solidary Unemployment Fund and the Unemployment Fund. Previously, both funds may only invest in the instruments listed in article 45 of DL 3,500. The Law modifies the former, establishing that the Solidary Unemployment Fund must be invested in the instruments, transactions and agreements listed in article 45 of the DL 3,500 and in the promise of payment and subscription of investment funds quotas agreements described in article 48 of the said DL. On the other hand, the Unemployment Fund must be invested in all the instruments, transactions and agreements listed in said article 45, excepting for those included in letter n).

- **Law No. 18,840 (Organic Constitutional Law of the Central Bank of Chile) is modified**, replacing the Cental Bank's power to create and regulate the operation of check and other securities clearinghouses to which banking companies and their subsidiaries attend to, for a broader power to create and regulate the operation of payment systems established in Chile, in which banking companies and other financial institutions controlled by the Superintendency of Banks and Financial Institutions participate, for the acceptance, settlement and liquidation of payment orders corresponding to money obligations, allowing the Central Bank to acknowledge payment systems established offshore. Additionally, it is indicated that transactions in accordance with the rules of these systems will be firm, i.e., final, irrevocable, binding and enforceable against third parties, and may not be affected by a declaration of nullity, unenforceability, inefficiency, challenge, forced liquidation, or any other cause, which seeks to limit or restrict the transactions carried out and remarking the principle of firmness and irrevocability of payment transactions of international payment systems.
- **Law No. 18,876 (Establishes the Legal Framework for the Incorporation and Operation of Private Deposit of Securities Custody Entities) is modified.** The assets that may be deposited are increased from only publicly offered securities, to include other assets, documents and agreements at the discretion of the Securities and Insurance Superintendency ("SVS"). Furthermore, Article 14 is replaced, regulating in detail the pledge and real rights on securities held on deposit. Thus, in order to give greater flexibility to this type of pledge, it is noted that pledges or real rights over the deposited securities: a) may be granted subject to other laws; or b) may be granted subject to a new type of pledge named "Special Pledge over Deposit Securities Registered in the Book Entries System", regulated in article 14 and in article 14 ter. This new pledge will be granted, modified and released pursuant to a framework agreement entered into by the deposit entity and the depositors, to which their corresponding principals may adhere as well, provided they are qualified investors.
- **Decree with Force of Law No. 251 (Insurance Companies Law) is modified**, allowing insurance companies to invest directly in public use infrastructure concession companies, and also allowing the SVS to exclude the shares of such companies from the prohibition of being subject to liens (these projects are generally subject to liens given the nature of their development).
- **Article 7 of Decree Law No. 1,123 of 1975 (Replace the Monetary Unit) is modified**, eliminating the $1 and $5 peso coins. Additionally, it is established that in the case of payments made in cash, the quantities equal to or less than $5 will be rounded down, and the quantities equal to or greater than $6 will be rounded up, not generating any tax effects or any obligation to modify tax documents that have been, or should be, issued.

<u>Main measures to promote the exportation of services</u>:

- **Article 41 A of the ITL is modified**, extending the foreign tax-credit benefit to any service qualified as an export service by the National Customs Service, no longer limiting it exclusively to technical and other similar services[2]; and extending the foreign tax-credit benefit for income arising from employed and independent work, when it comes from countries without a tax treaty to avoid double taxation. Article 59 of the ITL is also modified, eliminating the withholding tax rate increase for payments made to related parties on account of software and engineering services; and extending the withholding tax exemption to payments for technical or engineering works or services hired in order to export services from Chile.
- **Certain provisions of Law Decree No. 825 (Value Added Tax Law) are modified.** On one hand, the VAT exemption of number 16, letter E, of article 12 is modified, broadening the concept of export services in order to include services that are partially rendered in Chile and used abroad. Article 36 is also modified, allowing the recovery of the VAT associated with the acquisition of goods and services used to render services that are entirely provided and used abroad, when such services would have been subject to VAT if rendered in Chile and are levied with a tax of an identical or similar nature in the country in which they are rendered or used.

[1] This new withholding rule shall not apply when the terms of issuance of the respective instrument state that the withholding shall be governed by the rule applicable to representatives, custodians, brokers and other local entities designated by non-resident taxpayers for the purposes of complying with their tax obligations, in which case, the provisions of Article 74 No. 8 (formerly No. 7) shall apply.

[2] Retroactively applicable to services provided on or after January 1st, 2016.

Hogan Lovells

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 or 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.

Contacts

Jun Wei
Partner, Beijing
jun.wei@hoganlovells.com

Roy Zou
Partner, Beijing
roy.zou@hoganlovells.com

Liang Xu
Partner, Beijing
liang.xu@hoganlovells.com

Philip Cheng
Partner, Shanghai
philip.cheng@hoganlovells.com

Andrew McGinty
Partner, Shanghai
andrew.mcginty@hoganlovells.com

Mark Parsons
Partner, Hong Kong
mark.parsons@hoganlovells.com

NEW REQUIREMENTS RELATED TO MONEY TRANSFER SERVICES

As from the Amendment to the Law on the Supervision and Regulation of the Financial System which came into effect on August 2, 2015, legal entities engaged in money transfer services are subject to the supervision of the Superintendence of the Financial System of El Salvador ("SSF"). In accordance with the provisions of said Amendment, the Central Reserve Bank ("BCR") enacted the Technical Standards for the Registration and Operation of Money Transmitters ("NRP-12" or "Standard"), which became effective on January 4, 2016, to ensure the proper regulation and supervision of money transfer services.

The NRP-12 is applicable to legal entities providing money transfer services, systematically or substantially, by any means, directly or through an intermediary, at a national and international level, whose country of origin is the Republic of El Salvador. The Standard classifies such entities in Money Transfer Companies ("ETD" for its acronym in Spanish), agents and subagents (together referred to as "Entities"), according to the activity performed thereby within the remittance process.

The major change introduced by the new Standard is the compulsory registration of ETD and Agents in the Public Registry of the SSF set up for this purpose, upon the submission of the relevant application and the compliance with the corresponding legal requirements. Once the information is submitted, the SSF has 60 working days to analyze and approve the registration or request additional information as to continue with the registration process. The importance of this registration relies on that only duly registered entities may offer money transfer services in El Salvador.

Furthermore, NRP-12 introduces rigorous reporting requirements among which are:

i) Sending daily reports to the SSF on the operations performed the previous business day;
ii) Sending reports to the External Sector Department of BCR containing the statistical information of the operations;
iii) Reporting to the SSF on the compliance with legal and regulatory framework on Money Laundering and Financing of Terrorism, within the first ten working days of February and August each year;
iv) Reporting to the SSF any change in the registration information within 30 working days from their occurrence;
v) Reporting to the SSF and the BCR the establishment and termination of contracts with subagents, within the first 7 working days of the following month.

Regarding those entities which were formerly operating as money transfer service providers, the Standard established a term of 120 days from its entry into force, for these companies to submit the documentation pertaining to their registration before the SSF, whose term expired on May 3rd this year. Moreover, August 31st this year was the date scheduled to send the first daily information report to the SSF. Otherwise, the entities that are still pending in their compliance with the above are not currently authorized to operate.
On the other hand, with regard to banks, cooperative banks, savings and credit corporations, federations and other institutions regulated by special laws, supervised and authorized to engage in money transfer operations, which are interested in providing money transfer services as ETD or Agents, are required to inform the SSF at least 30 working days before they start operations and comply with applicable legal requirements as to perform this activity.

The breach of the previous obligations can result in penalties ranging from written warnings to fines, disqualifications, suspensions, cancellations in the respective register and/or revocation of authorizations, if any. Fines can be up to two percent of the assets of the Entities involved.

Please do not hesitate to contact us for more information on this or any other matter.

