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CONFERENCES & EVENTS

- 2011 October 15-18 - 50th International PRAC Conference - Singapore
Hosted by Rodyk & Davidson
- 2011 October (tba) - PRAC Members Gathering @ IBA Dubai
- 2012 April 21-24 - 51st International PRAC Conference - Houston
Hosted by Baker Botts LLP
- 2012 May 5 - PRAC Members Gathering @ INTA Washington
- 2012 October 20-23 - 52nd International PRAC Conference - Buenos Aires
Hosted by Allende Brea

Details at www.prac.org

PRAC Conferences and Events are open to PRAC Member Firms only

MEMBER DEALS MAKING NEWS

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- ▶ CAREY Y CIA Advises Banco de Chile, BancChile-Citi Global Markets and Deutsche Bank in US\$400 Million Senior Note Issuance by AES Gener S.A.
- ▶ CLAYTON UTZ Acts for Gindalbie Metals in A\$209 Million Equity Raising
- ▶ FRASER MILNER CASGRAIN Stillwater Mining Company to Acquire Peregrine Metals LTD
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- ▶ TOZZINIFREIRE Advises United Phosphorus Limited in the Acquisition of 51% Stake in DVA Agro do Brazil
- ▶ WILSON SONSINI Advises Electronic Arts in US\$750 Million Acquisition of PopCap Games

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CAREY APPOINTS DIRECTOR OF CRIMINAL LAW DEPT

Santiago, July 2011.

Attorney Marcelo Sanfeliú was appointed as new director in Carey y Cía., Chile's largest law firm with over 140 professionals, effective August 1.

Marcelo Sanfeliu is a member of Carey y Cia.'s Litigation Group and Head of its Criminal Law practice group and handles all matters of criminal law and specializes in anti-corruption and money laundering cases.

Mr. Sanfeliú studied law in the Universidad Diego Portales, and was admitted to the bar in 1997. He was the first public prosecutor named in Chile in 2000, following the reforms of Chile's criminal procedure. This way, he served as the Head District Attorney of La Serena, IV Región de Coquimbo, simultaneously serving as First Assistant to the Regional Attorney General.

Since 2006, Carey y Cía. has maintained a criminal law practice, specialized in economic and white-collar crimes, cyber crimes, intellectual property violations, infringements to the telecommunications law, the protection of sensitive company information and crimes against property in general among others.

The firm provides preventive advice to its clients in all the prosecutors' offices throughout the country, with extensive experience in oral litigation, acting either as plaintiff or defense attorney.

For additional information visit www.carey.cl

KING & WOOD SHANGHAI AND HANGZHOU OFFICES RELOCATE

July 18, 2011- King & Wood PRC Lawyers Shanghai office has been relocated to One International Commerce Centre (One ICC).

Contact details:

International Commerce Centre

16-18/F, One ICC
999 Huai Hai Road
Shanghai, 200031, PRC

Tel : 86 21 2412 6000

Fax : 86 21 2412 6150

July 31, 2011- King & Wood PRC Lawyers Hangzhou office has been relocated to Euro America Centre (EAC).

Contact details:

Euro America Centre

D Region, 12 F Euro America Centre
No. 18 Jiaogong Road
Hangzhou, Zhejiang, 310012, PRC

Tel : 86 571 5671 8000

Fax : 86 571 5671 8008

HOGAN LOVELLS WELCOMES PARTNER TO DENVER

Jodi Scott Joins Hogan Lovells As Partner in its Denver Office

DENVER, 8 August 2011 – Hogan Lovells announced today that Jodi Scott has joined its Food, Drug, Medical Device, and Agriculture practice as a partner in its Denver office. She was previously FDA Principal Legal Counsel for Medtronic, Inc., a leading medical technology company.

Scott will focus her practice on assisting the medical technology industry in navigating the complex requirements for achieving U.S. marketing authorization and maintaining compliance to the U.S. Food and Drug Administration's (FDA) quality and other postmarket regulatory requirements.

"With her years of experience as in-house counsel with a leading medical technology company, combined with her previous tenure as an associate at Hogan Lovells, Jodi will provide invaluable insights for our clients and play an important role in the development of the Denver office's Food, Drug, Medical Device, and Agriculture practice," said Cole Finegan, Managing Partner of Hogan Lovells' Denver office. "We are happy to welcome her back to Hogan Lovells."

Scott has applied her healthcare background to build regulatory strategies for the development of medical devices, including ensuring clinical, quality, and regulatory compliance and providing guidance and assistance in the formation of policies and procedures related to FDA legal matters. Jodi is experienced in counseling medical device manufacturers on various FDA-related issues, such as import/export and customs, FDA submission requirements, FDA inspections, FDA enforcement, advertising and promotion, mitigating the risks associated with the unapproved use of approved products (a/k/a off-label uses), and FDA policies and procedures.

Before joining Medtronic, Jodi was an associate with Hogan Lovells' legacy law firm, Hogan & Hartson. In this role, Jodi represented clients in negotiations with the FDA regarding clinical data requirements, clinical study design, and as-needed regulatory pathways.

Scott received her J.D. from the Columbus School of Law at Catholic University in Washington, D.C. Prior to her work as a lawyer, Scott was a registered pharmacist in the state of Virginia after having obtained a Bachelor of Science in Pharmacy from Drake University.

For more information visit www.hoganlovells.com

KOCHHAR & CO. EXPANDS IN HYDERABAD

Kochhar & Co. has achieved yet another milestone by acquiring Juris Prime, a full service law firm based in Hyderabad with a bench strength of 6 lawyers. Juris Prime was founded by Mr. V.V.S.N. Raju in the year 2005 after he moved from ICICI Bank, where he was the Corporate Legal Head, Andhra Pradesh at that time.

Mr. Raju has taken over as the Resident Partner and Head of the Kochhar Hyderabad office. Mr. Raju is a well-known and distinguished name in the corporate and financial sectors with over 17 years of experience in the State of Andhra Pradesh. Before establishing Juris Prime, he was working as the in-house counsel with the legal departments of Industrial Development Bank of India (IDBI) and ICICI Bank. Mr. Raju is also on the board of Venture Capital Management Company, which is a joint venture between ICICI Knowledge Park and NASSCOM.

With the induction of Mr. Raju, the Hyderabad presence of Kochhar & Co. stands substantially strengthened. The Hyderabad office has a full service practice and represents clients in diverse fields of Indian law including but not limited to Arbitration, Banking, Company and Commercial Laws, Cyber Laws, Financial Services, Infrastructure Laws, Intellectual Property, Labour Laws, Litigation, Project Finance and Real Estate.

Contact Details:

Kochhar & Co.

Plot No. 1263A/1,

Road No. 63A

Jubilee Hills

Hyderabad-500033, Andhra Pradesh

Tel: (91-40)40115222, 40205223

Fax: (91-40) 40205224

Contact person – Mr. V V S N Raju raju.v@kochhar.com

WILSON SONSINI FURTHER EXPANSION TO IP LITIGATION PRACTICE

Patent Litigation Expert Douglas H. Carsten Joins the Firm --

PALO ALTO, CA (June 27, 2011) - Wilson Sonsini Goodrich & Rosati, the premier provider of legal services to technology, life sciences, and other growth enterprises worldwide, is pleased to announce that Douglas H. Carsten has become a partner at the firm. Carsten's practice focuses on complex patent litigation in the pharmaceutical and life sciences industries.

"In the past several years, the firm has built a strong pharmaceutical practice, particularly in the generics field, where we have seen considerable demand from our clients for expertise in ANDA litigation," said CEO Steve Bochner. "In May, we added pharmaceuticals expert Jeff Hovden to our IP litigation practice in New York, and now we're delighted to welcome Doug to the firm. With his extensive experience representing generic drug companies in Hatch-Waxman patent litigation, he will be a terrific addition to our patent litigation team, and also will serve as a valuable resource for clients when it comes to other life sciences patent matters."

Prior to joining Wilson Sonsini Goodrich & Rosati, Carsten was an IP litigation partner at Foley & Lardner. Aside from his expertise in Hatch-Waxman patent litigation, including ANDA trials, Carsten has significant experience representing medical device and biotechnology companies in patent litigation matters. Earlier in his career, he was an attorney at Gray Cary Ware & Freidenrich (now DLA Piper) and Irell & Manella. Carsten received his J.D. from Georgetown University Law Center in 1998, an M.A. in organic chemistry from Harvard University in 1995, and a B.S. in chemistry and English literature from the State University of New York at Stony Brook in 1993.

For more information, please visit www.wsgr.com

ALLENDE BREA**ACTS FOR BANCO SANTANDER US\$2.1 BILLION SALE OF LATIN AMERICAN BANK INSURANCE BUSINESS**

Buenos Aires, July 2011: Banco Santander, S.A. in an arrangement with Zurich Financial Services in connection with the US\$2.1 billion sale of 51 per cent of Banco Santander's Latin American bank insurance business. Subject to the relevant regulatory and internal approvals and the terms of the arrangement between Zurich and Banco Santander, Banco Santander Río shall enter into a long-term agreement for the distribution of insurance products underwritten by Santander Río Seguros S.A.

Allende Brea represented Banco Santander S.A. in this occasion, and the AB attorneys acting in this transaction were Jorge I. Mayora (partner) and Laura I. Kurlat (associate).

For additional information visit www.allendebrea.com.ar

RODYK**ACTS IN SILECS SERIES E S\$16M FINANCING**

Rodyk acted for Silecs International Pte Ltd, a venture-backed developer and manufacturer of advanced Siloxane polymers, in the closing of a new US\$16 million Series E financing round. Having more than trebled its revenues in two years with its cutting edge semiconductor materials, Silecs is now poised to expand its research, production, and customer support capabilities from its traditional base in Finland into Asia, where it has established its new corporate headquarters in Singapore.

Singapore's leading global fund, EDBI (EDB Investments Pte Ltd), led the investment round with strong support from established European investors Tempo Capital Partners, Innovations Kapital, and Finnish Industry Investments.

Corporate partner Gerald Singham led this transaction assisted by associate Seow Jia Xian.

For additional information visit www.rodyk.com

CLAYTON UTZ**ACTS FOR GINDALBI METALS IN A\$209 MILLION EQUITY RAISING**

Perth, 19 July 2011: Clayton Utz is advising ASX-listed Perth-based iron ore producer Gindalbie Metals Limited in connection with its accelerated non-renounceable entitlement offer and associated placement to raise A\$209 million, announced today.

The offer will be undertaken as a 1 for 3 accelerated non-renounceable entitlement offer of ordinary shares at an issue price of \$0.67 per share. The non-Ansteel component of the entitlement offer (representing approximately \$134 million) has been fully underwritten.

If Gindalbie's major shareholder Ansteel (35.89%) is unable to participate in the entitlement offer, there will be a placement to Ansteel of \$75 million, subject to shareholder approval and on the same terms as the entitlement offer.

Ansteel is one of China's biggest steel makers.

Gindalbie will apply the funds raised towards development of the A\$3 billion Karara iron ore project in Western Australia's mid-west.

Clayton Utz Perth Corporate / M&A partner Mark Paganin is the firm's lead partner on the transaction, with support from Perth senior associate James Clyne.

For additional information visit www.claytonutz.com

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FRASER MILNER CASGRAINSTILLWATER MINING COMPANY TO ACQUIRE
PEREGRINE METALS LTD**Stillwater Mining Company to acquire Peregrine Metals Ltd. for US\$487 million**

On July 11, 2011, Stillwater Mining Company and Peregrine Metals Ltd. announced that they have entered into a definitive agreement pursuant to which Stillwater, by way of a Canadian plan of arrangement, will acquire all of the outstanding shares of Peregrine.

Under the terms of the Agreement, Stillwater will exchange 0.08136 shares of Stillwater common stock and US\$1.35 in cash for each common share of Peregrine. Based on the closing share price of Stillwater common stock as of July 8, 2011, which was US\$23.72, the Agreement places a value on Peregrine common shares of US\$3.28 (CDN\$3.16) per share. This represents a total purchase price of US\$487.1 million, and assumes the exercise of all outstanding Peregrine options and warrants resulting in a CDN\$34.4 million (US\$35.7 million) contribution to treasury, and implying a net equity value of US\$451.4 million. Upon completion of the transaction, Stillwater and Peregrine shareholders will own approximately 89.5% and 10.5%, respectively, of the combined company on a fully diluted basis.

Stillwater Mining Company is the only U.S. producer of palladium and platinum and is the largest primary producer of platinum group metals outside of South Africa and the Russian Federation. The Company plans to further delineate, develop and operate Peregrine's Altar porphyry copper-gold deposit, a large, undeveloped open-pit resource located in the San Juan province of Argentina following completion of the transaction. Stillwater's shares are traded on the New York Stock Exchange under the symbol SWC.

Stillwater Mining Company is represented by Fraser Milner Casgrain LLP with a team led by John Sabine and Linda Missetich, which included Eric Foster, Ralph Shay, Gary Sollis, Kristina Trevors, Zahra Nurmohamed, Matthew Peters, Sandy Walker, Peter Murphy and Timothy Banks.

