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RRP £85

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The Queen's Award for Enterprise 2008

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BEST OF THE BEST

Methodology

Welcome to the 2021 edition of the *Best of the Best*, the international legal market's leading guide to the top legal practitioners.

When first published in 1994, the Expert Guides were the first-ever guides dedicated to leading individuals in the legal industry. Since then we have continued to focus on individuals considered by clients and peers to be the best in their field. The *Best of the Best* compiles the top 30 practitioners in 19 areas of law. All the other practice areas we cover are included in the 2020 edition and will be updated in 2022. In the event of a tie on the number of nominations both practitioners are included.

Our research process involves sending over 4,000 questionnaires to senior practitioners or in-house counsel involved in each practice area in over 90 jurisdictions, asking them to nominate leading practitioners based on their work and reputation. The results are analysed and screened for firm, network and alliance bias. The list of experts is then discussed and refined with advisers in legal centres worldwide.

These specialists have been independently offered the opportunity to enhance their listing with a professional biography. The biographies give readers valuable, detailed information regarding each lawyer's practice and, if appropriate, their work and clients.

We owe the success of this guide to all the in-house counsel and firms that completed questionnaires and met our researchers. Thank you. We hope you find the guide to be a useful tool. All information was believed to be correct at the time of going to press.

Research team

EXPERT GUIDES RESEARCH

Expert Guides has been researching the world's legal markets for over 27 years, and has become one of the most trusted resources for international buyers of legal services.

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Each guide is also reprinted in full at www.expertguides.com

BANKING AND FINANCE

BANKING AND FINANCE

Japanese Usury Regulation Not Applicable to Corporate Bonds

Masahiro Ueno
Nishimura & Asahi
Tokyo

Article 1 of the Interest Rate Restriction Act of Japan (Act No. 100 of 1954) provides to the effect that the interest rate on a loan of money may not exceed:

1. 20% per annum, if the principal amount of the loan is less than JPY100,000;
2. 18% per annum, if the principal amount of the loan is JPY100,000 or more but less than JPY1,000,000; or
3. 15% per annum, if the principal amount of the loan is JPY1,000,000 or more.

It is generally held that these maximum interest rate restrictions are intended to protect borrowers from an unduly high interest rate. In January 2021, the Supreme Court of Japan held that such restriction shall not in principle apply to corporate bonds (Judgment of 26 January 2021, Supreme Court of Japan; the "2021 SC Judgment"), which means that bonds may bear interest at a rate higher than the maximum rate permissible under Article 1 of the Interest Rate Restriction Act (the "Maximum Permissible Rate"). This article analyzes the 2021 SC Judgment.

Facts

The facts of the 2021 SC Judgment are as follows:

1. Company X (the "Issuer") is a Japanese corporation (*kabushiki kaisha*) that engages in the development of systems relating to financial investment.
2. The Issuer offered to issue bonds in order to raise funds for the development of new systems. The Issuer allotted the bonds (the "Bonds") to Person Y (the "Defendant"), who purchased the bonds and subscribed JPY20,000,000 therefor in 2012. Thereafter through 2015, the Issuer paid interest on the Bonds in an amount in excess of the amount calculated at the Maximum Permissible Rate (15% per annum, in this case) as well as redeemed the principal of the Bonds to the Defendant.
3. During the period from March 2012 to November 2015, the Issuer issued 203 series of bonds (including the Bonds) in total. Each series of bonds was issued to a single purchaser only. Most of such bonds provided for an interest rate higher than the Maximum Permissible Rate.
4. In April 2016, the Issuer was declared bankrupt, and the bankruptcy trustee (the "Trustee") was appointed in respect of the Issuer.

JAPANESE CORPORATE BONDS MAY BEAR INTEREST AT A RATE HIGHER THAN 15% PER ANNUM

The Trustee alleged that any interest amount the Issuer paid to the Defendant in excess of the amount calculated at the Maximum Permissible Rate may not be treated as lawful interest payment but should be applied to partially redeem the principal of the Bonds. If an excessive amount is so applied to the principal, the Bonds would have been entirely redeemed before their stated maturity and there would have been a surplus amount (i.e., overpayment of interest). The Trustee sued the Defendant to demand that the Defendant refund such surplus amount to the Trustee. The lower court (the Tokyo High Court) dismissed the Trustee's claim. The Trustee filed an appeal with the Supreme Court of Japan.

Supreme Court Judgment

The Supreme Court affirmed the appellate court's judgment, noting the following points:

1. While a bondholder's claim under corporate bonds is similar to a lender's claim under loan transactions, corporate bonds are different from loans in that bonds are issued in accordance with the formalities provided under the Companies Act of Japan (Act No. 86 of 2005). In addition, corporate bonds are "securities" within the meaning of the Financial Instruments and Exchange Act (the "FIEA") of Japan (Act

BANKING AND FINANCE

No. 28 of 1948) and their issuance and distribution are regulated thereunder to ensure the fairness of the transaction.