Antonella Imbers E.
Associate
antonella.imbers@ariaslaw.com

GIDE
GIDE LOYRETTE NOUEL

client alert

FINANCE | DERIVATIVES | UNITED KINGDOM | 18 NOVEMBER 2016

DEFAULT INTEREST UNDER ISDA AND FRENCH MASTER AGREEMENTS - LESSONS FROM THE LEHMAN "WATERFALL II" APPLICATION

INTRODUCTION

On 5 October 2016, Mr Justice Hildyard handed down his judgment in the third tranche of what has become known as the "Waterfall II Application" ("**Waterfall IIC**")[1]. Waterfall IIC was filed in the context of the administration of Lehman Brothers International (Europe) ("**LBIE**") by LBIE's administrators in order to obtain directions as to the allocation of the surplus remaining after the payment in full of the proved debts. The surplus amounted to around £7 billion and, inevitably given such a large amount, created grounds for litigation between competing creditors.

Waterfall IIC is of particular interest for the derivatives market as it addresses, in the context of debts proved in an administration, the default interest payable on "close-out" amounts arising after a termination of certain standard form master agreements for derivatives transactions governed variously by English, New York or German law (namely the 1992 and 2002 ISDA Master Agreements and the German Master Agreement).

Initially, Waterfall IIC was also intended to address similar issues arising from master agreements governed by French law, namely the FBF and AFB Master Agreements (for derivatives transactions), the AFTB Master Agreement (for repurchase transactions) and the AFTI Master Agreement (for securities lending transactions) (the "**French Law Issues**")[2]. However, parties to Waterfall IIC with competing interests eventually reached an agreement on the issues relating to the Euro denominated claims arising under the FBF and AFB Master Agreements (the "**Agreed Position**"[3]) and also agreed that the other issues relating to the AFTB Master Agreement and the AFTI Master Agreement did not need to be resolved in either the proceedings in the High Court or in the Agreed Position as they were *de minimis*. All French Law Issues were therefore removed from Waterfall IIC[4].

---

1 A copy of the judgment is available here.

2 Issues 22 to 26 of Waterfall IIC.

3 A copy of the Agreed Position is available here.

4 Further to the pre-trial review held on 9 October 2015, the parties agreed, and Mr Justice Hildyard approved, in an order which was sealed on 30 October 2015 (the "**PTR Order**"), the removal of all French Law Issues from Waterfall IIC. A copy of the sealed PTR Order is available here.

This Client Alert focuses on the guidance on the construction of default interest provisions in standard form master agreements that can be drawn from the judgment rendered by the High Court (for the 1992 and 2002 ISDA Master Agreements) and the Agreed Position (for the FBF and AFB Master Agreements). It also incidentally addresses certain aspects of the default interest provisions in the AFTB and AFTI Master Agreements that can be inferred from the position papers and expert reports filed by the parties and their relevant experts in relation to the French Law Issues.

I. BACKGROUND: RULE 2.88 OF THE INSOLVENCY RULES 1986

In the context of an administration of the type applied to LBIE, Rule 2.88(7) of the Insolvency Rules 1986[5] provides that, if a surplus remains after the payment of the debts proved in the administration, such surplus shall, before being applied for any purpose, be applied in paying interest on those debts. Rule 2.88(9) further provides that such interest will be payable at whichever is the greater of (i) the rate specified in section 17 of the Judgments Act 1838 (which is 8 % for the period of LBIE's administration) and (ii) "*the rate applicable to the debt apart from the administration*".

In the case at hand, the "*rate applicable to the debt apart from the administration*" was the rate provided in the default interest provisions contained in the relevant master agreement, specifically:

- the "Default Rate" for the 1992 and 2002 ISDA Master Agreements;
- the default interest set out in clause 9.1 of the FBF Master Agreement and the AFB Master Agreement;
- the "Late Interest Rate" as defined in the AFTB Master Agreement; and
- the "Late Payment Interest" as defined in the AFTI Master Agreement.

Therefore, depending on the Court's interpretation of such provisions, LBIE's creditors would possibly be entitled to claim statutory interest at a rate higher than 8%, which would significantly increase the amount of the surplus to be allocated to the senior creditors and, as a consequence, substantially reduce the amount available for the subordinated creditors.

It is worth noting that under French law, interest is only payable by a party on a compounded basis if (i) it is expressly provided for in the applicable contract, and (ii) the interest has been due for at least a year[6], whereas under English law, contracting parties are free to agree whatever terms for the compounding of interest they choose. In practice, based on the drafting of the default interest provisions, and unless otherwise agreed in the schedule or annex to the relevant master agreement, interest will be paid at a daily compounding rate under the ISDA Master Agreement and the FBF and AFB Master Agreements (if due for over a year), but interest under the AFTB Master Agreement and AFTI Master Agreement will be paid on a simple or "flat-rate" basis.

[5] Rule 2.88(7) of the Insolvency Rules 1986 : "*any surplus remaining after payment of the debts proved [in the administration] shall, before being applied for any purpose, be applied in paying interest on those debts in respect of the periods during which they have been outstanding since the relevant date [i.e. the date on which the company entered into administration]*".

[6] Article 1343-2 of the French Civil Code.

II. CONSTRUCTION AND EFFECT OF DEFAULT INTEREST PROVISIONS CONTAINED IN THE MASTER AGREEMENTS

The cost of funding under the ISDA Master Agreement is a borrowing cost only

The "Default Rate" in the ISDA Master Agreement is defined as "*the cost […] to the relevant payee […] if it were to fund or of funding the relevant amount*"[7]. Therefore the High Court had to consider the meaning of "cost of funding" and principally whether that language referred to a creditor's cost of borrowing only or if it could be interpreted more broadly to include all types of funding, and in particular equity funding.

This issue was of particular importance given its potential financial impact. As a matter of fact, were the "cost of funding" to include only the cost of borrowing, creditors would be less likely to be able to claim statutory interest at a rate higher than 8%. Conversely, were the "cost of funding" to extend to all types of funding, the rate could be higher, making it more likely for senior creditors to be able to claim statutory interest at a rate in excess of the 8% provided for in the Judgments Act 1838.

Mr Justice Hildyard concluded that for both the 1992 and the 2002 ISDA Master Agreements the "*cost […] to the relevant payee […] if it were to fund or of funding the relevant amount*" is to be certified by reference to the cost which the relevant payee is required to pay in borrowing the relevant amount (i.e. the close-out amount), whether an actual cost, where the relevant payee goes into the market to raise funds, or a hypothetical cost, where it does not do so. In other words, only the price paid for money borrowed, and neither the other ways of funding nor any other costs, would fall within the "cost of funding" language. In particular, Mr Justice Hildyard did not accept the argument that "*the phrase 'cost of funding' should be given its broad and natural meaning and should not be read down or restricted to exclude recovery of loss occasioned by or incidental to perfectly legitimate and commonly used methods adopted by many users of the ISDA Master Agreements to fund their businesses*", nor the argument that "*financial institutions have to maintain certain ratios of debt to equity*" and that the "*recourse to equity funding to fill a hole in its capital position caused by a default 'forms a key part of the factual matrix against which the definition must be construed'*". Mr Justice Hildyard also provided interesting additional guidance as to the way the cost of funding should be assessed or calculated[8].

Default interest provisions in the French Master Agreements

The question was different in respect of the FBF and AFB Master Agreements since the default interest provisions in clause 9.1 of the FBF and AFB Master Agreements do not refer to the "cost of funding" but to the "overnight refinancing rate"[9]. The only guidance that was provided on the interpretation of such terms came from the parties who agreed in the Agreed Position that it is "*a question of fact to be determined objectively and by reference to the relevant overnight refinancing rates which would have been offered to the original contracting party by market participants at the relevant time if not specified by the parties in the schedule to the relevant AFB or FBF master agreement or otherwise*". This is less detailed than the guidance

---

[7] Section 14 of the 1992 and 2002 ISDA Master Agreements provides that the *"**Default Rate** means a rate per annum equal to the cost (without proof or evidence of any actual cost) to the relevant payee (as certified by it) if it were to fund or of funding the relevant amount plus 1% per annum".*

[8] See Answers to Issues 12 to 18 of Waterfall IIC.