For additional information visit us at www.fmc-law.com

GIDE LOYRETTE NOUELADVISES SOPRA GROUP AND AXWAY SOFTWARE ON
PROJECTED SPIN-OFF

June 2011 Gide Loyrette Nouel (GLN) has advised Capgemini Asia Pacific, part of the global Capgemini group (Capgemini), on its acquisition of Praxis (Beijing) Technology Ltd (Praxis), a specialist developer and provider of IT services in China.

Capgemini offers a suite of IT, consulting and outsourcing services in Asia Pacific and has experienced significant growth in the region. The acquisition of Praxis represents Capgemini's first acquisition of a China based company and forms part of Capgemini's strategy to expand its presence in China through strategic acquisitions of growth companies. The acquisition of Praxis, a mid sized technology company with a leading position in utilities and SAP solutions, will enable Capgemini to enhance its IT service offering, including SAP services.

The transaction will involve Capgemini acquiring 100% of the shares in Praxis and is expected to close in mid to late 2011, following receipt of all relevant regulatory approvals and licences. The transaction has already received approval from the Ministry of Commerce.

GLN advised Capgemini on all aspects of the acquisition including structuring, negotiation, documentation and regulatory formalities. The GLN team advising Capgemini was led by Thomas Urlacher, with assistance from Sun Jin and Xue Bing.

For additional information visit www.gide.com

KING & WOOD

COFCO GROUP TO COOPERATE WITH MITSUBISHI CORPORATION, ITOHAM AND YONEKYU

June 2011 China's largest state-owned food company, the COFCO Group, has signed a livestock production and meat processing agreement with Japanese companies Mitsubishi Corporation, Itoham, and Yonekyu. According to the agreement, the two sides will set up a cooperative joint venture, and invest RMB 10 billion before 2017, establishing an integrated business system comprising livestock production, meat processing and sales.

In this joint venture project, the three Japanese companies will acquire a 33% stake in a subsidiary of COFCO, through MIY, an investment company they established. The joint venture plans to build and enhance farming, processing and sales infrastructure, increase output from 20 thousand tons to 210 thousand tons, and achieve an annual sales goal of RMB 17.5 billion.

Mitsubishi is one of Japan's largest business organizations, and along with Itoham and Yonekyu, is one of the leaders in the poultry and livestock market. Through this agreement with COFCO, they will gain access to the Chinese market. This deal will also bring the safety benefits of Japanese meat processing technology to Chinese consumers.

King & Wood's Liu Xinyu, Susan Ning and Simon Yung led the project team.

For additional information visit us at www.kingandwood.com

HOGAN LOVELLS

SECURES LANDMARK REVOCATION OF ANTI-DUMPING DUTIES ON STAINLESS STEEL FOR THYSEENKRUPP

WASHINGTON, D.C., 15 July 2011 – Hogan Lovells secured a significant victory on behalf its client ThyssenKrupp at the U.S. International Trade Commission on July 7, 2011. The Commission voted 4 to 2 to revoke antidumping duties on stainless steel sheet and strip in coils from Mexico, and 5 to 1 to revoke the antidumping duty orders on stainless steel sheet and strip in coils from Italy and Germany. These victories benefit Hogan Lovells clients ThyssenKrupp Mexinox S.A. de C.V. in Mexico, ThyssenKrupp Nirosta GmbH in Germany, ThyssenKrupp Acciai Speciali Terni S.p.A. in Italy, ThyssenKrupp Stainless USA, Inc. in the United States, and many other affiliated ThyssenKrupp companies in the United States, Mexico, Germany, and Italy involved in stainless steel and related businesses.

"After many years of hard work, the efforts of our team and the ThyssenKrupp Stainless companies resulted in a well-deserved revocation of these antidumping duty orders. The ITC in general concluded that the Petitioners no longer needed the protection of these orders," said partner Craig Lewis.

The Hogan Lovells team representing the ThyssenKrupp companies was led by Washington, D.C. partners Craig A. Lewis, Lewis E. Leibowitz, and T. Clark Weymouth since the outset of these cases, as well as with associates Brian S. Janovitz and Wesley V. Carrington. Economic Consulting Services and ITR assisted in these cases.

For more information visit www.hoganlovells.com

CAREY Y CIA

ADVISES BANCO DE CHILE, BANCHILE-CITI GLOBAL MARKETS AND DEUTSCHE BANK IN US\$400 MILLION SENIOR NOTE ISSUANCE BY AES GENER S.A.

Carey y Cía. acted as Chilean legal counsel to Banco de Chile / Banchile-Citi Global Markets and Deutsche Bank in the issuance of 5.25% Senior Notes due 2021 by AES Gener S.A., one of the leading Chilean electricity companies. The value of the deal was of US\$400 million.

Carey y Cía. partners Diego Peralta and Francisco Ugarte led the team, formed also by associates Fernando Noriega and Sebastián Monge.

For additional information visit www.carey.cl

NAUTADUTILH

ADVISES INEOS LIMITED IN €110 MILLION ASSET ACQUISITION OF TESSENDERLO'S EUROPEAN CHLOR-VINYL BUSINESS

3 August 2011 - NautaDutilh assisted INEOS Limited in the acquisition of Tessenderlo's European Chlor-Vinyls Business and assets in Belgium, France and The Netherlands.

Kerling will through the transaction acquire all of Tessenderlo Group's PVC activities as well as the VCM, caustic soda, caustic potash and parts of its OCD (Organic Chlorine Derivatives) businesses including:

1. The chlor-alkali, vinyls OCD assets at the site in Tessenderlo Belgium,
2. the site in Maastricht (The Netherlands) with a benzyl alcohol plant,
3. the sites in Beek (The Netherlands) and Mazingarbe (France) with PVC plants,
4. approximately 850 employees.

As a result of the transaction Kerling and Tessenderlo Group will also enter into a number of raw material and product off-take agreements between them.

The total consideration for the businesses and assets acquired will be € 110 million in cash.

The NautaDutilh partners advising INEOS Limited are Benoît Feron and Jaap Jan Trommel.

For additional information visit www.nautadutilh.com

TOZZINIFREIRE

ADVISES UNITED PHOSPHORUS LIMITED IN ACQUISITION OF 54% STAKE IN DVA AGRO DO BRAZIL

TOZZINIFREIRE provided assistance to United Phosphorus Limited in the acquisition of 51% stake in DVA Agro do Brazil, a Brazilian company from DVA Group, Germany and other shareholders. The balance 49% will continue to be held by the existing shareholders. The status of the deal is completed and its value is U\$150,000,000.00.

About UPL

UPL is the largest Indian agrochemical Company and is engaged in research, manufacturing, marketing, sales & distribution of agrochemicals and specialty chemicals across the globe.

About DVA

The German group DVA operates worldwide for over 40 years marketing products of the highest quality and technology to agriculture, nutrition, human and animal health and plastics. In Brazil, DVA operates through DVA Agro Brazil with a differentiated product line of post-patent crop protection and nutrition products.

Partners Shin Jae Kim and Renata Muzzi Gomes de Almeida, and associates Luiz Renato Okumura, Raquel do Amaral de Oliveira Santos, and Alexandre Ismail Miguel acted in the transaction.

For additional information visit www.tozzinifreire.com.br

SKRINE

COURT OF APPEALS AFFIRMS HIGH COURT DECISION IN RETENTION SUMS WITHHELD BY EMPLOYER UNDER CONSTRUCTION CONTRACT ARE MONIES HELD IN TRUST

The Court of Appeal recently upheld the decision of the High Court in the case of Sediabena Sdn Bhd v Qimonda Malaysia Sdn Bhd. In this case, the High Court held that retention sums withheld by an employer under a construction contract are monies held in trust and does not form part of the employer's general funds in the event of the employer's liquidation, notwithstanding that the retention sums were not set aside in a designated account separate from the employer's general funds. The Court of Appeal affirmed the decision of the High Court Judge and dismissed the Appellant's appeal. The decision of the Court of Appeal was unanimous.

Skrine Partners, Leong Wai Hong, Ashok Kumar and Lam Wai Loon & Associate, Tan Lai Yee represented the respondent/contractor in The Court of Appeal which upheld the decision of the High Court in the case of Sediabena Sdn Bhd v Qimonda Malaysia Sdn Bhd.

For additional information visit www.skrine.com

WILSON SONSINI

ADVISES ELECTRONIC ARTS IN US\$750 MILLION ACQUISITION OF POPCAP GAMES

On July 12, Electronic Arts announced an agreement to acquire PopCap Games, a leading provider of games for mobile phones, tablets, PCs, and social networking sites, for approximately \$650 million in cash and \$100 million in shares of EA common stock. PopCap is also eligible to receive up to an additional \$550 million in earnouts.

Additional information can be found at http://news.ea.com/portal/site/ea/index.jsp?ndmViewId=news_view&ndmConfigId=1012492&newsId=20110712007011&newsLang=en or visit www.wsgr.com

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Banking & Workouts PRACTice Group
"Creditor Workouts in Asia"

PRACTice Management - Strategic Planning for Law Firms
"National v. International Law Firms - Strategies and Challenges in a Global Market"

Public Seminar Topic co-sponsored by Business Investment & International Trade PRACTice Group
"New Developments in Privacy Laws - The Public Fights Back"



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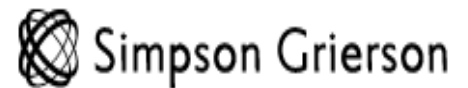
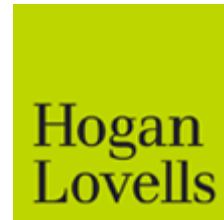


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Gide Loyrette Nouel



PRAC e-Bulletin is published monthly.
Member Firms are encouraged to contribute articles for future consideration.
Send to editor@prac.org.
Deadline is 10th of each month.

02 August 2011

Federal Court rules on copyright in pharmaceutical product information documents

In the recent case between Sanofi-Aventis Australia Pty Ltd and Apotex Pty Ltd [2011] FCA 846, the Federal Court of Australia addressed for the first time the issues of copyright subsistence and infringement in relation to product information documents (PI) for pharmaceutical products.

The Court held that the PIs for Sanofi's leflunomide product were works of joint authorship entitled to copyright protection, as their creation involved considerable skill and judgment on the part of Sanofi's employees who worked collaboratively in their creation.

The Court further held that the PI for Apotex's leflunomide product infringed the copyright in Sanofi's PIs as it reproduced the whole or a substantial part of those PIs, and a licence for Apotex to copy Sanofi's PI could not be implied in the circumstances.

However, the Court itself acknowledged that these complex issues have been rendered moot insofar as the future is concerned by the Therapeutic Goods Legislation Amendment (Copyright) Act 2011.

That Act amended the Copyright Act 1968 to insert a new section 44BA which provides that certain acts are not a breach of copyright "in a work that is product information approved under section 25AA of the Therapeutic Goods Act 1989 in relation to medicine".

The acts which do not constitute breach include acts of supplying, reproducing, publishing, communicating or adapting done under the Therapeutic Goods Act in respect of "some or all" of "product information approved under section 25AA of the Therapeutic Goods Act in relation to medicine".

Disclaimer

Clayton Utz communications are intended to provide commentary and general information. They should not be relied upon as legal advice. Formal legal advice should be sought in particular transactions or on matters of interest arising from this bulletin. Persons listed may not be admitted in all states or territories.

For additional information visit www.claytonutz.com



Administrative Law

BRAZIL: THE FEDERAL GOVERNMENT INITIATES THE PRIVATIZATION PROCEEDING OF THREE OF THE PRINCIPAL BRAZILIAN AIRPORTS

The Federal Government included three of the most important Brazilian airports in the National Privatization Program, namely: International Airport Governor Franco Montoro, in Guarulhos; International Airport of Viracopos, in Campinas and International Airport President Juscelino Kubistschek, in Brasília. The decision is set out in a Presidential Decree published on July 22, 2011.

The decree is the first formal measure adopted by the Federal Government to implement the privatization of some strategically located airports.

According to the decree, the National Agency of Civil Aviation - ANAC will be responsible for carrying out the bidding processes aiming at granting to private parties the performance of the airport infrastructure operation services, upon supervision of the recently created Civil Aviation Secretariat - SAC.

Although the Federal Government has already started the bidding process for granting the partial construction and operation of the São Gonçalo do Amarante Airport to the private sector, located in the Northeast of Brazil, it has stated that the privatization model to be adopted for Brazilian airports has not yet been defined.

The Federal Government's expectation is that the increase of the private sector participation in the airport sector will improve the efficiency of airport operations, resulting in its effective development.

Claudia Elena Bonelli
Partner - São Paulo
cbonelli@tozzinifreire.com.br

The Supreme Court of Canada Finds a Limit to the Scope of the Requirement to Pay under Section 224 ITA

The Supreme Court of Canada rendered a much awaited judgment in the case of *Canada Trustco Mortgage Co. v. R.* on July 15, 2011.

In that case, a lawyer, Mr. McLeod, owed tax to the federal government.

Revenue Canada issued requirements to pay to Canada Trustco Mortgage Co. (the «Bank»), in a branch of which Mr. McLeod maintained a trust account for the purposes of his legal practice. Mr. McLeod also maintained at the same branch of the Bank a joint account together with another person. The requirements to pay were issued pursuant to section 224 of the *Income Tax Act* («ITA»), which provides that the Minister of National Revenue (the «Minister») may require a person who is, or will be within one year, liable to make payment to a tax debtor to instead pay the money the person owes the tax debtor to the Receiver General.