2. The maximum interest rate limit on a loan under the Interest Rate Restriction Act is intended to prevent a lender from exploiting a debtor (who is assumed to be in an economically weaker position) by charging an unduly high interest rate. On the other hand, corporate bonds are issued by a company to raise operational funds in accordance with the terms and conditions established by the company. The issuer of bonds does not need to be protected by the Interest Rate Restriction Act. As such, the issuer should be able to freely design the terms and conditions of bonds and, in particular, determine the interest rate without restriction under the Interest Rate Restriction Act.
3. However, in an exceptional case where bonds are deemed to have been issued to circumvent the restriction on the maximum interest rate under the Interest Rate Restriction Act (for example, if a prospective bondholder has induced a company to issue bonds for the purpose of earning interest at a rate higher than the Maximum Permissible Rate), such restriction would apply to bonds.
4. In the case at hand, no such exceptional circumstance as stated in item (3) above is found. Accordingly, the restriction under the Interest Rate Restriction Act does not apply to the Bonds. Therefore, there would be no overpayment of interest and the Trustee's claim for the refund of any surplus amount should be dismissed.

Analysis

There has been a controversy as to whether the restriction on the maximum interest rate under the Interest Rate Restriction Act would apply to bonds issued by a corporation. Some law scholars say such restriction should apply to bonds as well, since the obligation of a bond issuer to redeem the principal thereof and pay interest thereon is similar to the borrower's obligation under a loan transaction. Others say, however, such restriction should not apply to bonds, which are "securities" and are different types of products from loans.

In the 2021 SC Judgment, the Supreme Court emphasized the difference between corporate bonds and loans. In particular, the court noted that bonds (which are "securities") are regulated by the FIEA. By contrast, loans (which are not "securities") are not regulated by the FIEA. However, it may be argued that the FIEA regulation is primarily intended to protect investors, which refers to bondholders/creditors (not issuers/debtors) in the case of bonds, so bond issuers/debtors still need to be protected by the Interest Rate Restriction Act, given its purpose of protecting those assumed to be in an economically weaker position.

Also, the court noted that a bond issuer should be able to freely determine the terms and conditions of bonds (with no restriction under the Interest Rate Restriction Act), depending on its business needs. This reasoning is persuasive if the issuer is a large-sized company. However, not all bond issuers are large-sized companies with sufficient negotiating power to determine terms and conditions as they would like. Rather, small-sized bond issuers would need to be protected by the Interest Rate Restriction Act.[1]

In addition, because both bonds and loans are characterized as debt, it may seem strange that bond interest would be treated differently from loan interest. Especially, in the case of the 2021 SC Judgment, the Issuer issued every series of bonds (including the Bonds) to a single purchaser. As bonds are generally supposed to be offered to multiple investors, the issuance of bonds to only one investor may be deemed to be more similar to a loan transaction and should arguably be treated in the same way as loans are treated for the purposes of the Interest Rate Restriction Act.

In any event, in the 2021 SC Judgment, the court ruled that, in the absence of any exceptional circumstances, corporate bonds may provide for an interest rate that is higher than the Maximum Permissible Rate. This would probably make it easier for bond issuers to flexibly structure profit participating bonds or indexed bonds, as the effective interest rate of these types of bonds may well exceed the Maximum Permissible Rate, depending on the business performance of the issuer or the level of underlying index. By contrast, loan transactions (which are always subject to restriction under the Interest Rate Restriction Act) may not be flexibly structured as profit participating loans or indexed loans if the effective interest rate might exceed the Maximum Permissible Rate. Incidentally, the court noted that in an exceptional case where bonds are deemed to have been issued to circumvent the restriction under the Interest Rate Restriction Act, such restriction would apply to bonds. If a company intends to issue bonds of which the interest rate may exceed the Maximum Permissible Rate, it is advisable that the deal be carefully organized so that the bonds would not be deemed to have been issued to circumvent such restriction.

1. By contrast, in the case of loan transactions, it is clear that the restriction on the maximum interest rate under the Interest Rate Restriction Act applies irrespective of whether the borrower/debtor is a large-sized or small-sized company. No one would argue that such restriction should not apply if the borrower is a large-sized company.

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Masahiro Ueno is a partner at Nishimura & Asahi. His areas of expertise are in securities, finance and banking law with an emphasis on structured finance. He has advised on numerous transactions relating to M&A finance, project finance, real estate finance, and securitization, including the first deals of those types in Japan.