[9] Clause 9.1 of the FBF and AFB Master Agreements provides that "*In the event of a delay in payment by one of the Parties of any amount due under the Agreement, such Party shall pay to the other default interest […] at the overnight refinancing rate of the Party entitled to receive the relevant amount, in the relevant Currency, plus one per cent. per annum. Interest shall be capitalised if due for a period in excess of a year*".

that can be drawn from the High Court's judgment in respect of the ISDA Master Agreement, but the stakes for the parties in respect of the French Master Agreements were not as substantial and, as such, the issue was not considered in the same level of detail.

As regards the AFTB and AFTI Master Agreements, the default interest provisions are drafted differently to those in the ISDA Master Agreement and the FBF and AFB Master Agreements, distinguishing between Euro and non-Euro denominated claims[10] (instead of providing a single rate applicable for all currencies). Whereas the default rate applicable to non-Euro denominated claims is defined rather broadly as "*the average of the overnight rates available to the beneficiary of the late payment*" (similar to the approach followed in the ISDA Master Agreement or the FBF and AFB Master Agreements), the default rate applicable to Euro denominated claims is a specifically identified rate (namely "*the highest rate charged by the European Central Bank for supplying liquidity to the beneficiary of the late payment*" for the AFTB Master Agreement and "*EONIA*" for the AFTI Master Agreement). If the default interest definition for Euro denominated claims removes scope for interpretation by using a designated rate, the more general definition for non-Euro denominated claims is still subject to interpretation as regrettably, no agreement was reached between the parties as to its exact meaning[11]. As a matter of fact, one could argue that those default interest provisions should be understood broadly to mean any "*overnight rate available to the beneficiary of the late payment*", whereas one could consider that the default rate is to be construed as the rate charged by the institution equivalent to the European Central Bank (for the AFTB Master Agreement) or the equivalent rate to EONIA (for the AFTI Master Agreement) for the applicable contractual currency.

III. THE RELEVANT "PAYEE"/"PARTY" IS LBIE'S ORIGINAL CONTRACTUAL COUNTERPARTY

The High Court also had to consider the identity of the relevant "party" or "payee" by reference to which the default interest rate was to be determined. This was of particular importance in the context of LBIE's administration as, in many cases, LBIE's counterparties had transferred their close-out amount claims to third party purchasers, and it is these third party purchasers that are claiming interest in LBIE's administration, in their capacity as assignees of such claims.

Consequently, the question that was debated at length in Waterfall IIC was whether the relevant "party" or "payee" following any assignment of such claims should be LBIE's original contractual counterparty or the third party to which such claim was transferred. The conclusion reached by the High Court for the 1992 and 2002 ISDA Master Agreements and by the parties in the Agreed Position for the FBF and AFB Master Agreements was that the relevant "party" or "payee" shall be LBIE's original contractual counterparty.

ISDA Master Agreements

Arguments put forward by the parties in respect of the ISDA Master Agreement were based primarily on grounds of construction and, for the party arguing that the cost of funding should always be determined by reference to the original contractual counterparty (regardless of the

[10] The AFTB Master Agreement provides that the Late Interest Rate is "*unless otherwise indicated (i) for Euro, the highest rate charged by the European Central Bank for supplying liquidity to the beneficiary of the late payment; and (ii) for any other Currencies, the average of the overnight rates available to the beneficiary of the late payment for the relevant period*" and the AFTI Master Agreement provides that the rate for calculating late payment interest is "*for Euro, EONIA for the relevant period, plus 1% per year and for other Currencies, the average of the overnight rates available to the beneficiary of the late payment for the relevant period, plus 1% per year*".

[11] The AFTB and AFTI Master Agreements were not part of the Agreed Position.

number of assignments), on the principle that the transferee cannot recover more than the original transferor could have recovered.

Mr Justice Hildyard concluded that the "relevant payee" in the 1992 and 2002 ISDA Master Agreements is LBIE's original contractual counterparty and not the third party to which LBIE's original counterparty transferred its interest in any of those close-out amounts. To illustrate this, Mr Justice Hildyard added figuratively that "*the transferee is entitled to the tree planted by the transferor and such fruit as had grown and would grow on it when transferred, and not to fruit of a different variety or quantity which might have grown had the transferee planted the tree*".

French Master Agreements

Arguments put forward by the parties on the French law side were slightly different, based primarily on the means of assignment effectively used for the transfer of the close-out amount (namely by way of a *cession de créance* (assignment of receivables) or by way of a *cession de contrat* (transfer of contract)) and the different legal regimes - and related consequences - in each case.

On the one hand, it was argued that, when a transfer of rights under an FBF or AFB Master Agreement from LBIE's original contractual counterparty to a third party has been effected by way of a *cession de contrat* (but not otherwise), the interest payable under clause 9.1 is calculated by reference to (i) the refinancing rate of the original contractual counterparty for the period before the date of the relevant transfer and (ii) the refinancing rate of the third party for any period thereafter. A different reasoning was followed for the AFTB Master Agreement and AFTI Master Agreement on the basis that the default interest provisions under such agreements were different, but still led to the same conclusion, i.e. that the default rate shall be determined by reference to the current transferee.

On the other hand, it was argued among other things that, as a matter of French law (and assuming implicitly that the transfer of the close-out amount was made pursuant to a *cession de créance*), the assignee of a claim cannot recover more from the debtor than the assignor could have recovered and accordingly the default interest rate to be payable under each of the FBF, AFB, AFTB and AFTI Master Agreements was to be calculated by reference to the relevant rates applicable to LBIE's original contractual counterparty.

In the Agreed Position, the parties contemplated both means of assignment (*cession de contrat* and *cession de créance*) and recognised that the two means may lead to different conclusions. However, the parties ultimately concluded that in these circumstances (the transfer of a close-out amount), a *cession de contrat* under French law would not be relevant, meaning that the way to transfer a close-out amount claim was by way of a *cession de créance*. As a result, the overnight refinancing rate referred to in the FBF and AFB Master Agreements (compounded annually if overdue for at least one year) was the rate applicable to LBIE's original contractual party, whether before or after the date of the relevant transfer.

No "agreed position" was reached by the parties on the issues arising from the AFTB and AFTI Master Agreements; however, given the similarity of contexts in which those provisions arise, logically, it would seem reasonable to infer that, notwithstanding the differences between the default interest provisions in the AFTB and AFTI Master Agreements and those in the FBF and AFB Master Agreements, the same conclusions as to the identity of the "relevant party" would apply.

CONCLUSION

The decision in Waterfall IIC provides welcome clarification for derivatives practitioners on the meaning of the "cost of funding" in the definition of the "Default Rate" in the ISDA Master Agreement, both in its 1992 and 2002 versions. In summary, default interest payable under an ISDA Master Agreement is to be calculated by reference to the cost of borrowing an amount equal to the close-out amount, such borrowing cost being that of the original contractual party, regardless of whether the close-out amount claim was subsequently assigned to a third party.

Although the parties reached the same conclusion as to the identity of the relevant "party" by reference to which the default interest provisions under the FBF and AFB Master Agreements should be determined, the Agreed Position did not provide the same level of guidance on the construction of such default interest provisions as the one provided by the High Court for the ISDA Master Agreement. In any event, parties may always reduce uncertainty by agreeing a specific default rate when negotiating the relevant annex to their master agreements. This is commonly the case for FBF Master Agreements where the parties generally elect in the annex the EONIA rate as the applicable "overnight refinancing rate" for the purpose of clause 9.1.

CONTACTS

KARINE IMBROSCIANO
Partner
tel. +44 (0)20 7382 5543
imbrosciano@gide.com

CLAIRE-MARINE
COSTA-DE JONCKHEERE
Associate
tel. +44 (0)20 7382 5605
costa@gide.com

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		a. Pharmaceutical wholesalers; and b. Governmental pharmaceutical stock storage facilities.
Pharmaceutical wholesalers		a. Other pharmaceutical wholesalers; b. Pharmacies; c. Governmental pharmaceutical stock storage

		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 of 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.