The case concerns cheques which Mr. McLeod drew on his trust account, made payable to himself, and deposited in the joint account, during the period of effectiveness of these requirements to pay.

The Bank credited the proceeds of the cheques to the joint account notwithstanding the requirements to pay. The Minister accordingly assessed the Bank pursuant to section 224 ITA. The Bank filed an objection which the Minister rejected. The Bank unsuccessfully appealed to the Tax Court of Canada, and thereafter to the Federal Court of Appeal.

In a divided decision, the Supreme Court of Canada allowed the Bank's appeal and overturned all decisions below.

The majority emphasized at the outset two important concessions made by the Minister. On the basis of existing and unchallenged case law interpreting section 224 ITA, it was acknowledged that the requirements to pay did not apply to funds on deposit in the trust account, nor to funds on deposit in the joint account.

It was also undisputed that the Bank was not indebted to Mr. McLeod by reason only of the fact that the cheques payable to Mr. McLeod were drawn on the Bank. Section 126 of the Bills of Exchange Act («BEA») provides that a bill «does not operate as an assignment of funds in the hands of the drawee available for the payment thereof, and the drawee of a bill who does not accept [i.e., certify] is not liable on the instrument».

It followed that the central question on appeal was whether the Bank had become indebted to Mr. McLeod in the course of the receipt of the cheques by the Bank for deposit to the joint account, and presentment of the cheques to itself for payment out of the funds in the trust account.

The Minister argued that «the best way to view the receipt of the cheques for deposit is to break the transactions down in two steps: at the first, Mr. McLeod demanded to be paid as payee of the cheques and also demanded, as drawer, that the amounts be repaid out of the funds owed to him in relation to the trust account; at the second, he instructed [the Bank] to deposit the funds into the joint account. In other words, notional payments were made to Mr. McLeod before the funds were deposited into the joint account.»

The majority rejected this argument. It noted that Mr. McLeod's instructions were to deposit the funds into the joint account, and that he did not demand that any payment be made to him as payee. In addition the record showed that the joint account was credited with the funds prior to the cheques being paid and funds being debited from the trust account. The Bank accordingly made no payment to Mr. McLeod prior to crediting the amounts of the cheques to the joint account.

The majority then considered the Bank's obligations as collecting bank. It found that the Bank collected the cheques on behalf of Mr. McLeod and Mr. Meier jointly, not of Mr. McLeod alone, as the contract that imposes on the Bank the duty to collect the cheques is one between the Bank and the holders of the joint account. Consistent with section 126 BEA, the majority stressed that there is no contract between the Bank and Mr. McLeod as payee of the cheque.

Finally, the majority considered the Bank's obligation to pay the cheques as drawee, which it found «is triggered only at the time the holder presents the cheque to the drawee for payment», consistent with section 86 BEA. At the time of presentment, Mr. McLeod was no longer the holder of the cheques. The Bank was, in the accomplishment of its collection duties on behalf of the joint account holders.

It followed that in the course of the receipt of the cheques by the Bank for deposit to the joint account, and presentment of the cheques to itself for payment out of the funds in the trust account, the Bank had not become indebted to Mr. McLeod.

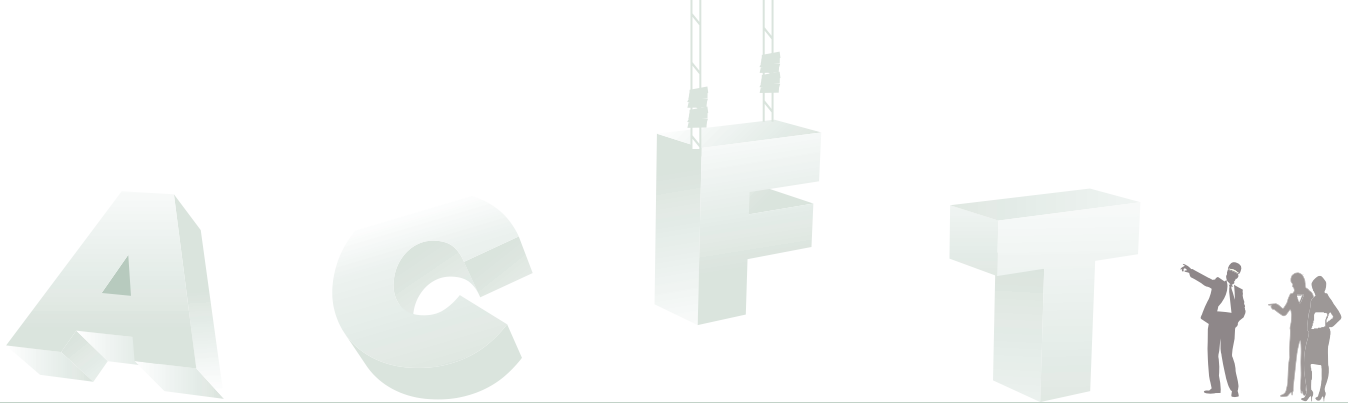
While agreeing with the majority that «[o]rordinarily, the bank on which a cheque is drawn (the drawee bank) is under no liability to pay the payee of a cheque», the dissenting justices found that «where the payee and the drawer are the same person [...], the [drawee] bank is liable to the payee once the cheque is presented [for deposit by the payee]». They also expressed the view that the cheques were payable to the Bank as agent of the payee.

These views do not sit well with established principles governing banking and bills of exchange law, and given the outcome they must now be considered to be without merit.

The dissenting justices were obviously influenced by the equities of the case and the fact that the requirement to pay was frustrated by cheques which the tax debtor wrote to himself. They expressed concerns that the view of joint accounts adopted by the majority «may negatively impact other areas of the law»: «Child and spousal support ought not to be defeated by the mere existence of a joint account».

These dissenting remarks, as well as the majority's conclusions, send a strong message to federal and provincial legislators: the current scope of application of the requirement to pay

under section 224 ITA and perhaps other comparable garnishment provisions in other areas of the law (including family law) is limited, and suffers from a loopholes which from a policy perspective it may be appropriate to remedy by a revision of the applicable statutes.



Latest Development and Characteristics of Chinese Trade Unions

By Linda Liang

In recent years, the All-China Federation of Trade Unions ("ACFTU") has been actively promoting the establishment of trade unions in enterprises. Many enterprises have received notices from trade unions at higher levels requiring them to set up their own unions. In addition, since last year, there have been several collective labor disputes and mass labor disturbances taking place around China, posing great challenges to the industrial relations and the human resource management of the enterprises. In view of the above, this article provides a brief summary of the latest development and characteristics of Chinese trade unions, with an aim of assisting enterprises dealing with issues they may face during the process of the establishment of trade unions.

I. Trends on the Developments of Trade Unions

A. ACFTU: Promoting the Establishment of Trade Unions and Union Membership

In July 2010, at the 4th Plenary Session of ACFTU's 15th Executive Committee, ACFTU Chairman Wang Zhaoguo proposed a "two universality" work requirements, i.e. facilitating the universal establishment of trade unions and the universal implementation of collective wage bargaining in all enterprises in accordance with laws. ACFTU's goal is to raise the unionization rate of enterprises above 60% nationwide by the end of 2010, above 80% by the end of 2011, and to achieve the universal establishment of trade unions in all enterprises by the end of 2012. Thus, promoting unionization among all types of

enterprises, especially foreign invested enterprises and Hong Kong/Macao/Taiwan invested enterprises, has become a top priority on the work agenda of trade unions at all levels in China.

In order to implement the "two universality" requirements, from September to December of 2010, ACFTU launched the "Broad Survey, Deep Unionization, and Full Coverage" campaign across the country. In Beijing, Shanghai, Shenzhen and other regions, the local trade unions at different levels have set up active plans based on particular local conditions and have carried out a series of intensive unionization campaigns.

During the same period, with regard to unionization in foreign invested enterprises and Hong Kong/Macao/Taiwan invested enterprises, ACFTU has worked on the "Promotion of Unionization Work among the World's Top 500 and Other Multinationals". Moreover, ACFTU has set up a special task force, overseeing directly the unionization effort of some of the world's top 500 companies' Chinese headquarters and their subsidiaries or branch offices. According to press reports, by the end of 2010, the unionization rate among the Chinese headquarters of the world's top 500 companies and other multinationals has reached over 90%.

In addition, ACFTU also plans to release the *Measures of Democratic Elections for Base-Level Trade Union Organizations* this year to standardize base-level trade unions' electoral system. This clearly shows the great



efforts ACFTU has made to intensify unionization in enterprises.

B. Beijing: Promoting the Collection of Trade Union Funds and Trade Union Establishment-preparation Funds through Local Tax Bureaus

Since July 1, 2010, the Beijing Federation of Trade Unions has introduced two pilot programs, the “collection of establishment-preparation funds” and the “collection of trade union funds (establishment-preparation funds) by local tax bureaus”, in Xicheng District (i.e. former Xuanwu District), Fengtai District and Changping District.

Firstly, enterprises without their own trade unions shall pay trade union establishment-preparation funds equivalent to 2% of the total wages of all of their employees every month ;

Secondly, the trade union funds as well as the trade union establishment-preparation funds shall be collected by the local tax authorities where the enterprises are located. This approach changes the traditional collection model, for it links the collection of trade union funds to the compulsory collection power of the tax authorities to ensure the payments of trade union funds by the enterprises.

The above two programs will be expanded to more districts in Beijing this July and will cover all districts in Beijing next January.

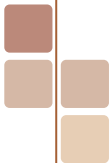
C. Shanghai: Facilitating Enterprise Unionization by the Workers Congress System

Regulations of the Shanghai Municipality on Workers Congress (“Regulations”) has already become effective as of May 1, 2011. According to the Regulations, all enterprises, including Hong Kong, Macao and Taiwan invested enterprises and foreign invested enterprises shall establish and implement the Workers Congress system, and trade unions of enterprises are the operating mechanism of the Workers Congress and undertake its daily work. In addition, Chapter 5 “Rules of Procedure” and Chapter 6 “Operating Mechanism” of the Regulations repeatedly mention the separation and cooperation between the trade union and the Workers Congress. Thus, the Regulations clearly require enterprises to set up trade unions for the democratic management of the enterprises.

D. Shenzhen: Innovating on Trade Unions’ Establishment Models and Organizational Forms

In Shenzhen, the unionization rate of the enterprise, especially the big multinationals, is high relative to the national level. Statistics from the Shenzhen Federation of Trade Unions show that, the unionization rate of all enterprises in Shenzhen and that of the world’s top 500 companies in Shenzhen have both reached over 90%.

In this context, the Shenzhen Federation of Trade Unions is now considering innovations in the



organizational forms of trade unions. For instance, for some large enterprises, it plans to adopt the concept of trade union federation, i.e. to form a united trade union by combining the trade union of the parent company with those of its affiliates and adopting a full-time trade union president, in contrast with the present model of establishing trade unions in the parent company and its affiliates respectively. The purpose for this is to facilitate the unified management by trade unions at higher levels and increase coordination among the trade unions in the same enterprise group. Moreover, this is helpful to the collective bargaining mechanisms to be carried out in the near future. Though this arrangement is still in the early stages, it deserves special attention since it represents a possible future development trend of trade unions of large enterprises in Shenzhen.

II. The Characteristics of Chinese Trade Unions

Enterprises face a variety of questions in the context of ACFTU's promoting the establishment of enterprise level trade unions. For example, companies may ask, "Is unionization necessary?" "What types of unions should be established?" "How does an enterprise establish a trade union?" etc. The answer to these questions requires both an accurate understanding of Chinese macro policies for the present and a full appreciation of the characteristics of Chinese trade unions. Compared with trade unions in Western countries, Chinese trade unions have the following peculiarities:

A. The Nature of Chinese Trade Unions: Mass Organizations under the Leadership of the Party

The *Chinese Trade Union Constitution* explicitly stipulates that Chinese trade unions accept the leadership of the Communist Party of China ("CPC") and are important social pillars of the state power. This is the most important difference between trade unions in China and those in Europe and the U.S. Serving as the president of ACFTU, Mr. Wang Zhaoguo is also a member of the Politburo of the CPC Central Committee and the Vice Chairman of the Standing Committee of the National People's Congress. Likewise, the Vice President and the First Secretary of the Secretariat of the ACFTU, Mr. Wang Yupu, is also the alternate member of the Seventeenth CPC Central Committee. In addition, the staff of all levels of trade unions in China receives the same treatment and benefits as the personnel of the state organs.

In typical parliamentary democratic countries in the West, trade unions are politically independent of any political parties. But sometimes, for the rights and interests of the workers that they represent, trade unions also need to solicit certain parties to speak for them in the parliament, so as to contend with those representing capital. Therefore, trade unions and political parties in Western countries are both cooperative and competitive with each other.

B. The Structure of Chinese Trade Unions: A Unified Organizational System Headed by ACFTU

Chinese trade unions are structurally unified under the leadership of ACFTU. To be more specific, firstly, ACFTU is established at the national level as the highest leading body of all levels of local trade unions and industrial unions, and all trade unions in China are subordinate to ACFTU. Secondly, higher level trade

union organizations lead the lower level ones, and the establishment of various levels of trade unions must be reported to the trade union at the next higher level for approval. Moreover, enterprise trade unions are established taking the enterprise as a unit, and they are the base level trade union organizations.