Additionally, his other area of expertise is in the resolution of financial disputes by way of out-of-court negotiation and settlement. Resolving disputes involving specialized and complicated financial transactions often requires profound knowledge and understanding of financial products (including derivatives, structuring techniques, regulatory aspects and so on) as well as market practices. There are very few court precedents dealing directly with such complicated disputes, so litigating these disputes in court would not always lead to an appropriate resolution. Rather, negotiating among the parties to the dispute and their counsel who is familiar with the financial transactions in dispute can facilitate a resolution which has due regard to the circumstances behind the transactions and which would be satisfactory to all the parties. Mr Ueno has handled various types of structured finance transactions and complicated regulatory matters, and has gained extensive experience in relation to those areas. He has sufficient knowledge to appropriately resolve financial disputes because of such experience. He has assisted many clients in resolving difficult financial disputes.

Also, troublesome circumstances may sometimes occur to finance transactions. On many occasions, he has advised on the restructuring of finance transactions that are facing difficulties and might otherwise go into default.

Mr Ueno graduated from the University of Tokyo in 1984 with an LLB and earned an LLM from the University of Pennsylvania Law School in 1991. He is admitted to practice in Japan and New York State. He has authored various articles on Japanese management buy-out transactions, project finance, and syndicated loans. Furthermore, as an international editor (Tokyo) for the Journal of Banking and Finance Law and Practice (an Australian journal), he has written a number of pieces on the development of Japan's finance-related law.

Nishimura & Asahi provides a wide range of services in the area of banking and finance. For example, the firm engages in securitization in all asset classes, fields and structural features. The firm also deals with real estate finance, which includes the formation of real estate funds, REITs and nonrecourse loans, and issuances of commercial mortgage backed securities. The firm advises on creating deal structures, solving legal issues, negotiating with various parties and regulatory authorities in Japan and overseas, and preparing and drafting many varieties of documents from contracts to regulatory documents with the aim of devising the market standard, and is actively contributing to the development of structured finance transactions.

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Gerold Zeiler is a founding partner of Zeiler Floyd Zadkovich and an expert in national and international dispute resolution, with a strong focus on international commercial arbitration and complex litigation. Gerold has 25 years of experience, acting as chairman, sole arbitrator, party-appointed arbitrator and expert witness, as well as counsel in more than 200 ad hoc and administered arbitration proceedings, including proceedings under the Vienna Rules (VIAC), the ICC Rules of Arbitration, the UNCITRAL Arbitration Rules, the Rules of the Arbitration Court of the Economic Chamber of the Czech Republic, the Rules of the Court of International Commercial Arbitration attached to the Chamber of Commerce and Industry of Romania, as well as ICSID arbitration proceedings. Moreover, he is a seasoned litigator before Austrian courts. He is admitted to the Austrian bar (1993) and the Bar of California (2018).

Gerold graduated at the University of Vienna (Mag.iur. 1988; Dr.iur. 1996) and Washington University in St. Louis (LL.M. 2016). In 2018, the ICC World Council appointed Gerold as the Austrian member of the ICC Court. He is also listed on the panel of arbitrators of the Vienna International Arbitral Centre (VIAC), the Singapore International Arbitration Centre (SIAC), the Korean Commercial Arbitration Board (KCAB), the International Commercial Arbitration Court at the Ukrainian Chamber of Commerce and Industry, the Arbitration Court at the Chamber of Commerce and Industry of Romania, the Russian Arbitration Center at the Russian Institute of Modern Arbitration, the Indian Council of Arbitration, the Thailand Arbitration Center (THAC) and the Czech Arbitration Court.

Gerold is a co-editor of the Austrian Yearbook on International Arbitration, a member of the Publications Board of the ABA Section of Dispute Resolution, a Fellow of the Chartered Institute of Arbitrators (FCIArb) and a former president of the Austrian Arbitration Association (ArbAUT). His published work includes a comprehensive commentary on Austrian arbitration law (Schiedsverfahren, 2nd edition, 2014), and more recently he co-authored the Austrian chapter in Balthasar (ed.), International Commercial Arbitration: A Handbook, 2nd Edition. He regularly speaks at international conferences, recently at ICC Austria's Arbitration and Dispute Settlement Seminars on "Revision of the ICC Arbitration Rules", and guest lectures a university course at Graz University.

Zeiler Floyd Zadkovich is an international commercial law firm with offices in New York, Vienna, London, Mexico City, Chicago, Houston and Sydney. One of the main practice areas the firm specializes in is international commercial arbitration, adding to employment, shipping, litigation, commodities and energy specializations.