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

Unit No. 50-8-1, 8th Floor, Wisma UOA Damansara, 50 Jalan Dungun, Damansara Heights, 50490 Kuala Lumpur, Malaysia.
T: +(603) 2081 3999 F: +(603) 2094 3211 E: skrine@skrine.com W: www.skrine.com

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.

Unit No. 50-8-1, 8th Floor, Wisma UOA Damansara, 50 Jalan Dungun, Damansara Heights, 50490 Kuala Lumpur, Malaysia.
T: +(603) 2081 3999 F: +(603) 2094 3211 E: skrine@skrine.com W: www.skrine.com

(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.

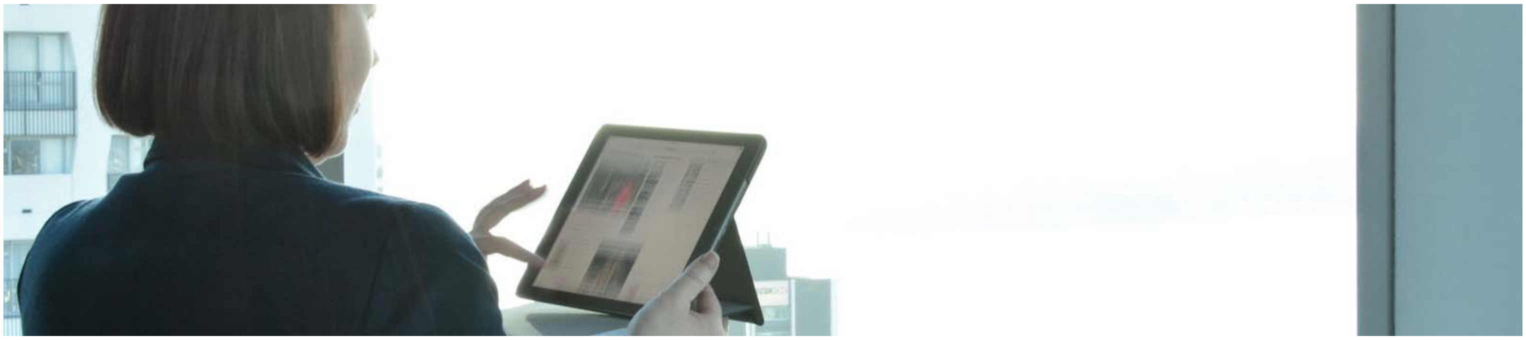
CONCLUSION

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 RAJAN (shannonrajan@skrine.com)
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.

Simpson Grierson



Director residency requirements under the Companies Act

November 15, 2016

Contacts Partners **Peter Stubbs**

The High Court recently considered what it means to live in New Zealand for the purposes of the director residency requirement in the Companies Act. We consider what this case and other upcoming changes to the Companies Act will mean for you.

The directory residency requirement

The Companies Act 1993 (**Act**) was amended in 2015 to require New Zealand registered companies to have at least one "resident" director. The purpose of this amendment was to ensure that all companies would have at least one person living in New Zealand (or an approved "enforcement country") who would be responsible and accountable for the company's affairs.

Following the amendment, the Registrar of Companies (**Registrar**) (drawing from the Income Tax Act) issued a notice clarifying that New Zealand based resident directors need to be present in New Zealand for at least 183 days a year to satisfy the residency requirement.

High Court test case

The Registrar's stance on the 183 day residency requirement was recently tested in the High Court, with the Court taking a more commercially practical approach to the residency requirement.

Mr Carr, the sole director of a number of New Zealand registered companies, typically spent only a third of the year in New Zealand. Applying the 183 day threshold, the Registrar ruled that Mr Carr did not live in New Zealand. As such, the companies of which he was sole director were non-compliant with the resident director requirement. Mr Carr appealed against the Registrar's decision.

The Court considered that the Registrar's 183 day test served well as an initial threshold, but determined that it was open to directors to meet the residency requirements by other means.

The Court examined Mr Carr's circumstances and found that he had "many of the trappings of a New Zealand resident". This included a home in which his partner resided most of the year, ownership of other properties, a New Zealand driver's licence, membership of various clubs and organisations, a New Zealand GP as primary physician and businesses here employing a significant number of staff who, at times, required his personal oversight. The High Court ruled that Mr Carr was a resident in New Zealand for the purposes of the Act's residency requirements.

You can read the full judgment of the High Court **here**
https://forms.justice.govt.nz/search/Documents/pdf/jdo/19/alfresco/service/api/node/content/workspace/SpacesStore/97ca0e89-4aac-4547-a5e1-d7893feca931/97ca0e89-4aac-4547-a5e1-d7893feca931.pdf

Upcoming changes to the director residency requirements

Currently, New Zealand companies can comply with the resident director requirement if one or more of the directors of the company:

1. lives in an enforcement country (Australia is currently the only enforcement country); and
2. is a director of an incorporated company in that enforcement country.

The Regulatory Systems (Commercial Matters) Amendment Bill (**Bill**) is currently before Parliament. This Bill will make some minor changes to the provisions relating to directors living in enforcement countries. These include:

- requiring that directors living in enforcement countries are directors of a body corporate that is registered under a law equivalent to New Zealand's Companies Act; and
- clarifying the information that needs to be submitted about the enforcement country body corporate required with an application to register a company.

The Bill is currently at Select Committee stage.

What does this mean for you

The High Court's judgment demonstrates that there is no blanket rule as to what constitutes being resident in New Zealand. This development can be seen as an attempt by the courts to ensure that our legal requirements match commercial reality, where those at the executive level often travel and stay outside New Zealand.

When trying to determine whether your directors are resident in New Zealand in order to meet the requirements of the Act, you should consider:

- what kind of personal ties the director has to New Zealand (such as ownership of property); and
- the nature and strength of any business connections that director has in New Zealand.

Additionally, businesses should keep an eye on the Bill and be sure that they comply with any amendments that are brought into law once the Bill passes through Parliament.

If you have any concerns about the residency of your directors or your compliance with any aspects of the Companies Act, give us a call. We're always happy to help.

Contributors
melissa.fini@simpsongrierson.com
tim.parker@simpsongrierson.com
fiona.ryan@simpsongrierson.com

NautaDutilh

Belgium | Luxembourg | Netherlands | EU

Dutch Supreme Court narrows the application of the VAT exemption for management of (real estate) investment funds

Wednesday 7 december 2017

The Dutch Supreme Court (Hoge Raad der Nederlanden) decided on 25 November 2016 that the VAT exemption for the management of real estate investment funds is applicable only if the (manager of the) relevant investment institutions is actually subject to supervision / licensing requirements (as referred to in the then applicable Investment Institutions Supervision Act - in Dutch: Wet toezicht beleggingsinstellingen, "WTB"). The decision in in line with a recent judgment rendered by the Court of Justice of the European Union ("ECJ") on the matter.

According to the ECJ, funds are only considered special investment funds (the management of which is exempt from VAT) if the applicable national law provides for "specific State supervision". In line with the ECJ, the Dutch Supreme Court decided that the supervision as provided in the WTB (which was applicable at the time of the facts) can be considered as "specific State supervision". Investment institutions falling under the scope of WTB would in principle benefit from the VAT exemption. As of 1 January 2007 the WTB was replaced by the Dutch Financial Supervision Act (in Dutch: Wet op het financieel toezicht, "WFT"). Investment institutions that are subject to supervision under the WFT should in principle be able to benefit from the VAT exemption. This means that investment institutions that are licensed (or have a manager that is licensed) by the Netherlands Authority for the Financial Markets ("AFM") will be able to benefit from the VAT exemption. It follows from the Dutch Supreme Court decision that if a Dutch investment institution is not licensed nor managed by a licensed manager, but is only registered as an exempt institution or manager, it cannot benefit from the VAT exemption.

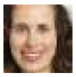
The decision seems to have narrowed the application in the Netherlands of the VAT exemption for the management of investment funds. Funds and managers currently operating in the Netherlands may have to review their VAT position. Management activities provided to funds that are expressively exempt from licensing and registering requirements may be subject to Dutch VAT. This could lead to an actual cost increase at the level of the funds, if such funds are not able to fully of partly deduct the input VAT charged by the manager.