By contrast, in the West, trade unions are divided primarily by the nature of the industry, and there are various kinds and different forms of trade unions. Therefore, the diverse characteristics of trade unions in these countries are very obvious. For example, usually a number of trade unions for different industries coexist in the same enterprise, thus making it possible for employees to join one or more trade unions of different nature according to his/her own needs. As different trade unions always represent different interests, the pluralistic structure could possibly affect the respective power of these trade unions. But in power struggles between labor and capital, trade unions are often unified as one. Hence, the antagonism between labor and capital is relatively more obvious.

C. The Coverage of Chinese Trade Unions: Universality

Statistics from ACFTU show that, as of August 2010, there are 1,800 base level trade unions and 200 million union members throughout China, with more than 50% of all enterprises having a trade union. It is said that both the unionization rate of enterprises and that of employees are expected to reach 90% and above by the end of 2012.

In Western countries, thanks to their developed legal systems, the protection of a union member's rights is

not much different from that of a nonunion worker's rights. As a result, the union membership rate in these countries is not high, usually about 20% to 30%.

D. The Function of Chinese Trade Unions: Assisting the Enterprise in Exercising its Business Management Rights

Article 38 of the *PRC Trade Union Law* clearly prescribes that the trade union shall support the enterprise in exercising its power of operation and management in accordance with law. It is thus clear that what is particularly unique about the Chinese trade union is that it not only represents and protects the workers' legitimate rights and interests, but also needs to respect and support the enterprise's executive power and production needs. Furthermore, the Chinese trade union has no right to organize the workers to strike.

In conclusion, Chinese trade unions are not completely antagonistic to the enterprises; instead, the trade union and the management shall treat each other with mutual respect and support. On the one hand, an enterprise trade union may fight for more economic interests for workers through negotiation; and on the other hand, it can also provide the employer with a stable work force in order to avoid shutdowns, strikes and other mass emergencies affecting the normal production and operation activities of the enterprise.

(This article was originally written in Chinese, the English version is a translation.)





Wednesday, 29 June 2011 00:00

NEWS BRIGARD &
URRUTIA

Foreign Trade and Customs

News Flash Número: 123

0% import duty for raw leathers and agrochemicals, among other goods

On June 13 of 2011 the Ministry of Commerce, Industry and Tourism of Colombia issued Decrees 2049, 2050, 2051 and 2052 of 2011, which partially modified Decree 4589 of 2006, and reduced to 0 % the applicable import duties for more than 35 subheadings.

Notably, this reduction to 0% applies to raw leathers and agrochemicals, providing an opportunity for reducing the costs of importation of these goods.

These benefits will be in force until December 31 of 2011, except the benefit for agrochemicals which will be in force for an entire year.

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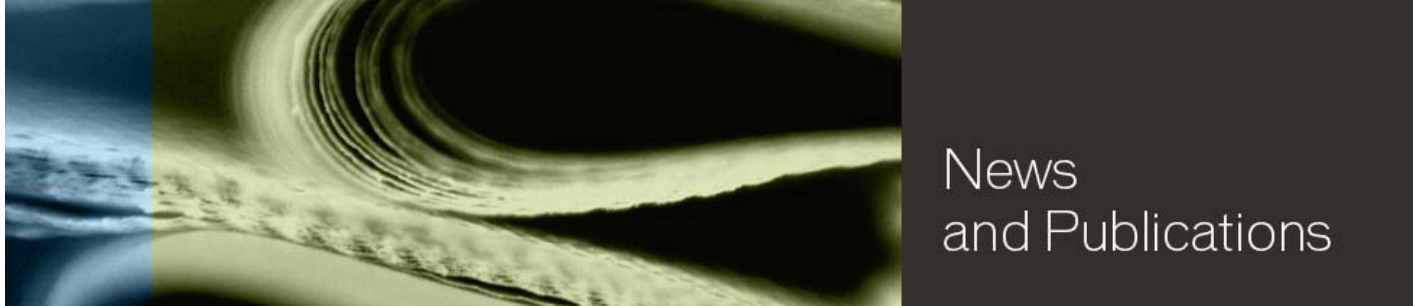
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25/07/2011

NEW RULES ON PUBLIC COMPANY TAKEOVERS

Through his Decree No. KEP-264/BL/2011, the Chairman of the Indonesian Capital Market and Financial Institution Supervisory Agency (Bapepam-LK) has recently revised Rule Number IX.H.1 on Takeovers of Publicly Listed Companies.

The definition of 'takeover', the procedures and requirements for a tender offer and the requirement to do divestment after the exercise of a tender offer that causes the new controller to own more than 80% shareholding have not been changed, except for the introduction of the beneficial owner concept that is applicable to the new controller.

Also introduced by these new rules is the possible extension of the period for the mandatory divestment of the shares in the event of the occurrence the following:

- a. The Composite Stock Price Index (Indeks Harga Saham Gabungan or "IHSG") on the Stock Exchange falls more than 10% (ten percent) for 3 (three) consecutive trading days;
- b. The Stock Exchange where the shares of the Public Company are listed and traded is closed;
- c. The trading of the shares the Public Company in the Stock Exchange is suspended;
- d. Natural disasters, wars, riots, fires, and/or strikes, which significantly influence to the business survival of the Public Company;
- e. The stock price at the time of the divestment is never equal or higher than the price of the Mandatory Tender Offer, and/or
- f. The new controller has exerted efforts to divest the shares, but the obligation cannot be satisfied.

The deferral of the divestment obligation because of the circumstances in point 1 letter e and f may be applied for to Bapepam - LK in the following manner:

The application should be submitted by the new controller to Bapepam-LK no later than one business day after the expiration of the period of the obligation to divest the shares;

For the circumstance in point e above, the application must be accompanied by the data and information regarding the share price which prove that the share price at the time of re-transfer has never been equal or higher than the price of the Mandatory Tender Offer.

For the circumstance in point f above, the application must be accompanied by explanation of the following:

- 1) efforts that have been made with regard to the implementation of the obligation to divest the shares; and
- 2) difficulties faced in the implementation of the obligation to divest the shares.

The deferral of the obligation to divest the shares may be granted for a period of 6

(six) months as of the date of issuance of the approval by Bapepam-LK. The Decree became effective on May 31, 2011. (By: Freddy Karyadi)

THE ARBITRATION (AMENDMENT) ACT 2011

Ashok Kumar explains the changes under the Arbitration (Amendment) Act 2011

The Arbitration Act 2005 ("Principal Act") was a long-awaited and much needed change to the landscape of arbitration practice in Malaysia. The Principal Act is based on the UNCITRAL Model Law and came into force on 15 March 2006 ("Commencement Date").

Being a relatively new legislation, the jurisprudence surrounding the Principal Act is still developing and different interpretations of the provisions and different approaches have been adopted by the Malaysian courts, no doubt due, in part, to the courts' lack of familiarity with the arbitral process and the UNCITRAL Model Law.

The Arbitration (Amendment) Bill 2010 ("Bill") was introduced to address the inconsistency in the interpretation of the provisions of the Principal Act and to give effect to some of the representations by the arbitral community.

The Bill passed into law as the Arbitration (Amendment) Act 2011 ("Amendment Act") upon receipt of Royal Assent on 23 May 2011 and publication in the *Gazette* on 2 June 2011. The Amendment Act will come into operation on a date to be appointed by the Minister by notification in the *Gazette*.

This article highlights the main changes that will be made to the Principal Act upon the Amendment Act coming into operation.

SECTION 8

The objective of Section 8 of the Principal Act is to restrict curial intervention in arbitration proceedings to the circumstances set out in the Principal Act, such as those set out in Sections 11, 37, 38, 39 and 42 thereof.

Notwithstanding the aforementioned provision, views have been expressed from the Bench that curial intervention may be permitted in a case of "patent injustice" (per Hamid Sultan, JC in *Taman Bandar Baru Masai Sdn Bhd v Dindings Corporations Sdn Bhd* [2010] 5 CLJ 83, 98) or in the exercise by the Court of its "inherent jurisdiction" (per Abdul Malik Ishak, JCA in *Albilt Resources Sdn Bhd v Casaria Construction Sdn Bhd* [2010] 7 CLJ 785, 799 to 804).

The Amendment Act has now re-cast Section 8 to state that "No Court shall intervene in matters governed by this Act, except where so provided in this Act."

The Explanatory Notes to the Bill states *inter alia* that the purpose of this amendment is to limit court intervention to situations specifically covered by the Principal Act and to discourage the use of inherent powers.

With this amendment, it is hoped that the original objective of Section 8 will be achieved.

SECTION 10

The Amendment Act amends Section 10 of the Principal Act in three respects.

First, it removes the ground to stay arbitration proceedings in Section 10(1)(b) where the Court is satisfied that there is no dispute between the parties with regard to the matters which are to be referred. The Explanatory Notes to the Bill state that this provision is unnecessary.

The effect of the foregoing is that the only ground to stay arbitration proceedings under the amended Section 10(1) is where the Court is satisfied that the arbitration agreement is null and void, inoperative or incapable of being performed.

An instance where Section 10(1)(a) of the Principal Act has been applied is *Lembaga Pelabuhan Kelang v Kuala Dimensi Sdn Bhd* [2010] 9 CLJ 532 where the Court of Appeal held that the arbitration clause in the principal agreement had been abandoned and rendered null and void, inoperative and incapable of being performed when the parties executed various supplemental agreements which contained provisions whereby they agreed to submit to the jurisdiction of the court.

Secondly, the Amendment Act introduces special provisions in relation to admiralty proceedings which permit the Court to order that any property arrested, or bail or other security given, be retained as security for the satisfaction of any award that may be given in the arbitration proceedings or to order that a stay of court proceedings be conditional upon equivalent security being provided for the satisfaction of any award that may be given in the arbitration proceedings.

“ The expression “substantially affects the rights of one or more of the parties” ... may be fertile ground for litigation ”

Thirdly, the Amendment Act introduces a new sub-section (3) to the Principal Act which provides that the provisions of Section 10 of the Principal Act apply to an international arbitration where the seat of arbitration is not in Malaysia.

SECTION 11

Section 11 of the Principal Act confers express powers on the High Court to make interim orders in respect of the matters set out in sub-paragraphs (a) to (h) of Section 11(1) of the Principal Act, including an order to prevent the dissipation of assets pending the outcome of the arbitration proceedings.

The Amendment Act clarifies that the power of the High Court under Section 10(1)(e) of the Principal Act to make interim orders "to secure the amount in dispute" extends to the arrest of property or bail or other security pursuant to the admiralty jurisdiction of the High Court.

A new sub-section (3) extends the powers of the Court under



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Section 11 to an international arbitration where the seat of arbitration is not in Malaysia. The effect of this amendment is that the decision of the High Court in *Aras Jalinan v Tipco Asphalt Public Company Ltd & Others* [2008] 5 CLJ 654 is no longer good law insofar as it held that the Malaysian High Court has no jurisdiction to grant interim orders in arbitration matters where the seat of jurisdiction is outside Malaysia.

SECTION 30

Sub-section (1) of Section 30 of the Principal Act provides that in a domestic arbitration where the seat for arbitration is in Malaysia, the arbitral tribunal shall decide the dispute in accordance with the substantive law of Malaysia.

In other words, the provision appears to impose a mandatory obligation on the arbitral tribunal to apply the laws of Malaysia in every domestic arbitration where the seat for arbitration is in Malaysia.

The Amendment Act amends this provision to dispense with the requirement for the arbitral tribunal to apply Malaysian law where the parties to the dispute have agreed that the dispute is to be governed by the laws of a jurisdiction other than Malaysia.

SECTION 39

This section sets out the grounds on which the High Court can refuse to recognise or enforce an arbitration award.

The Amendment Act replaces the reference to "Malaysia" in Section 39(1)(a)(ii) with the words "the State where the award was made". This means that determination of the validity of the arbitration agreement should be determined in accordance with the laws of the State where the award was made and not necessarily under the laws of Malaysia.

Section 39(2)(a)(v) of the Principal Act confers the right on the Court to not recognise or enforce an arbitration award which contains decisions on matters beyond the scope of the submission to arbitration.

The Amendment Act introduces a new Section 39(3) to the Principal Act which reduces the harshness of Section 39(2)(a)(v) by providing that where the decision on matters submitted to arbitration can be separated from those which have not been submitted, the Court may recognise and enforce those parts of the award on matters that have been submitted for arbitration.

SECTION 42(1A)

Section 42(1) of the Principal Act allows any party to refer to the High Court any question of law arising out of an award.

The Amendment Act introduces a new Section 42(1A) to the Principal Act which confers power on the High Court to dismiss a reference under Section 42(1) unless the question of law

substantially affects the rights of one or more of the parties.

The expression "substantially affects the rights of one or more of the parties" is unclear and may be fertile ground for litigation until such time that the Malaysian Courts make an authoritative ruling as to the circumstances that fall within the ambit of that expression.

SECTION 51

Section 51(2) of the Principal Act provides *inter alia* that the provisions of the Arbitration Act 1952 will continue to apply to arbitration proceedings which have been commenced before the Commencement Date. Under the English language text of the Principal Act, the sole criterion for determining whether this saving provision applies to an arbitration is whether the arbitration were commenced before or after the Commencement Date.

Section 51(2) of the Bahasa Malaysia text of the Principal Act was inconsistent with the English text in that it provided that the saving provision applied where an arbitration agreement is made or where arbitration proceedings are commenced before the Commencement Date.

The Amendment Act amends Section 51(2) of the Bahasa Malaysia text to remove the inconsistency with the English text of the Principal Act, the latter of which is the authoritative text.

The Amendment Act introduces a new sub-section (4) to Section 51 of the Principal Act which provides that the Principal Act will govern all court proceedings relating to arbitration which are commenced after the Commencement Date notwithstanding that such proceedings arise from arbitration proceedings that were commenced before the Commencement Date.

In other words, while arbitration proceedings which are commenced before the Commencement Date continue to be governed by the Arbitration Act 1952, any court proceedings which arise from such arbitration are to be governed by the provisions of the Principal Act.

CONCLUSION

The amendments are welcomed as they provide greater clarity and certainty in the law as well as finality in the arbitral process and enforceability of awards.



Renewable Energy, Mexican potential.

By Mónica Santoyo (*)

Although Mexico is considered rich in fossilized natural resources, such as oil, allowing energy production through their combustion. We know that oilfields are limited and the time will come when they will disappear, as any non-renewable resource. However, energy demand will not cease to increase year after year, therefore, meeting same is a problem that cannot be overlooked.

It is a matter of fact that besides being a finite resource, crude oil byproducts used in energy generation produce carbon dioxide, among other gases, affecting the ozone layer and causing global warming, therefore, it has been necessary to seek efficient, clean and lasting alternatives, establishing to reduce the use of fossilized energies in order to stop the planet's overwarming.

Even when oil continues being the main fuel in the energetic mix of the countries, a competitive growth in the renewable energy field has taken place all over the world.

Mexico is not only oil-rich, our country has all the elements to generate solar, wind, geothermal or hydraulic renewable energy, having a very high potential. It may even have the future capacity of maintaining the level in energy generation by means of these renewable systems.

Renewable energy generation, besides being beneficial for the environment upon using locally available resources without generating damaging emissions, is also a window of opportunity since it provides income and work to local populations.

Since 2006, the Mexican government announced that there would be a significant increase in the generation of hydraulic, wind and geothermal energy between 2005 and 2014. By the end of 2007, fifty projects corresponding to the generation of 1400 MW of electricity were completed. In accordance with the Energy Regulatory Commission (CRE), Mexico presently has a 13400 MW installed capacity based on renewable sources, which amounts to twenty four percent of the country's capacity. That is, seven percent of the energy generated in Mexico is renewable. Projects continue increasing and the goals toward is 2024 is to increase the participation of clean technologies in a thirty five percent.

An example of the wind energy generation capacity is La Ventosa project in Oaxaca, operated by the Federal Electricity Commission (CFE), with a 1.5 MW installed capacity and aero generators and aero pumps capacity of about 2.4 MW. These projects have been open to the private sector participation. CFE called for bids in 2008 in order to construct La Ventosa substation and to expand the existing substation. This way, it is guaranteed that the technologies used will be state-of-the-art and that exploitation of the resources will be at their maximum level.

In relation to hydraulic energy, in accordance with the CFE, it represents twenty six percent of all the electric energy generation capacity. Among these dams we have the ones of Mal Paso, La Angostura and Chicoasén located in the state of Chiapas. In addition, the micro hydraulic projects have an energetic exploitation of 3200 MW and are growing.

Between 2009 and 2010, the use of solar energy for electric energy production has increased from an average of 630 KW to 860 KW, for 2011, a production 2500 MW is expected. It should be noted that both the CFE and the private sector are presently participating in the development of electric energy generation projects by means of photovoltaic technology, making use of the potential that Mexico has.

It should be mentioned that as part of the Federal Government strategy in matters of promotion of the renewable energies use, the Secretariat of Energy published several patterns of contracts for energy renewable sources, as well as the methodologies to determine the transmission costs of the renewable energy generated by individuals and the costs for sale of energy coming from plants generating renewable electric energy, that CFE must be subject to. This, within the framework of offering benefits to the generators of clean energy, as well as legal protection.

Likewise, to date, diverse solar parks are being developed throughout the Mexican Republic, seeking to meet the electric needs of individuals and contributing to the improvement of the environment by means of the use of clean technologies with efficient projects. This type of project is based on the provisions of the Electric Energy Public Service Law and its Regulations, which allow the installation of electric energy generating plants (renewable or not) under the self-supply system.

The development costs of an electric energy generation project have been benefitted with the incentives that the Mexican Government has introduced: depreciations of the equipment purchased, preferential transmission rates, surplus buying and selling costs, among others.

For the above, we foresee that the development of renewable energy projects of all sizes, from particular self-consumption, such as self-supply societies, up to those called for bids by the CFE, will continue booming in the next years.

This way, we may verify that the renewable energy field in Mexico has a huge potential. This is only the beginning of an industry in which everybody wins: the government, the private sector and the planet.

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Takeovers Code: "Tripping" Private Companies

04 Aug 2011

The Takeovers Code has been in force now for more than a decade. The "fundamental rule" is at the core of the Code's requirements, stopping anyone getting more than a 20% shareholding, unless every existing shareholder has the chance to sell into the offer or very specific procedures are followed.

The Code's enactment has certainly regularised the takeover process for listed entities. It has created opportunities for all participants in the public markets space - target companies, bidders, cornerstone shareholders, and retail investors - to share in the benefits which flow from changes in corporate control. The Takeovers Panel has also done a fine job of vigilantly overseeing these processes and the proper application of the Code's regulatory requirements.

Despite these benefits, there remains one area where we think the Code's reach goes too far: in its jurisdiction over unlisted private companies which have more than 50 shareholders.

We are regularly confronted by the significant and adverse economic and opportunity costs of the Code's requirements in this area. It is the one area where we believe a fundamental reconsideration of the policy behind the Code's application is warranted.

What's the history?

Many of you will remember the history here. Our Code, from the outset, applied to private companies, with 50 or more shareholders, where the company also had more than \$20 million in assets. The philosophy was to capture widely-held and significant private companies, to ensure the Code's fundamentals - equal treatment for all shareholders etc - applied across the spectrum. For the reasons noted here, we believe this philosophy was incorrect.

What's a private company?

Since the outset, the Code's private company net has been extended even further. The \$20 million threshold test was abandoned, so that any widely-held private company was within the Code, irrespective of its asset base.

More recently, the Panel has expressed its view on how you count your shareholding base, for the purposes of determining whether or not you have 50 shareholders. (We believe the removal of the asset threshold was inappropriate, but we would still hold the views expressed here if it had

remained - the Code should only apply to listed companies, unless the legislators can come up with a more meaningful alternative than the current Code company definition.)

Two people, holding one share parcel, are counted as two shareholders (although we do not share the Panel's view here and, in any event, there is a law change proposed to address this). Given the preponderance of trust structures for personal asset holdings, where two or more trustees typically appear on a share register, the net effect is that a financially modest company, with a few share parcels held through trusts, is as likely as not to be a Code company or at least treated as one by the Panel. The alternative is for these companies to seek out and pay for advice, and design artificial holding structures, to ensure that is not the case.

Where's the need?

Most investors in a private unlisted company, whether big or small, are often somehow connected into the activities, operations, or history of the company. They may be existing or former employees, the founder or following family generations, persons with whom the company has a significant trading connection, private equity investors who have taken board seats, and so on.

Generally they can be expected to understand that their investment is not particularly liquid. There is no ready market for their shares nor, in most cases, for the holdings of other co-shareholders. So there is some inherent protection that they will not end up co-investing with other parties they do not know or like, or that anyone else will get out of the company more easily or with a better deal than them.

Historically, private company investors have also been able to protect, or enhance, this base line co-investment position through a variety of mechanisms, including shareholders' agreements. One of the most standard mechanisms used which can be used is the pre-emptive rights arrangement. This arrangement requires that, if any shares are issued or transferred to anyone, existing investors have a pro-rata right of first refusal. This means they get a chance to buy up more stock ahead of anyone else. A right to sell out to any potential buyer that comes along, while not a stock-standard mechanism, is also something investors can seek, if they need it as a condition of their investment, when they invest. If they have got enough bargaining power, they can get these "tag-along" rights; if they don't, they don't - and they can decide whether this suits them or not before they put their money in.

So, we ask, why the need for the Code's application to private companies in the first place?

What about listed companies?

This is in stark contrast to the situation with listed company stocks. Here the basic proposition is that investors' stock is liquid, and certainly must be freely transferable to any person without any restriction. Minorities in a listed company are usually far more distant from the activities and operations of the listed company than those who have invested in private companies. They are along for the financial ride, but probably not much else.

So you can see, in a listed company context, the far greater likelihood of transactions occurring where the minorities are left out in the cold, and where they have had no ability to change or influence that position at any time in the investment cycle. Hence, in this context, the Code makes good sense.

The bite really comes when you get into capital raising for private companies.

If a private company needs cash, larger existing investors usually have the greatest capacity to pay in. (Of course, pre-emptive rights might often mean that minorities have a chance to put money in if they want. But, more often than not, they are not in a position to put in a meaningful or any contribution to the funding required.) In the ordinary course of events, directors have to act in the best interests of the company in deciding that they will seek money from an existing, or even a new, investor on a basis that dilutes others. Directors also have to be comfortable, and certify, that the amount that is paid in, and the extra shareholding given out, is a fair and reasonable deal - for both the company and the existing shareholders.

These seem to us to be appropriate protections. But the 20% Code shareholding limit looms large in these circumstances. These larger investors often simply cannot put in more money that the company sorely needs, without the expense of going to a shareholder vote, with independent expert reports obtained, and at which they cannot vote. And, even assuming minority shareholders are comfortable voting in the increased shareholding position of these investors this time (and any lack of comfort may be more contrived than real when shareholders realise they have disproportionate and unintended power), the shareholders putting their hands in their wallets now know that next time the company is strapped for cash, the company's fortunes effectively sit in the hands of other shareholders... Catch 22. So why would you put more money in? Perhaps you do, but you certainly price in this risk, which means you expect more shares for your cash, and more dilution for minorities.

Another strange twist in a private company context is the Code's compulsory acquisition rule. Once anyone gets a 90% shareholding in a private Code company, that shareholder must offer to buy out all of the others. And the others have to sell out. No matter how satisfied the shareholders were with their respective positions, the law says they cannot stay that way (unless, of course, you go back to the lawyers and pay for some artificial restructuring to save you from all this fuss).

What's more, more often than not you see this feature used as a device by large (90% or more) shareholders in private non-Code companies to suck out their co-investors. If all it takes is 50 shareholders to become a Code company, a large shareholder simply puts a handful of shares out to 49 nominees and, lo and behold, compulsory acquisition is at its doorstep. So where is the protection for the minorities here?

Where are the winners?

So let's get back to the core policy question. Why is it a good idea to place material regulatory

constraints on the capital raising process for private unlisted companies that are looking to grow? If the rationale is to ensure minorities are treated fairly, the outcome is somewhat perverse.

There are one of two very likely side effects of the regulatory constraints. The first is that the capital cannot be raised. The growth it was to fund does not happen. Minority shareholders, and for that matter everyone, are undoubtedly worse off. The second is that the capital is raised, but, in our experience, at undoubtedly a *significantly* increased cost in every sense, which increase is attributable *only* to the regulatory regime required under the Code. So, ultimately, less free capital is then available to fund the growth, and minorities are more significantly diluted than need necessarily be the case. Yet again, minority shareholders are undoubtedly worse off. In fact, everyone is; there are no winners.

We believe this is a critical area, not only for the companies affected, but also for New Zealand and its economy. It would be a very simple matter to limit the operation of the Code to avoid these adverse conditions.

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RESOURCES

The Bank's Duty Of Care And Investment Advice

June 2011 | Finance | Business Bulletin

LEE Yin Wei
WONG Cui Lian

Introduction

Since the recent credit crunch, there has been much attention on the duty of care owed by financial institutions regarding investment advice. In particular, is a bank obliged to warn their clients against substantial investment risks?

The landmark case of *JP Morgan Chase Bank v Springwell Navigation Corporation* [2008] EWHC 1186 ("Springwell"), affirmed locally in *Go Dante Yap v Bank Austria Creditanstalt AG* [2010] 4 SLR 916 ("Bank Austria"), shows that the courts will not lightly find the existence of an additional duty within a banking relationship that is already governed by contract. For there to be a duty, there must be conduct amounting to an assumption of responsibility coupled with reliance. Factors relevant to determining if such conduct exists include the level of sophistication of the investment and whether the parties have contractually defined the terms upon which they will conduct business.

The relevant legal principles in determining duty

In *Springwell*, the defendant customer brought a counterclaim against the plaintiff bank in contract and in tort after it suffered losses to its portfolio as a result of the Russian financial crisis. The customer alleged that there was an advisory relationship between the bank and the customer which obliged the bank to advise what investments were appropriate for the customer, having regard both to the particular characteristics of individual investments and the balance of the portfolio as a whole.

Gloster J in *Springwell* identified the following "lower level" factors that serve as indicators of the existence or otherwise of any contractual or tortious duty of care:

- (1) the contractual context (including the terms of the relevant contractual documents and disclaimers, and the absence of any written advisory agreement);
- (2) what, if anything, was said to the customer by the bank's representatives;
- (3) the roles played by the parties;
- (4) the extent of the customer's financial experience or sophistication;
- (5) the extent of the customer's reliance on the bank, including the extent to which it was foreseeable that reliance would be placed upon the investment advice that, allegedly, should have been given; and
- (6) the regulatory background.