Please let us know if you have questions in relation to the decision and/or your VAT position in the Netherlands.

Contact me

 Frederike Manzoni | Amsterdam | +31 20 71 71 944

 David van Dijk | Amsterdam | +31 20 71 71 420

 Larissa Silverentand | Amsterdam | +31 20 71 71 716

 Kees Koetsier | Amsterdam | +31 20 71 71 633

NautaDutilh | Challenge the obvious

International Law Firm | Amsterdam · Brussels · London · Luxembourg · New York · Rotterdam

ARIFA
ARIAS, FABREGA & FABREGA

PH ARIFA, piso 10
West Boulevard
Santa Maria Business District.
P.O. Box 0816-01098
Panama, Republic of Panama
Tel: +507 205 7000
Fax: +507 205 7001

ARIFA LEGAL FLASH

Contáctenos

Gian Castillero
gcastillero@arifa.com

Federico Alfaro
falfaro@arifa.com

Rogelio Fernández
rfernandez@arifa.com

Rubiela Samaniego
rsamaniego@arifa.com

Bianca Bergantino
bbergantino@arifa.com

What you should know about the recently enacted Law 52 of October 27th, 2016

The new legislation shall take effect as of January 1st, 2017.

The Republic of Panama recently enacted Law 52 of October 27th, 2016, which establishes the obligation of keeping accounting records and underlying documentation to all legal entities that do not carry out their operations within the Republic of Panama ("offshore"), and other applicable provisions.

What are accounting records?

Information that clearly and precisely indicates the commercial operations of the legal entities; assets, liabilities and equity, which would allow to determine the financial situation of the legal entity, as well as allow in preparing financial statements for such legal entity. The type of accounting record to be kept by the entity, shall depend on the type of activities and transaction such legal entity engages in.

Period

The accounting records and underlying documentation shall be maintained and available for a period of 5 years after the transaction(s) have been completed or when the legal entity has ceased its operations.

What is underlying documentation?

All financial records including agreements, invoices, receipts or any other documentation necessary to evidence any and all assets, liabilities and/or transactions that the legal entity keeps.

To whom does this Law apply?

To every Panamanian company (S.A.), limited liability company (SDRL) or any other kind of company with commercial purposes, as well as private interest foundations, that do not carry out their operations within the Republic of Panama.

Obligations

1. Location of the accounting records and underlying documentation: the accounting records and underlying documentation may be kept at the offices of the Registered Agent or in any other place within our outside the Republic of Panama. In the latter case, the legal entity shall be obliged to provide to the Registered Agent the following information, in writing:

- **a)** Physical address where the accounting records and underlying documentation are being kept.
- **b)** Name and contact details of the person who keeps custody of the accounting records and underlying documentation.

In the case of any change in the above mentioned information, the Registered Agent shall be informed within 15 business days.

2. Request of information by competent authority: when the accounting records and underlying documentation is kept outside the Republic of Panama, the legal entity shall be obliged to deliver such documentation to the Registered Agent within 15 business days following any notification of request from the authority.

If the Registered Agent fails to receive the requested documentation within the abovementioned deadline, the Registered Agent shall be obliged to resign as such within the following 10 business days as of the expiration of said deadline. If the Agent fails to resign as required, a fine of US$500.00 shall be imposed to the Registered Agent.

3. Share Register: The Registered Agent shall be obliged to keep copies of an updated Share Registry of the Panamanian companies (S.A.) for which it acts as Agent.

Sanctions

Any legal entity that does not comply with the obligations established under the provisions of this Law, shall be sanctioned by the competent authority in the following manner:

a) Fine of US$1,000.00

b) Fine of US$100.00 for every day that elapses without remedying the cause of the breach.

Suspension of corporate rights

The Panamanian Public Registry shall suspend the corporate rights of legal entities in the following cases:

a) When it remains without a Registered Agent for more than 90 days.

b) When it incurs in non-payment of its annual franchise duties for more than 3 consecutive years.

c) When the same is outstanding in the payments of any fine or penalty imposed and duly executed, upon order of the competent authority.

Reactivation of legal entities

Once the suspension has been recorded with the Public Registry, the legal entity shall have a term of 2 years in order to be reactivated, which will entail a fine of US$1,000.00.

If the abovementioned term expires, the Public Registry shall proceed with the definitive cancelation, thus being considered that the legal entity is dissolved.

Basic Accounting Services

Arias, Fabrega & Fabrega, by means of an affiliate, shall offer such services to the legal entities. These services shall include assistance in the preparing and issuing of the accounting records and underlying documentation required by Law.

25 November 2016

Amendments to "Regulations Governing Tender Offers for Securities of Public Companies" & "Regulations Governing Information to be Published in Tender Offer Prospectuses"

In light of the recent incident under which the tender offeror failed to close its purchase of shares in XPEC Entertainment Inc. case, and in an attempt to better protect rights of tendering investors who intend to sell securities held in a public company being acquired through a tender offer, the Financial Supervisory Commission (the "FSC") announced the following Amendments to "Regulations Governing Tender Offers for Securities of Public Companies," and "Regulations Governing Information to be Published in Tender Offer Prospectuses" (collectively, the "Amendments") on November 18, 2016, which took effect immediately on the same date. Highlights of the Amendments are as follows:

I Amendment to "Regulations Governing Tender Offers for Securities of Public Companies"

1. An attorney shall review the tender offer filing documents and issue a legal opinion. The tender offeror shall provide documents to support its ability to settle the consideration for the tender offer. In the event that the consideration for the tender offer is in cash, the following supporting documents shall be provided (Article 9):
   (1) a letter confirming such tender offeror's ability to settle the tender offer consideration, to be issued by a financial consultant qualified as a securities underwriter, or by a certified public account responsible for auditing and attestation of the financial reports of public companies, in either case the tender offeror's source of funding is reviewed and the letter is issued in due process; or
   (2) a letter of performance guarantee to be issued by a financial institution.

2. To increase the accountability of the board of directors and review committee of the subject public company being acquired, with respect to their verification on importation information of the tender offer (Articles 14 and 14-1):

(1) It is specified that, the board of directors shall verify the important information concerning the tender offer, including the identity and financial status of the tender offeror, fairness of the tender offer conditions, and reasonableness of the source of the consideration for the tender offer, and shall provide shareholders with its recommendation based on the results of its verification; in the case of a review committee, the committee shall submit to the board of directors the result of its verification on the same information together with results of its review. If an expert is engaged, such expert's opinion shall be included concurrently in the public announcement.
(2) The minutes of the board meeting shall include the directors' specific concurring or dissenting opinions and reasons thereof so as to clarify each person's accountability;
(3) For the benefits of the verification operations of the subject company and review committee, the length of period for submitting responses is amended to 15 days; there are new provisions concerning the requirements on the attendance and meeting procedures of the review committee members.

3. Except for Acts of God or emergency, the date, method and place of the settlement of the tender offer consideration shall not be changed (Article 7-1).

4. To strengthen the disclosure of tender offer information, a tender offeror shall, within two days following the circumstances below, file a report to the FSC and copy the same to the mandated institution (Article 19):
(1) Obtaining the approval or disapproval document from another competent authority prior to the satisfaction of the tender offer conditions;
(2) The tender offer conditions become satisfied;
(3) The tender consideration has been settled in full in an exclusive tender account under the name of the mandated institution; and
(4) After the satisfaction of the tender offer conditions, the number of shares tendered reaches the maximum projected purchase volume.

5. It is specified that where the conditions of the tender offeror are not satisfied on the expiration date of the tender offer period, or the number of the securities tendered exceeds that of the securities proposed to be acquired, the tender offeror shall return the deposited but unsettled securities to the tenderers on the next business day after the abovementioned expiration date. To protect the rights of tendering investors, where the conditions of the tender offer have been satisfied but the tender offeror fails to settle the tender offer consideration as scheduled in the tender offer prospectus, a tenderer may cancel the tender offer agreement without notification; the mandated institution shall then return the deposited securities to the tenderer on the next

business day thereafter (Article 19).