It was held that if there was an assumption of legal responsibility whereby one party undertakes to perform a task or service for another, the contract between the parties may modify or exclude the scope of any existing tortious duties arising out of that assumption of responsibility. However, if there was no assumption of responsibility by either party, the contract will generally be completely determinative of the scope of the parties' duties.

The court in *Springwell* referred to the decision in *Titan Steel Wheels Limited v The Royal Bank of Scotland Plc* [2010] EWHC 211 (Comm) where it was held that the scope of the obligations owed by the bank to its client were fully defined in the contractual terms. Steel J held that these terms expressly provided that the bank would not provide advisory services and that any opinions expressed by the bank did not constitute investment advice and the client, Titan, was to take independent advice as might be necessary.

The terms outlined in the contracts between the parties were consistent with the conclusion that Titan and the bank were agreeing to conduct their dealings on the basis that the bank was not acting as an advisor nor undertaking any duty of care regardless of what recommendations, suggestions or advice were tendered.

Likewise in *Credit Industrial et Commercial v Teo Wai Cheong* [2010] SGHC 155 ("CIC"), Philip Pillai JC decided that the question whether a private bank owes a duty to advise its client will ultimately depend on the contract and the conduct of the parties. CIC involved structured equity products known as accumulators and the dispute was whether or not the defendant had purchased the accumulators from the plaintiff.

The Singapore High Court held that the plaintiff was under no contractual obligation to ensure that the defendant understood the full import and implications of all the terms of the accumulators. The term sheet of the disputed accumulators had set out the relevant disclaimers relating to the defendant's need to make his own risk assessments. It was up to the defendant to request information or clarification about terminating the accumulators if it was required.

Both cases were affirmed in *Bank Austria*. In *Bank Austria*, the plaintiff claimed that the bank had breached its duty owed to the plaintiff, in contract and/or tort, by failing to advise the plaintiff that it was imprudent to have maintained the investment portfolio that he was holding during the period of the Asian financial crisis. It was alleged that the bank owed concurrent and co-extensive duties in both contract and tort to advise him as to the prudence of his investment portfolio.

Adopting the lower level factors in *Springwell*, the court affirmed the principle in *Springwell* and *CIC*. The court held that a private bank is not acting as a trusted advisor of its client when the standard printed forms highlight that the client is responsible for the risks in his transactions and recommends that he takes advice from other professional advisers and that the bank does not make recommendations or give advice, the latter being borne out by the evidence of conduct and the extent of the investor's financial experience and sophistication, depending on the particular factual matrix concerned.

The nature and terms of the contractual relationship between the parties will determine the scope of the responsibility assumed and can, in some cases, exclude any assumption of legal responsibility to the plaintiff for whom the defendant has assumed to act.

The court held that the terms of the principal contractual documents upon which the bank relied on clearly showed that the parties were dealing with each other on a stipulated and accepted basis that, whatever advice or recommendations may have been given by the bank in the course of their trading relationship, no obligations to give appropriate investment advice, or duties of care as an investment advisor, were being assumed.

Conclusion

As financial products become more complex, financial institutions act in varying capacities *vis-a-vis* their clients. As investors naturally look to apportion blame in times of financial crisis, the

decisions cited above are cause for relief for financial institutions. It is evident that a strict test remains in place for parties wishing to contradict clear contractual documentation governing the way these financial institutions transact with their clients.

In the absence of fraud, misrepresentation or the finding of any conduct amounting to reliance, the courts will treat the contractual documentation as normally precluding any implied terms incorporating a duty of care on the part of the financial institutions. A specifically contracted trading and banking relationship between the parties thus negates the assumption of a general or specific advisory duty.

CLEARANCE GRANTED TO COMBINATION REGARDING ESTABLISHMENT OF A LICENSING COMPANY FOR A PATENT POOL

©Stephen Wu / Yvonne Hsieh

At its March 31, 2011 commissioners' meeting, the Fair Trade Commission (FTC) conditionally permitted a proposed combination for the joint operation of One-Blue, LLC ("One-Blue") by Hitachi, Panasonic, Philips, Samsung, Sony and Cyberlink. One-Blue will act as a licensing agent for the patent pool to license essential blue-ray disk (BD) patents for the manufacturing of backward-compatible BD products. Upon the consummation of the combination, the participating parties will respectively acquire a 1/6 shareholding and then jointly operate One-Blue.

The relevant market of One-Blue is defined as "the domestic product market, technology market, and innovation market which are related to BD." The basis for such broad definition is that the participating parties not only hold technologies for the manufacturing of BD products but are also engaged in the manufacturing of BD products.

As to the competition analysis, the FTC held that the proposed combination would not give rise to competition restraints due to the following arrangements in the applicable pool agreements:

- Only essential patents will be included in the patent pool and the essentiality of the patents will be determined by independent patent experts, according to the pool agreements. Through such mechanism of periodic review by independent experts, the essentiality of patents in the pool can be secured and any substitutable patents will be excluded.
- The patent pool will be open to all patent holders and thus is not a closed pool. Meanwhile, all licensors of the patent pool are required to conduct individual licensing activities for any licensee requesting individual licenses on a RAND (reasonable and non-discriminatory) basis. Therefore, licensors and licensees are free to coordinate their technology to promote a competitive technology.
- Licensors are prohibited from disclosing their confidential information so as to ensure that the confidential information will not be exchanged between licensors resulting in a conspiracy among pool members. Additionally, the pool agreements stipulate that licensors cannot have access to licensees' information provided for the application of per-batch license before each shipment of product.
- The scope for the grant back provision is limited to essential patents and the royalties paid under the applicable pool agreement will qualify for the royalty rate for the grant back of essential patents. Licensors of such grant back licensing are free to individually license

their patents, and thus the incentives for further R&D by such licensors will not be affected. Such arrangement promotes future innovation. Also, no provision under the pool agreements prohibits the licensors from using competing technologies or developing competition standard or products.

The FTC further explained that as for BD technology, Taiwanese enterprises are in a position to adopt technologies which have been developed by others. If this combination is prohibited, Taiwanese BD products manufacturers will have to negotiate for licenses with patent holders individually and the transaction cost of individual negotiation and the accumulated royalties are expected to be higher than being granted licenses through One-Blue. Therefore, licensing the essential BD patents through a patent pool is expected to make it easier for Taiwanese manufacturers to obtain the licenses for essential patents, lower the transaction cost and avoid the risk of infringement and litigation, which will promote competition among Taiwanese manufacturers, with the consumers being the ultimate beneficiary.

On the other hand, since participating parties are also engaged in the manufacturing and sales of BD products, the patent pool will increase the opportunity for third parties to use the licensors' essential patents, which may stimulate competition in the downstream market. The licensors will not acquire sensitive information such as cost data, and will refrain from exchanging sensitive information between themselves, and thus upstream and downstream vertical competition will not be negatively affected.

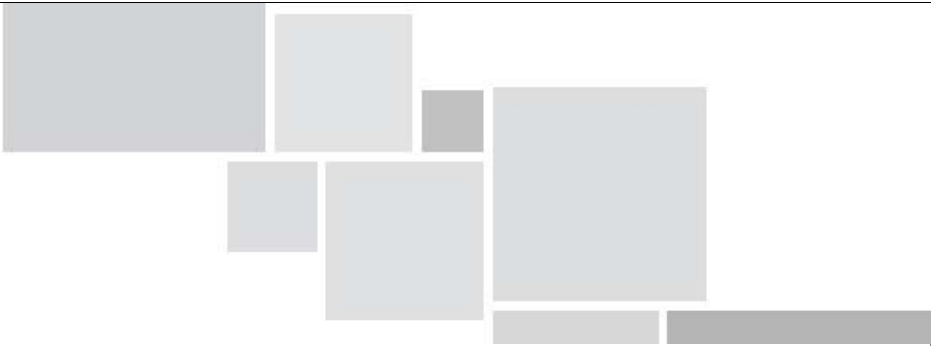
To sum up, the combination should be deemed helpful to lower transaction costs for Taiwanese enterprises when applying for licenses and thus the overall economic benefit of the combination indeed outweighs the disadvantages from competition restraints. However, in order to prevent the participating parties from stifling competition through the patent pool, the FTC attaches six necessary conditions to eliminate any disadvantages from possible competition restraints, and to ensure the overall economic benefit as follows:

- The participating parties should not engage in any concerted action by entering into any agreement restricting the quantities or prices of BD products or by exchanging important transaction information.
- The participating parties and One-Blue should not restrict licensees' scope of technology use, trading counterparts and product prices.
- The participating parties and One-Blue should not forbid licensees from challenging the essentiality and validity of the licensed patents.
- The participating parties and One-Blue should not forbid licensees from researching and developing, manufacturing, using and selling competing products and/or adopting competing technologies during the license term or after expiration of the license.
- The participating parties and One-Blue should not refuse to provide licensees with the content, scope and term of the licensed patents.
- The participating parties are required to provide executed copies of the pool agreements for the FTC's review.

This case is noteworthy because this is the first time the FTC reviewed a case concerning a patent pool. Therefore, the FTC's views of market definition, recognition of patent essentiality review mechanism, and standards for competition assessment of a patent pool are expected to serve as guidelines for future patent pool filing.

Lee and Li Bulletin 2011

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LITIGATION UPDATE - AUGUST 8, 2011

Federal Court Resolves Open Question in Short Swing Profit Rules

On August 8, 2011, the U.S. District Court for the Southern District of New York dismissed the plaintiff's claims in *Michael D. Gibbons v. John C. Malone and Discovery Communications, Inc.* and issued an opinion clarifying the scope of short swing profit liability under Section 16 of the Securities Exchange Act of 1934. In the action, the plaintiff alleged that profits in connection with purchases and sales of Discovery Communications voting and non-voting common stock by entities related to a Discovery director were subject to disgorgement under the statute. The director-defendant argued that purchases and sales of non-voting and voting stock, which confer different voting rights on the holders and trade under different ticker symbols and at different prices, are not matchable under Section 16(b). Accordingly, the director-defendant argued that transactions across such classes are not subject to disgorgement of profits.

Whether Section 16(b) allows the matching of purchases and sales of a class of non-voting stock with those of a class of voting stock of the same company was an issue of first impression, as prior to this decision, no court had ever addressed whether purchases and sales involving different classes of common stock possessing different voting rights could be matched for purposes of Section 16(b). The Southern District has now firmly held that such matching is not captured by the statute. In its decision, the court held that:

- the plain text of the statute requires that the purchase and sale be of the same equity security;
- a significant correlation between the prices of two equity securities is insufficient to permit a court to treat them as the same equity security when neither security is convertible into or exercisable for the other; and
- where two equity securities have different voting rights and stock dividend preferences, they are not the same class for purposes of Section 16(b).

The court's ruling provides a clear guideline for corporate insiders of companies that have both voting and non-voting stock outstanding. Based upon this ruling, insiders should now be able to trade in the two classes of stock without the threat that trades of voting stock may be matched with trades of non-voting stock to create Section 16(b) liability.

Baker Botts L.L.P. represented the director-defendant in this action.

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Treasury Department Issues Final Rule on “Prepaid Access” Under the Bank Secrecy Act

07.29.11

By Andrew J. Lorentz and Brian J. Hurh

On July 27, 2011, the Treasury Department’s Financial Crimes Enforcement Network (FinCEN) released its much anticipated final rule (Final Rule) applying the anti-money laundering requirements of the Bank Secrecy Act to certain open and closed-loop prepaid payment products in a comprehensive manner for the first time.

The Final Rule redefines “stored value” as “prepaid access” and imposes significant regulatory obligations on both “providers” and “sellers” of “prepaid access,” including certain anti-money laundering program, reporting and recordkeeping requirements. Notably, in response to public comment, the Final Rule significantly enlarges the exemptions for closed-loop retailer gift card programs and narrows the definition of “seller of prepaid access,” as compared to the proposed rule. A copy of the Final Rule, as published in the Federal Register, is available [here](#).

Overall assessment

The scope of the Final Rule reflects FinCEN’s effort to balance persistent law enforcement concerns about the abuse of “prepaid access” programs for money laundering¹ against strong consumer demand for such products as reflected in the growth of the industry. While the Final Rule suggests FinCEN gained important industry insight as to the value of prepaid programs during the rulemaking process, the Final Rule may still have a significant adverse impact on the development of innovative payment systems and products. The efficacy of the Final Rule in preventing money laundering or terrorist financing remains to be seen, and the case for the necessity of the Final Rule remains—at most—incomplete.

Key definitions

Prepaid Access and Prepaid Programs: The Final Rule defines “prepaid access” to mean “access to funds or the value of funds that have been paid in advance and can be retrieved or transferred at some point in the future” through physical (e.g., card or other device) or non-physical (e.g., code, electronic serial number, mobile identification number, personal identification number) means. The change from “stored value” to “prepaid access” is intended to capture not only physical cards but payment devices that are used today or that may emerge in the future.

A “prepaid program” is an arrangement in which one or more persons act together to provide prepaid access. Any prepaid access operation that does not fall within one of the enumerated exemptions (discussed below) is subject to the Final Rule.