6. There are new provisions requiring the mandated institution to set up an exclusive account to receive and deduct payments for securities only, and provisions concerning negative qualifications preventing an institution to be mandated (Article 15).

7. The maximum length of extension period is amended to not exceed 50 days. There are new provisions stating that, the legitimate reasons for a tender offeror applying to FSC for exemption of the one-year restriction on the re-tender offer action may include: a previous tender offer is not completed due to the absence of a domestic competent authority's reviewing conclusion, and such tender offer has obtained the approval from another competent authority afterwards (Articles 18 and 24).

II Amendment to "Regulations Governing Information to be Published in Tender Offer Prospectuses":

1. There are new provisions requiring the tender offer prospectus to include the specific information below for investors' reference, and requiring the signature or seal of an outside expert with respect to the content of the prospectus for which he/she is accountable (Articles 4 and 13-1):
   (1) An attorney's legal opinion.
   (2) Documents supporting the tender offeror's sufficient funding to complete the tender offer, as set forth in Article 9 of Regulations Governing Tender Offers for Securities of Public Companies.
   (3) An appraisal report or opinion issued by other experts.

2. Where the tender offer consideration is proposed to be paid in cash, in a case of multi-level acquisition, the investment structure, the background of the investors at each level, and the source and details of the funding, including the identity of the ultimate funding supplier and information related to the arrangement of the funding shall be disclosed. Where a tender offeror is a company and the source of its funding comes from its own capital, it shall, based on its financial reports of the last two years, provide a detailed analysis and explanation on the reasonableness of the funding source for the subject tender offer (Paragraph 1, Article 7).

3. The tender offeror's public announcement of its tender offer prospectus shall also include an undertaking to honor its obligation to settle the tender offer consideration, and all the agreements or documents related to its capital arrangement (Paragraph 2, Article 7).

4. The tender offeror shall disclose the material details of its plans to acquire material assets after the take-over of the subject public company is completed (Article 12).

5. The tender offer conditions concerning the disclosure of the information and risks associated with the tendering are amended to include, among

others, the risk of obtaining tender offer consideration in a delayed manner in case of the tender offer period being extended according to law, and once the publicly announced tender offer conditions have been satisfied, a tenderer shall not be allowed to revoke its tender unless the law provides otherwise (Articles 6 and 8).

The Amendments have entered into force. They are intended to aggravate a tender offeror's responsibility related to fund-raising, and to increase the accountability of the subject company's board of directors. Those who are planning to conduct a tender offer are advised to observe the new requirements of the Amendments.

LEE AND LI, ATTORNEYS-AT-LAW 7F, 201 Tun Hua N. Road, Taipei 10508, Taiwan, R.O.C.
Tel: +886-2- 2715-3300 Fax: +886-2- 2713-3966

BAKER BOTTS

Ideas

Continued Misappropriation After May 2016 Allows Cause of Action Under Defend Trade Secrets Act

December 2016

IP Reports

While there are many options available that afford protection for intellectual property, trade secrets are one way that companies can protect their valuable and proprietary intellectual property. By keeping ideas a secret, companies potentially avail themselves of longer protection than may otherwise be afforded to them by publicly disclosing and patenting these ideas. Choosing to keep IP a secret, however, has it risks. Congress has recently enacted a statutory framework that affords individuals and companies a new option if its trade secret information is stolen or misappropriated.

Historically, the only remedy available to victims of trade secret theft was by filing a civil action in state court, typically under some version of the Uniform Trade Secrets Act (the "UTSA"). And, while 48 states have adopted some form of the UTSA, each state varies in its wording, application, and interpretation of the law. In an effort to address the interstate inconsistencies in the application of the UTSA, Congress recently passed the Defend Trade Secrets Act (the "DTSA").[1] Enacted on May 11, 2016, the DTSA creates a federal cause of action for the misappropriation of trade secrets, so long as "the trade secret is related to a product or service used in, or intended for use in, interstate or foreign commerce".[2] In addition to providing access to the federal court system, the DTSA provides a "single, national standard for trade secret misappropriation with clear rules and predictability for everyone involved."[3]

The provisions of DTSA cannot be applied retroactively, but instead may only be applied to an act that occurred "on or after the date of the enactment of this act."[4] Generally speaking, this means that victims of any trade secret theft which occurred prior to May 11, 2016 are restricted to those remedies available under state law. Recent decisions by some federal circuit courts, however, indicate that despite the act not applying retroactively, in cases where there is continuing misappropriation, a plaintiff may be entitled to at least partial DTSA relief if any occurrence of misappropriation takes place after May 11, 2016. In particular, the Federal District Court for the Middle District of Florida addressed a case involving such circumstances in *Adams Arms, LLC v. Unified Weapon Systems, Inc.*[5]

In *Adams Arms v. Unified Weapon Systems*, the plaintiff Adams Arms ("AA") filed suit, alleging, among other things, that the defendants, United Weapon Systems ("UWS") misappropriated AA's trade secrets. In its complaint, AA argued that this misappropriation arose both through UWS's acquisition of secret information by improper means, and by UWS's further disclosure of those secrets to a third party. AA sought relief under the provisions of the DTSA for these wrongful acts.

Responding to the complaint, UWS filed a motion to dismiss AA's claim under the DTSA. In its motion to dismiss, UWS did not dispute the existence of any theft of trade secrets, but instead argued that any claim under the DTSA should be dismissed because the events amounting to the alleged misappropriation occurred prior to the enactment of the DTSA. While AA did not dispute that the original act of misappropriation - the wrongful acquisition of trade secrets - occurred prior to the enactment of the DTSA, they argued that continuing acts of misappropriation - the disclosure of these acquired trade secrets to a third party - occurred *after* the enactment of the DTSA. Therefore, AA argued that it was entitled to relief under the DTSA, at least so far as any damage that resulted from this post-enactment disclosure of trade secrets.

Objecting to AA's argument, UWS pointed to a provision in the DTSA which states that "a civil action under [the DTSA] may not be commenced later than 3 years after the date" of misappropriation and, "for purposes of this subsection, a continuing misappropriation constitutes a single claim of misappropriation."[6] Based on this provision, UWS argued that any continuing misappropriation should be treated as one act of misappropriation under the act, and thus it is irrelevant if any continuing acts of misappropriation took place after the enactment of the DTSA; the court however disagreed.

In its analysis, the court first emphasized that the DTSA provision cited by UWS only addresses the timing of a misappropriation claim for the purpose of determining the statute of limitations, but does not address whether a plaintiff can recover under the DTSA for misappropriation that occurs *both* before *and* after the effective date of the act.[7] Instead, the court looked to section 2(e) of the DTSA which states that the act applies to "*any misappropriation* . . . for which *any act occurs*" after the effective date.[8] Based on this reasoning, the court in *Adams Arms* denied UWS's motion to dismiss AA's DTSA claims, finding that at least partial recovery for trade secret theft is available under the DTSA where an act of misappropriation occurred after the effective date of the DTSA.

Based on the findings in this and other cases, it is evident that there remains potential for plaintiffs to benefit from the provisions of the federal Defend Trade Secrets Act, even though the timing of initial misappropriation may have otherwise restricted them to remedies under state law.[9] As long as a plaintiff can show that *at least one act* of misappropriation occurred on or after May 11, 2016, at least partial recovery may still be available in federal court.

[1] Defend Trade Secrets Act, Pub. L. No. 114-153, 130 Stat. 376 (2016).
[2] *Id.*
[3] H. Rep. No. 114-529, at 6 (2016)
[4] Defend Trade Secrets Act, at 130 Stat. 382.
[5] Case No. 8:16-cv-1503-T-33AEP (M.D. Fla. Sept. 27, 2016)
[6] Defend Trade Secrets Act, at 130 Stat. 380.
[7] *Adams Arms* at 15.
[8] *Id.*; Defend Trade Secrets Act, at 130 Stat. 381-82 (emphasis added).
[9] *See e.g.*, *Syntel Sterling Best Shores Mauritius Ltd v. Trizetto Group, Inc.*, Case No. 15-CV-211 (S.D.N.Y. Sept. 23, 2016) (The United States District Court for the Southern District of New York refused to dismiss the defendants' counterclaims of trade secret misappropriation under the DTSA, because even though the initial acts of alleged misappropriation took place before the enactment of the DTSA, the plaintiff continued its alleged wrongful use of the defendant's intellectual property after the date of the DTSA's enactment).