Provider of Prepaid Access: A provider is the participant in a non-exempt prepaid program that serves as the principal conduit for access to information from its fellow program participants. The Final Rule adopts the “agreement approach” such that the “provider” is deemed to be whichever party in the prepaid program is designated by agreement among the participants. One party must serve as the designated provider for purposes of registering with FinCEN and complying with its money services business (MSB) regulations.

If the parties to a prepaid program are unable to agree who should be designated as the “provider,” FinCEN will determine who has “principal oversight and control” based on five factors: (1) who organizes the prepaid program; (2) who sets the terms and conditions of the program; (3) who determines the parties that may participate in the program; (4) who controls or directs initiation, suspension or termination of the program; and (5) who actually engages in the activities that demonstrate principal oversight and control. These elements are retained from the proposed rule.

Seller of Prepaid Access: A “seller of prepaid access” is any person who “receives funds or the value of funds in exchange for an initial loading or subsequent loading of prepaid access.” To implement a “targeted approach” to regulating prepaid access, the Final Rule only applies to “sellers” that (1) sell prepaid access under a non-exempt prepaid program that can be used before customer verification (i.e., immediately usable prepaid access); or (2) sells any type of prepaid access (whether exempt or not) to funds that exceed \$10,000 to any person during any one day, without having implemented policies and procedures “reasonably adapted” to prevent such a sale. Sellers must comply with certain anti-money laundering obligations, but unlike providers, they are not required to register as a money services business. According to FinCEN, the narrow definition of “seller” excludes all but a small percentage of retailers. Indeed, a retailer can avoid “seller” status by either requiring post-purchase activation and verification before use of the prepaid access (standard for open-loop cards), or more simply, implementing “policies and procedures reasonably adapted to prevent” the sale of prepaid access to funds exceeding \$10,000 to any person on any day. Together with the \$2000 exclusion for closed loop programs noted below, these limitations may significantly mitigate the impact of the Final Rule on the operations of retailers at the point of sale.

Exempted prepaid access programs

The Final Rule identifies five specific types of prepaid programs that pose a low risk of money laundering or other illicit behavior, and thus, are excluded from the definition of a “prepaid program.” Providers and sellers of these types of exempt prepaid programs are therefore not subject to the Final Rule.

1. *Closed-loop programs that do not exceed \$2000 on any day:* This exemption will include the vast majority of retailer gift cards, thus reducing the regulatory burden on these popular programs. International use, transfers within the prepaid program, and loading from non-depository sources are allowed without loss of exempt status, in contrast to the proposed rule.
2. *Government-funded programs:* This exemption applies to prepaid programs funded solely by federal, State, local, Territory and Insular Possession, or tribal government agencies. International use, transfers within the prepaid program, and loading from non-depository sources are allowed without loss of exempt status.
3. *Pre-tax health care or dependant care spending programs:* Pre-tax flexible spending arrangements for health care and dependent care expenses, or Health Reimbursement Arrangements for health care expenses, are exempt. International use, transfers within the prepaid program, and loading from non-depository sources are allowed without loss of exempt status.
4. *Employer-funded payroll programs:* This exemption only applies to payroll programs where the employer, and not the employee, may add funds to the account. However, the exemption does not apply (and thus prepaid program status is triggered) if (i) funds can be added from other sources, including non-depository institutions; (ii) the program allows international transmission of funds; or (iii) it permits transfers within the program.
5. *Limited-value programs:* Programs that limit account balances to \$1,000, and limit loading, use or withdrawal to \$1,000 per day, are exempt. The same carveouts to the exemption apply as for employer-funded payroll programs (other sources, international transmission, or account-to-account transfers).

Obligations of providers and sellers of prepaid access

The Final Rule revises the money services business regulations to require both providers and sellers participating in non-exempt programs to implement anti-money laundering programs, which must include the following elements:

1. Procedures to verify the identity of purchasers of prepaid access and the collection and retention of customer information (including name, birthday, address, and identification number). Sellers in particular must establish procedures to verify the identity of persons who obtain prepaid access to funds in excess of \$10,000 per day. Providers must retain this information for five years from the last use of the prepaid access. Sellers must retain this information for five years from the sale of the prepaid access.

2. Reporting of suspicious transactions (SARs). The obligation to submit SARs is a significant change for prepaid program participants, which previously were exempted under an exception for “issuers, sellers or redeemers of stored value.” However, the SARs requirement only applies to transactions of \$2,000 or more; thus, the actual impact on most prepaid providers may be somewhat limited.
3. Retaining transactional information generated in the ordinary course of business for a period of five years. Providers are responsible for compliance with this recordkeeping requirement.
4. Registration as an MSB. This requirement only applies to providers of prepaid access. As part of registration, the provider must submit a list of the prepaid programs for which it serves as the provider.

Effective dates

The Final Rule becomes effective Sept. 27, 2011 (60 days after publication in the Federal Register, which occurred on July 29, 2011). Compliance is required by Jan. 29, 2012 (6 months after publication).

For further information please contact Andrew Lorentz or Brian Hurh.

FOOTNOTE

¹ These concerns have not always been well-grounded in a sound understanding of the prepaid industry or its products . See, e.g., Assessment, *Prepaid Stored Value Cards: A Potential Alternative to Traditional Money Laundering Methods*, U.S.D.O.J. Nat'l Drug Intelligence Center, 2006-R0803-001 (Oct. 31, 2006), available at <http://www.justice.gov/ndic/pubs11/20777/20777p.pdf>.

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Medical Device Alert

4 August 2011



See note below about Hogan Lovells.

FDA issues draft 510(k) device modification guidance

On Wednesday, 27 July 2011, the Food and Drug Administration's (FDA or "the Agency") Center for Devices and Radiological Health (CDRH) issued a draft guidance addressing the types of device modifications that require the submission of a new premarket notification (510(k)).¹ The draft guidance, titled *Draft Guidance for Industry and FDA Staff – 510(k) Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device* (Draft Guidance), provides a framework for manufacturers to use when determining whether a change to a 510(k)-cleared device necessitates a new 510(k) submission, as well as examples of device modifications that illustrate the guiding principles. If finalized, this Draft Guidance would supersede the earlier guidance document, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, issued 10 January 1997 (1997 Guidance).

Background

The Draft Guidance comes on the heels of the FDA's review of the 510(k) process. In August 2010, CDRH released a preliminary report of an internal agency working group evaluating ways to improve the premarket notification 510(k) program. In January 2011, the FDA released its summary and overview of comments to the August 2010 report, and unveiled a plan containing 25 actions that it intends to implement in 2011. One of the key initiatives of the action plan included updating the 1997 Guidance to address issues associated with software and other evolving technologies and to provide additional clarity about device changes that do not require a new 510(k).

Comparison to the 1997 Guidance

The basic framework of the Draft Guidance is very similar to the 1997 Guidance, and does not appear to significantly alter the type of analysis that the FDA expects manufacturers to conduct in response to a device change. Both guidance documents seek to clarify the FDA regulation, 21 C.F.R. § 807.71(a)(3), which requires that a manufacturer submit a new 510(k) when a change or modification "could significantly



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affect" either the safety or effectiveness of a device. Like the 1997 Guidance, the Draft Guidance outlines the general principles for manufacturers to follow in determining whether a change to a cleared device is considered "significant" and thus requires submission of a new 510(k). Both the 1997 Guidance and the Draft Guidance identify categories of potential device changes, including labeling changes, technology, engineering, and performance changes, and materials changes. However, there are several changes that are worth noting and may have an impact on future 510(k) device modification analyses.

- **Elimination of flowcharts** - In the 1997 Guidance, the FDA provided several flowcharts to serve as the basis for a manufacturer's device modification analysis in determining whether a new 510(k) was warranted. In contrast, in the Draft Guidance, the FDA only provides examples to illustrate the types of changes to a cleared device that may or may not require submission of a new 510(k). It is important to note that these examples do not provide all instances of changes that may require the submission of a new 510(k) submission; rather, they are provided to generally demonstrate the FDA's position on a particular type of device modification. In addition, it is important to note that the elimination of the flowcharts also appears to reflect a narrowing of the types of technological changes that may be implemented via a memorandum to file. Previously, the guidance indicated that for certain types of technology changes, no new 510(k) was required if three criteria were satisfied: (1) no change in indications; (2) no need for clinical testing; and (3) no new issues arising from verification/validation testing. The new guidance eliminates these three criteria, providing instead illustrative examples of what types of technological changes may be regarded as significant and, therefore, require a new 510(k). For example, in the case of a change in performance specifications, under the old guidance if the manufacturer answered in the negative for each of the questions mentioned above, theoretically no new 510(k) would be required. However, in the Draft Guidance, if such a change "significantly alters" the performance specifications, then a new 510(k) is likely required. Manufacturers should carefully review the examples provided by the FDA in order to gain clarity regarding the types of changes that may or may not require a 510(k).
- **Modified device comparisons** - Like the 1997 Guidance, the Draft Guidance requires manufacturers to compare the modified device to the most recently cleared version of the device and to determine whether the modification could significantly affect the safety or effectiveness of the device. In the Draft Guidance, however, the FDA clarifies that the modified device should not be compared to multiple devices; nor should the manufacturer compare the modified device to a version of the device that has not yet received clearance by the FDA. Although this is consistent with the Agency's past position on the correct approach, the Draft Guidance explains this in more detail. The Agency also advises a manufacturer to avoid comparisons to any other devices produced by the manufacturer or another manufacturer, even if the other device could serve as a predicate to the modified device. Thus, to the extent that a manufacturer has used a memorandum to file process to make non-significant changes to a device, each new individual change to the device must be compared to the version of the device that was last cleared by the FDA, not to the most recent iteration of the device, and should take into account the effect of all prior changes.
- **Labeling changes** - In the Draft Guidance, the FDA clarifies that the term "labeling" as used in the guidance refers not just to the instructions for use, but consistent with the FDA's current interpretation of the term, refers to "all written, printed, or graphic matter on or accompanying a medical device." As a result, manufacturers should be aware that changes to the promotional materials for a device may require a new 510(k) submission if they meet the criteria laid out in the FDA's Draft Guidance. While this general requirement is not new, in a change from the 1997 Guidance, the FDA specifically distinguishes a modification in the indications for use that removes certain indications or limits use within the currently cleared indication, depending on the reason for the change. If the labeling change is "due strictly for marketing reasons" (e.g., the marketplace has changed and eliminated the need for one of the indications), then that change does not require a new 510(k). If, however, a manufacturer limits the indications due to other reasons, such as other changes made to the device or due to complaints or corrective actions, the FDA could consider the removal of the indications for use as a "major change" that requires a new 510(k).
- **How a device is used in practice** - For the first time, the FDA addresses changes that affect

how the device is likely to be used in practice. The Agency notes that these kinds of changes may require changes in the labeling, such as new directions for use. However, a change made regarding off-label uses of a device, such as a limitation to address the potential that an off-label use could cause harm, is identified by the FDA as requiring a new 510(k). Furthermore, if the device is modified to alter or expand the use of the device, or address use of the device in a new, expanded, or more specific patient population, a new 510(k) may be warranted. This section of the updated guidance reflects principles similar to some of those articulated in the FDA's 1998 *Guidance for Industry: General/Specific Intended Use*.

- **Home use** - The Draft Guidance notes that changes intended to allow a device to be used by a lay person outside of a clinical setting are likely to require a new 510(k). Previously, the 1997 Guidance had provided this as an example of a change that would not typically trigger the need for a new 510(k) so long as the device remain prescription use only.
- **Changes in ergonomics or patient/user interface** - In the Draft Guidance, the FDA introduces ergonomics or patient/user interface changes, and explains that changes that are made only to increase comfort and could not affect safety or effectiveness do not require a new 510(k). The FDA further explains that manufacturers must consider the change's effect on the safety or effectiveness of the device since simple changes could have unintended consequences. The FDA uses as an example a surgical handpiece handle that was modified to make the device less bulky by relocating the motor closer to the proximal end of the device. Because changing the proximity of the motor had the potential to cause burns in the patient or affect device performance, the FDA recommends that a new 510(k) be submitted for this change.
- **Change in dimensional specifications** - Also unaddressed in the 1997 Guidance are changes to the dimensional specifications of a device, which the Draft Guidance now indicates may require a new 510(k). In particular, the FDA singles out a change to a device dimension that is related to the performance of a device outside of the cleared dimensional tolerance range. To the extent a manufacturer changes the dimensional specifications of a device, the FDA recommends that the manufacturer discuss this change with the appropriate review board.
- **Software changes** - Given the incorporation of increasingly complex software in devices since the issuance of the 1997 Guidance, the Draft Guidance provides expanded discussion about the types of software changes that will require a new 510(k). Generally, manufacturers must consider whether the software change could expand the capability of the device or affect device performance, in which case a new 510(k) would be required. Thus, it is possible that software updates may require a new 510(k), depending on the particular changes made to the software. Moreover, the FDA notes that changes that could affect a clinical algorithm (an algorithm that controls how software analyzes, interprets, or uses patient data), would also warrant a new 510(k). Changes that affect how the device receives, transmits, or displays electrical signals or data would also require a new 510(k). Furthermore, device changes that take control of the device away from the user or are used to assist or take away decision-making from a user are viewed as potentially introducing new risks and therefore necessitating submission of a new 510(k). In summary, manufacturers should carefully analyze any software changes to determine whether they fit within the category of changes identified by the FDA as requiring a new 510(k). The increased focus on software changes is consistent with the recent increase in the FDA focus on related products, including medical device data systems.²
- **Nanotechnology** – The Draft Guidance also introduces nanotechnology to the device modifications guidance. With respect to devices that contain nanomaterials or involve nanotechnology, the FDA recommends that manufacturers consult with the Agency for any nanotechnology changes to determine whether and how the proposed change may affect the safety and effectiveness of the device.
- **Manufacturing process changes** – Another new category of changes introduced in the Draft Guidance relates to manufacturing process changes. At the time of the 1997 Guidance, the FDA's Quality System Regulation had not yet been issued. According to the Draft Guidance, the FDA will view manufacturing process changes as important and likely to require a new 510(k) if the manufacturing process information was reviewed in the original 510(k) submission.

However, where the manufacturing process was not part of the original 510(k) review, a new 510(k) may not be required. In addition, changes to device specifications may also require a new 510(k) as they can significantly affect device performance and thus safety and effectiveness.

- **Clinical data** - The Draft Guidance elevates a statement regarding the effect of clinical data on the need for a new 510(k). The 1997 Guidance contained a note, in the section addressing technology, engineering, and performance changes, clarifying that if a manufacturer determined that a change required clinical data to assess safety or efficacy, then a new 510(k) should be submitted. The Draft Guidance moves the discussion of the need for clinical data to a separate section and notes that a manufacturer's determination that clinical data is needed because bench testing or simulations are not sufficient to assess the safety or effectiveness of a modified device is a "sure sign" that the change could significantly affect safety or effectiveness and that a new 510(k) is required.

Conclusion

The Draft Guidance updates the FDA's policy regarding which types of changes to a legally marketed device require the submission of a new 510(k). Generally, the Draft Guidance has the same basic principles as the original 1997 Guidance; however, the updated Draft Guidance no longer relies on a flowchart to assist manufacturers in making the determination that a device change requires a new 510(k). Instead, the FDA provides several examples as illustrations of the types of changes that may require a new submission. The FDA also expands upon the types of changes addressed in the guidance, including manufacturing process changes and further discussion about software changes. Although the Draft Guidance does not dramatically alter a manufacturer's approach to determining whether a specific device change requires a new 510(k), certain of the changes may impact the conclusions reached in the future regarding whether a new 510(k) is needed. Given the direction of the Draft Guidance, manufacturers can expect to submit an increasing number of new 510(k)s for modifications made to their devices, and may no longer rely on a memorandum to file to document many of these changes. In addition, given the recommendations made in the recent Institute of Medicine report on the 510(k) process,³ it is possible that the FDA will ultimately strengthen some of the guidance language when the final version is issued.

The FDA is seeking comments on the Draft Guidance. Comments must be submitted by 25 October 2011.

¹ Food and Drug Administration, *Draft Guidance for Industry and FDA Staff – 510(k) Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device* (27 July 2011).

² Food and Drug Administration, Medical Devices; Medical Device Data Systems, 76 *Fed. Reg.* 8637-8649

³ Institute of Medicine, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, available at www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx

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WSGR ALERT

AUGUST 2011

FEDERAL CIRCUIT VALIDATES CLAIMS DRAWN TO ISOLATED DNA, INVALIDATES CLAIMS DRAWN TO ANALYZING OR COMPARING DNA WITHOUT TRANSFORMATION STEP

On July 29, 2011, the U.S. Court of Appeals for the Federal Circuit issued a decision in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 2010-1406, holding that several claims drawn to isolated DNA sequences encoding the BRCA1 and BRCA2 genes, as well as methods of using those sequences to screen for cancer, were valid as being drawn to statutory subject matter under 35 U.S.C. § 101. The decision overturns the lower court's decision for these claims, but the Federal Circuit upheld the lower court's holding that claims drawn to methods of using those sequences to detect cancer that did not recite any machine, apparatus, or transformative step were invalid. The much-awaited decision confirmed the expectation that the Federal Circuit would hold isolated DNA sequences as patentable. These holdings by the Federal Circuit should not affect well-counseled diagnostics companies.

Several factors in this case mean that it is "business as usual" for claims involving isolated DNA sequences. First, the claims drawn to isolated DNA were upheld as valid, so older patents with such claims are still valid and newly filed or pending applications with such claims will continue to be examined by the U.S. Patent and Trademark Office (PTO) under the same rules that have been in place for decades. Second, the method claims held invalid in this decision do not recite any machine, apparatus, or transformative step—limitations that post-*Bilski* claims typically contain. Thus,

diagnostic companies typically will be in the same legal position as they were prior to this decision.

Overview

Under 35 U.S.C. § 101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

U.S. Supreme Court cases addressing this statute have ruled that the language is to be given broad scope and applicability; however, the scope of patentable subject matter is not unlimited. A longstanding limitation on this scope was provided in *Diamond v. Chakrabarty*, where the Supreme Court held that laws of nature, physical phenomena, and abstract ideas fall outside the scope of patentable subject matter. Under this rule, unmodified living organisms, pure elements, and mathematical algorithms are not patentable. Under current law, which regards isolated DNA as a patentable purified chemical, the PTO grants patents on isolated genes or other sequences, but denies patents on genes or sequences naturally occurring, and still intact, within a living organism.

The Supreme Court also recently addressed patentable processes in *Bilski v. Kappos*, rejecting the so-called "machine-or-transformation" test developed by the Federal

Circuit as the only test to define a patentable process. Under the machine-or-transformation test, a process is patentable if it is tied to a machine or apparatus, or if it has a transformative step. However, the Supreme Court held that the machine-or-transformation test offers "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101."

Brief Case Summary

BRCA1 and BRCA2 are forms of a human gene linked to the development of breast cancer and ovarian cancer. Myriad, the owner of several patents drawn to isolated BRCA1 and BRCA2 genes and their use in diagnostic and research tests, is the sole provider of clinical and other tests for BRCA1 and BRCA2. The *Association for Molecular Pathology* case was initiated by multiple plaintiffs, including several nonprofit associations and individual doctors and scientists, in order to challenge the Myriad patents. The multiple plaintiffs in the case alleged that the claims in suit from seven Myriad patents are invalid under Section 101, and they further alleged that the PTO practice of allowing such claims is unconstitutional.

Holding Regarding Isolated DNA Claims

At issue were two basic types of claims: composition claims and method claims. The type of composition claim drawn to isolated DNA is exemplified by claim 1 of U.S. Patent

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No. 5,747,282, which recites:

“An isolated DNA coding for BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”

In addressing the validity of the composition claims at issue, the panel examined whether the isolated DNA is a product of nature and therefore not patent-eligible subject matter, or if it is a human-made invention and therefore patent-eligible subject matter. Judge Alan Lourie applied a test based on the Supreme Court drawing “a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given ‘markedly different,’ or ‘distinctive,’ characteristics.” Applying this test, the majority concluded that the composition claims are drawn to patentable subject matter, as the claimed molecules are markedly different, with a distinctive chemical identity and nature from molecules that exist in nature.

In determining that the claimed isolated DNA was markedly different, the three judges on the panel, Judge Lourie, Judge Kimberly Moore, and Judge William Bryson, all agreed that cDNA is patentable. However, while both Judge Lourie and Judge Moore agreed that isolated DNA and not just cDNA is patentable, the reasonings provided by Judge Moore and Judge Lourie differ. Judge Bryson, on the other hand, dissented, stating that while cDNA is patentable subject matter, fragments of genes are not.

The majority concluded that isolated DNA has been cleaved or synthesized to consist of a fraction of a naturally occurring DNA molecule. Thus, the isolated DNA is not the same molecule as exists in the body, imparting the fragment with a distinctive chemical identity from that of native DNA. The majority also made the distinction between isolated DNA and purified DNA, in that the claimed isolated DNA molecules do

not exist in nature, where it occurs within a physical mix that needs to be purified. The isolated DNA in question must be chemically cleaved, not simply purified. Thus, the court concluded that isolated DNA, as a portion of a native DNA molecule, has a markedly different chemical structure than native DNA and is therefore patentable subject matter.

Both the majority opinion and Judge Moore’s concurrence further noted that the PTO has been granting patents directed to isolated DNA molecules for almost 30 years, and that the Supreme Court has consistently held that any changes to longstanding practice should come from Congress and not the courts. Judge Moore’s concurrence also added that Congress is well aware of this issue and has chosen not to amend Section 101 to exclude isolated DNA from patentable subject matter.

Observations on the Holding Regarding Isolated DNA Claims

The decision regarding the patentability of claims drawn to isolated DNA represents an upholding of the longstanding practice of the PTO granting patents directed to DNA molecules. Though the decision was unanimous for cDNA, there was dissent as to the validity of claims directed to gene fragments. Given the split decision, the plaintiffs likely will request an *en banc* hearing or file a petition for a *writ of certiorari* with the Supreme Court.

Although it provides good news for holders of patents with claims to isolated DNA, the decision will have little impact on most diagnostic companies. Many patents with claims drawn to particular isolated sequences are older patents with little term left. For example, the Myriad patents at issue have only three to four years of their terms remaining. Additionally, many patents and applications with claims drawn to isolated DNA have been abandoned. Thus, this decision will likely not have a broad-ranging effect for most diagnostic companies even if it is overturned after further appeals.

Holding Regarding Method Claims

The second type of claims (method claims) was further divided into two categories by the court. The first category, which was held to be unpatentable under Section 101, contained no transformative step. This is exemplified by claim 1 of U.S. Patent No. 5,709,999 (the ‘999 patent), which recites:

“A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.”

The panel was unanimous in holding that method claims to “analyzing” or “comparing” two gene sequences with no transformative steps, as exemplified by claim 1 of the ‘999 patent, fall outside the scope of patentable subject matter because they claim only abstract mental processes. Furthermore, the panel found that method claims to analyzing or comparing two gene sequences related to processes that use isolated DNA sequences to compare and test patient or experimental samples for BRCA1 and BRCA2 mutations do not recite a particular apparatus or transformative step. Myriad argued that these method claims satisfied the machine-or-transformation test because each requires a transformation of extracting and sequencing DNA molecules from a human sample before the sequences could be compared or analyzed. Myriad further stated that this is how the claim is interpreted, as the term “sequence” refers not to information, but rather to a physical DNA molecule whose sequence must be determined before it can be compared.

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The panel disagreed and stated that these method claims to analyzing or comparing two gene sequences recite nothing more than abstract mental steps for comparing nucleotide sequences. The panel noted that the claims do not specify any action prior to comparing or analyzing, and that the terms do not include or imply sample-processing steps. The panel also disagreed with Myriad's arguments that the term "sequence" refers exclusively to a physical DNA molecule, since the specification states that the sequences refer broadly to the linear sequence of nucleotide bases. The court noted that although the application of a formula or abstract idea to a process may constitute patentable subject matter, that was not the case in this instance because the entire process consists solely of the act of comparing two DNA sequences. Thus, the court held that this first category of method claim did not meet the patentability requirements of Section 101.

In contrast, the second category of method claim, which the panel held to be patentable, is exemplified by claim 20 of U.S. Patent No 5,747,282 (the '282 patent), which recites:

"A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic."

The panel was unanimous in overruling the lower court's decision that the second category of method claim is patent-ineligible subject matter. Instead, the panel found that

the method claim directed to screening potential cancer therapeutics included transformative steps. Specifically, the court held that growing a host cell and determining the growth rate of the cell were transformative steps. The majority noted that both steps involve the physical manipulation of the cells, and that both steps are central to the purpose of the claimed process. The panel also noted that the claim was not so "manifestly abstract" as to claim only a scientific principle. Thus, the court held that these differences allowed this claim to meet the patentability requirements of Section 101.

Observations on the Holding Regarding Method Claims

This decision affirmed the lower court's holding that the method claims directed to comparing and analyzing sequences consist of an abstract mental process that is not drawn to patentable subject matter. As with the holding regarding isolated DNA, this part of the decision is not likely to have broad-ranging effects for diagnostic companies or the biotechnology industry post-*Bilski* because well-counseled diagnostics companies have been approaching method claims with the machine-or-transformation test in mind for some time now. Claims incorporating such limitations by linking diagnostic methods to a particular apparatus or providing some transformative limitation should fulfill the requirements under Section 101.

Summary

The holding in this case means business as usual for diagnostics companies and others with patents to isolated DNA sequences and their uses. Although it is likely that this ruling will be appealed, the ultimate outcome likely will have limited effects on diagnostics and other biotechnology companies regardless of whether the Federal Circuit's opinion is upheld or reversed. Because practitioners have been developing claims in light of the *Bilski* decision, most modern claims reciting

uses of isolated DNA tie that use to a transformation or machine. Thus, those types of claims should be patentable under Section 101. However, even if the decision is reversed, factors such as limited remaining patent terms for isolated DNA claims and limited reliance by diagnostic companies on such claims diminish the real-world effects of a holding that results in such claims being found as unpatentable.

Further Guidance

For further guidance on how to evaluate your patent portfolio and patent strategy in light of this decision and its potential implications, please contact Vern Norviel or another attorney in the intellectual property practice at Wilson Sonsini Goodrich & Rosati.



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