Related Professionals

Andrea Longworth

Associate

Quarterly Securities Enforcement Briefing

October 2016

Articles

- Supreme Court Poised to Revisit Scope of Insider Trading Liability
- SEC Settles Case with Company and Its General Counsel Over Disclosure Failures
- D.C. Circuit Hands SEC First Win on In-House Court Constitutionality

Supreme Court Poised to Revisit Scope of Insider Trading Liability

By David A. Maas

It has been more than three decades since the Supreme Court last weighed in on insider trading liability in Dirks v. SEC, 463 U.S. 646 (1983). Meanwhile, the high profile trials of Martha Stewart, Jeff Skilling, Raj Rajaratnam, to name a few, have kept insider trading in the spotlight. On Oct. 5, 2016, the Supreme Court heard oral argument in Salmon v. U.S., an insider trading case that stands to make waves in the trading community and courtrooms across the country.

In Salmon, an investment banker shared material non-public information with his brother, who in turn shared that information with his future brother-in-law. The future brother-in-law was convicted for making a series of profitable trades based on that non-public information. The 9th Circuit affirmed. In his briefing to the Supreme Court, the defendant argued that the government should have had to prove the investment banker – the original source of the tip – personally benefited from the tip to his brother. The defendant based his argument on a recent 2nd Circuit decision that held a personal benefit sufficient to trigger insider trading liability must be "an exchange that is objective, consequential, and represents at least a potential gain of a pecuniary or similarly valuable nature." United States v. Newman, 773 F.3d 438 (2d Cir. 2014), cert. denied, No. 15-137 (U.S. Oct. 5, 2015).

The government advocates that a tip to a relative or friend is itself a personal benefit to the tipper. The government's position is rooted in the language of Dirks: "The elements of fiduciary duty and exploitation of nonpublic information also exist when an insider makes a gift of confidential information to a trading relative or friend. The tip and trade resemble trading by the insider himself followed by a gift of the profits to the recipient." 463 U.S. at 664.

At oral argument, the justices were hostile to a narrow or concrete interpretation of what constitutes a "personal benefit." For instance, Justice Kagan stated to the defendant's counsel "[y]ou're asking us to cut back significantly from something that we said several decades ago, something that Congress has shown no indication that it's unhappy with, and in a context in which, I mean, obviously the integrity of the markets are a very important thing for this country." Justice Kennedy echoed this loyalty to Dirks: “Dirks says there's a benefit in making a gift… [Y]ou certainly benefit from giving to your family.”

The Justices’ questioning at oral argument suggests that the defendant’s conviction is likely to be affirmed. However, the government made a fairly significant concession, stating that the Supreme Court “doesn’t have to reconceptualize Dirks…. If the Court feels more comfortable given the facts of this case of reaffirming Dirks and saying that was the law in 1983, it remains the law today, that is completely fine with the government.” That position walks back the more government’s more aggressive stance in briefing, which sought to expand liability by treating a tip to an acquaintance as a personal benefit.

SEC Settles Case with Company and Its General Counsel Over Disclosure Failures
By Jeff Coopersmith

On Sept. 9, 2016, the SEC brought a lawsuit in federal court in Washington, D.C., against RPM International, Inc., and its general counsel for alleged failure to timely disclose a loss contingency, or record an accrual for an anticipated settlement, to resolve an investigation of the company by the U.S. Department of Justice. The company came under DOJ investigation in 2011 regarding whether it overcharged the government on some government contracts. The SEC alleges that the general counsel knew but failed to disclose to the CEO, CFO, Audit Committee, and independent auditors that RPM had sent the DOJ several analyses showing the overcharges were at least $11.9 million, that RPM agreed to submit a settlement offer to DOJ by a certain date, and that RPM then revised its overcharge estimate up to $27-28 million. The SEC alleges that the general counsel’s failure to disclose these matters resulted in a failure by the company to disclose any loss contingency or accrual on RPM’s financial statements. This made periodic filings the company submitted to the SEC in 2012 and 2013 materially false and misleading. RPM settled the DOJ matter for almost $61 million in Aug. 2013.
The SEC’s complaint alleged violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act of 1933, and Section 13(a) of the Securities Exchange Act of 1934 and its corresponding SEC rules. These charges are negligence-based against the general counsel (and a combination of negligence and strict liability against the company). The lack of fraud claims will allow the general counsel to escape being barred from serving as an officer and director of a public company if he is found liable. The SEC is seeking injunctive relief, as well as penalties and disgorgement. The company has stated it intends to vigorously defend. According to RPM’s website, the general counsel continues to serve in that role.

D.C. Circuit Hands SEC First Win on In-House Court Constitutionality
By Conner G. Peretti

Our coverage of the challenges to the constitutionality of the SEC’s in-house courts continues with news of the SEC’s first federal appellate ruling to find that the SEC’s in-house courts are constitutionally sound. In Raymond J. Lucia Companies, Inc., et al v. SEC, the District of Columbia Circuit denied an investment advisor’s petition for review of a decision of the Securities and Exchange Commission. The investment advisor claimed that the SEC’s in-house courts are unconstitutional under the Appointments Clause on the grounds that the President must appoint the SEC’s in-house judges. Most of our coverage has been of cases where parties named as defendants in an SEC in-house court proceeding tried to challenge the constitutionality of those administrative courts in federal district court, in order to avoid having to go through the in-house proceeding altogether and force the SEC to proceed instead in federal court. We reported on those cases here. Federal appellate courts in those cases addressed whether the parties could bring the constitutional challenges before exhausting the administrative process. The 2nd and 11th Circuits held they could not, and that the petitioners had to return to the SEC administrative process, obtain a final ruling, and if the ruling was adverse they could then petition for review to the court of appeals.

In Lucia, Mr. Lucia completed the administrative proceeding and then filed an appeal from the SEC's administrative judgment to the D.C. Circuit. The in-house SEC court and the SEC had found that the in-house court and its judges did not violate the appointments clause. On appeal, the D.C. Circuit panel reasoned that the commission itself still retained "full decision-making powers" by issuing a final order after the in-house judge made a decision. The commission therefore acted on its own rather than using in-house judges to make final decisions in potential violation of the delegation statute and appointments clause. Mr. Lucia has filed a petition for rehearing en banc, which has not yet been ruled on.

U.S. House of Representatives Passes 21st Century Cures Act, Including Numerous Device-Related Provisions

07 December 2016
Medical Device Alert

Last Wednesday evening (November 30), the House overwhelmingly passed (by a vote of 392-26) a compromise version of the 21st Century Cures Act. House and Senate Republican leaders released a revised draft on November 25, the result of diverse stakeholders' lobbying for or against provisions of an earlier House bill of the same name (which passed the House in July 2015 but then stalled in the Senate). The final version ultimately passed was framed as a House amendment to a Senate amendment to unrelated legislation (H.R. 34), and is slightly shorter but reflects no additional substantive changes to FDA-related provisions.

The 21st Century Cures Act contains provisions that would significantly streamline how the Food and Drug Administration (FDA or the Agency) reviews and approves drugs and medical devices. It would also give FDA US$500 million in new funding with which to help implement various efforts such as improving mental health, fighting opioid addiction, and supporting the Precision Medicine Initiative.

Some of the key medical device FDA-related provisions of the bill that just passed the House, and their regulatory implications, include:

- *Expediting the development, and prioritizing FDA review, of "breakthrough" technologies* (Section 3051). The bill creates a new accelerated pathway to market for devices that address unmet needs for life-threatening or irreversibly debilitating human diseases or conditions. Importantly, this new pathway builds on FDA's existing Expedited Access Pathway (EAP), but would now be open to more device types – those subject to 510(k) clearance as well as those eligible for PMA approval or *de novo* requests.
- *Expanding the scope of diseases/conditions eligible for a humanitarian device exemption (HDE)* (Section 3052). FDA's existing HDE program offers a simplified approval pathway for devices addressing an unmet need for a rarely occurring disease or condition, allowing companies to obtain approval based on safety data and probable benefit. 21st Century Cures makes it possible for companies to obtain an HDE for diseases affecting up to 8,000 people, doubling the ceiling from its prior limit of <4,000. This significant increase would enable more devices to take advantage of

this pathway, and could increase patient access to new devices for a greater variety of diseases.

- *Encouraging FDA to rely more on real-world evidence to demonstrate device safety and effectiveness* (Section 3022). Industry has long pushed for FDA to consider more types of data to help fulfill post-approval requirements or to support premarket clearance/approval of a new indication for a previously cleared/approved device. This past July, the Agency released a draft guidance explaining how and under what circumstances real-world data can support regulatory decision-making in these contexts. By providing a statutory basis for this shift, the 21st Century Cures Act supports FDA recognition of a broader scope of data, which will be particularly beneficial for companies for which the historical gold standard in data collection, prospective clinical trials, is less practical or feasible.
- *Requiring additional validation data prior to marketing certain reusable medical devices* (Section 3059). Largely fueled by the recent incidents of disease transmission between patients through use of duodenoscopes, 21st Century Cures instructs FDA to specify a list of reusable device types for which 510(k) clearance will require validated instructions for use as well as validation data regarding cleaning, disinfection, and sterilization. This is intended to reduce the likelihood of disease transmission, but it will also require companies whose devices are on the list to provide more comprehensive data for FDA review prior to marketing.
    - This section of the bill also obligates FDA to finalize its guidance on when changes to legally marketed devices subject to 510(k) requirements necessitate obtaining a new clearance from FDA by November 2017. The final guidance will supersede the draft guidance issued in August and solidify Agency policy on a topic that is critical for any manufacturer seeking to commercialize a modified or updated version of a previously cleared device.

- *Streamlining the review process for combination products* (Section 3038). Notably, the bill clarifies the designation of a combination product's "primary mode of action (PMOA)," which is the basis for determining which FDA Center is responsible for its regulation. It significantly reduces ambiguity in this area by specifying that FDA should not deem a combination product to have a drug PMOA based solely on its having a chemical action. Consequently, contrary to FDA's current default position, combination products with device components that have some chemical function but for which that function is not the *primary* intended purpose[1] should be designated as having a device PMOA.
- *Making certain types of low-risk software functions not generally subject to regulation as medical devices* (Section 3060). The 21st Century Cures Act contains a significant carve-out for medical and certain clinical decision support (CDS) software, namely software functions that are intended (1) for administrative support of a healthcare facility; (2) as non-diagnostic, non-therapeutic mechanisms to encourage a healthy lifestyle; (3) to serve as electronic patient records, except for interpreting patient data for diagnosis/treatment; and (4) for transferring, storing, converting formats, or displaying data/results and associated findings by a healthcare professional (*e.g.*, medical device data systems), unless intended for analysis of data, results, or findings. Still, FDA maintains the authority to regulate any such software function deemed "reasonably likely to have serious adverse health consequences." Notably, this part of the Act would solidify into statute FDA's current regulatory approach, as reflected for example in the Agency's *General Wellness* and *Mobile Medical Applications* guidance documents.

- This section of the bill also amends the Federal Food, Drug, and Cosmetic Act to say that accessories are to be classified based on their intended use, notwithstanding the classification of any other device with which they are meant to be used (in line with FDA's January 2015 draft guidance).

- *Requiring publication and regular updates on 510(k) exemption* (Section 3054). The bill instructs FDA to publish in the Federal Register a notice that lists each type of Class I and Class II device that is to be exempted from the requirement for clearance/approval. The Agency has 90 days after enactment of the legislation to release the first such list for Class I devices, and 120 days to issue the first such list for Class II devices; it is then expected to renew these lists at least every 5 years thereafter. Under this provision, FDA may act more quickly on its proposals to make certain products 510(k)-exempt, which would allow manufacturers of those types of devices to get to market much more quickly.
- *Enhancing Institutional Review Board (IRB) flexibility* (Section 3056).[2] The bill modifies requirements for sponsors of medical device trials related to IRB review to align more with the approach taken for drug trials, specifically acknowledging the possibility of allowing one IRB to oversee a multicenter clinical trial. This change is likely to make clinical trial oversight more efficient by consolidating all IRB functions in one centralized entity when appropriate, as well as to reduce unnecessary expenses and duplication of effort in the conduct of multicenter clinical trials, which have become significantly more common.
- *Emphasizing the least burdensome standard for device review* (Section 3058). 21st Century Cures clarifies the expectation that FDA reviewers will be trained on, and required to consider, the least burdensome approach for demonstrating a reasonable assurance of safety and effectiveness when requesting additional information from device manufacturers during review of premarket submissions. This includes consideration of the role that post-market information can play in this process. The Act also requires the FDA Ombudsman to audit its implementation. This update, while not dramatic, should reassure industry that the Agency will be held more accountable for performing consistent and reasonable premarket reviews.
- *Expanding CLIA Waivers* (Section 3057). The bill requires FDA to revise its 2008 guidance on Clinical Laboratory Improvement Amendment (CLIA) waivers for *in vitro* diagnostic devices to replace a gold-standard-based accuracy requirement with a demonstration of accuracy through comparable performance between waived and moderate-complexity laboratory users. This provision will make it easier to show that certain IVD tests present a low risk of error and thus can be appropriately exempted from routine inspections and most requirements under CLIA.
- *Accelerating approval of regenerative advanced therapies* (Section 3034). In line with recent pressure to enable making the benefits of stem cell therapies available to more patients, 21st Century Cures calls for devices used in the recovery, isolation, or delivery of a stem cell product to be deemed moderate risk unless the Agency determines that the device or its use should be classified as higher risk.
- In addition, while not specific to FDA, the following additional pieces of the 21st Century Cures Act may also be of interest to the medical device industry:
- The bill establishes a new Medicare Pharmaceutical and Technology ombudsman within CMS whose task will be to address complaints/requests raised by drug and device manufacturers

related to the coverage, coding, and reimbursement of medical technologies.
- To help fund the bill, Medicaid reimbursement to states for durable medical equipment (DME) will be limited to Medicare competitively bid rates by January 1, 2018 (instead of 2019).
- Payments for infusion drugs provided through DME will be reduced starting in 2017, pursuant to a finding that such payments have often been excessive.
- Medicare coverage will be expanded to include support for telehealth services, including remote monitoring.

Following House passage, the Senate voted overwhelmingly (85-13) on Monday afternoon to end debate on the bill and proceed to a vote on its substance. The Senate is expected to pass the legislation tomorrow. The bill has faced a more uphill battle there than it did in the House; among its most vocal opponents is Senator Elizabeth Warren (D-MA), who maintains that it will effectively result in lower standards for drug/device safety and effectiveness. Nevertheless, the Act is now expected to pass in the Senate as well and then to be sent to President Obama to be signed into law later this week.

President-elect Donald Trump has said he will work to eliminate "red tape" at the FDA but has not commented on the 21st Century Cures Act specifically. It remains to be seen how the Trump administration will interpret the review and clearance/approval procedures for medical devices as modified by this legislation and, more broadly, how much it will seek to influence FDA policy.

---

1 The statutory definition of medical device (FFDC Act § 201(h)) requires that a product "not achieve its primary intended purposes through chemical action within or on the body of man or other animals." However, recent cases (*e.g.*, *Prevor v. FDA*) have generated criticism that "chemical action" is being defined too broadly by FDA.

2 This policy shift has already been introduced for drugs and biologics; see *Guidance for Industry – Using a Centralized IRB Review Process in Multicenter Clinical Trials* (March 2006).