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Dr Colin Ong, QC is a Chartered Arbitrator and Queen's Counsel at 36 Stone (London); and Counsel at Eldan Law LLP(Singapore). He has over 28 years of experience as lead counsel and arbitrator. He is a Civil Law professor, and known for his experiences in handling complex legal issues in arbitrations governed under Civil law. He actively regularly leads many international teams as well as sits as arbitrator across 7 main countries. His practice areas include banking/finance; infrastructure projects (airports / bridges / pipe-lines / ports / railways and roads), entertainment industries, insurance, energy disputes (coal mining / supply disputes / production sharing contracts / electricity supply / gas and oil contracts), information technology, insolvency shipping, intellectual property (bank ATMs / computing / software licensing / games software / reverse engineering); insurance, manufacturing issues (automobile parts / military equipment / pharmaceutical / software), Post-M&A disputes; telecoms, technology transfer and general commercial trade related matters. He is the first ASEAN national practitioner lawyer to be appointed English Queen's Counsel and also to be elected Master of the Bench (Inner Temple).

He has sat as arbitrator or acted as counsel in over 380 arbitrations governed under civil and common law in commercial disputes and investment disputes governed under most institutional rules including AAA / BANI / CIETAC / HKIAC / ICC / ICDR / KCAB / KLRCA / LCIA / LMAA / OIC / SIAC / SCMA / TAI / UNCITRAL and WIPO rules under diverse applicable laws including Chinese / English / Hong Kong / Indian / Indonesian / Japanese / Kazakh / Korean / Malaysian / New York / Philippine / Singapore / Thai / Swiss and Vietnamese law. Ranked as *Thought Leader* by *Who's Who Legal* ("WWL") in Arbitration/Construction and Litigation. Author of arbitration publications with 2 books listed as End-note 1 reference books in CIArb Practice Guidelines (Costs and Interim Measures). Author of texts on advocacy including chapter one for the GAR Guide to Advocacy. Listed as arbitrator in over 25 international arbitration panels (including PRIME and WIPO).

At the 2016 GAR Awards, the split decisions in PT Perusahaan Gas Negara v CRW [2015] SGCA 30, where he was lead counsel, were named runner up most important decision of 2015. He was lead counsel in an earlier arbitration which led to amendments to the 1999 FIDIC Form Contracts (http://fidic.org/node/1615)

He holds LLB (Sheffield) / LLM /PhD (Queen Mary) / FCIArb / FMIArb / FSIArb / DiplCArb / Chartered Arbitrator (CIArb) and Chartered Arbitrator (IDRRMI, HK).

President (AABD, Brunei); Chairman, International Advisory Board (THAC, Thailand); Advisory Council (BANI, Indonesia); Appointing Council, Chinese-European Arbitration Centre (CEAC, Germany); Council Member, HKCICA (Hong Kong); Chair, Advisory Board (JIIART, Japan); Chairman, Regional Arbitral Institutes Forum; Co-Chair, IBA APAG; Vice-President, APRAG; and Advisor, China-ASEAN Legal Research Center; He was a GAR 45 under 45; member of ICC Commission on Arbitration (2020); ICCA-Queen Mary Task Force on Third-Party Funding and outgoing Vice Chair (Arbitration), Inter Pacific Bar Association. *WWL Arbitration* 2020 describes him as "*a staple of the international arbitration field, and extensive recommendations around the world for his strong work as arbitrator, also winning widespread plaudits for his work as lead counsel in both civil and common law matters.* WWL Banking 2020:- "*wins widespread praise for his outstanding work on high-value banking disputes.*".

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José Rosell is a leading arbitrator currently based in Paris and Copenhagen. He is a member of the Barcelona Bar and an Honorary Member of the Paris Bar. He has been registered with the Danish Bar between 2016 and 2020.

José Rosell has been actively involved in international arbitration since 1978 and currently focuses his activity serving as an arbitrator. He has acted as counsel for states, state-owned institutions, banks, and multinational companies, and has served or is serving as chairman, sole arbitrator, or co-arbitrator in more than 170 arbitrations. His practice as arbitrator is devoted to international commercial arbitrations and investor-state arbitrations. José Rosell can conduct arbitrations in English, French and Spanish, and has working knowledge of Italian and Portuguese.

He is a member of the ICC Commission on Arbitration and ADR. He is a member of several working groups on international arbitration issues established by the ICC. José Rosell is a member of the ICC Latin American Arbitration Group. He has actively participated in the drafting and review of the arbitration rules of the major arbitration institutions. José Rosell has also been a member of the drafting group of the Prague Rules. He is a member of the panel of arbitrators of the leading international arbitration institutions.

José Rosell has written several articles on international arbitration. He has participated as a speaker and moderator in numerous conferences and gives lectures in several universities. He is a board member of the French Branch of the International Law Association (ILA) and a member of the ILA International Committee on International Commercial Arbitration.

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James Kwan is an International Arbitration partner in Hogan Lovells' Hong Kong office. He has extensive experience in arbitrations involving the infrastructure, engineering, energy, life sciences, chemicals and technology sectors. He has represented clients in arbitrations in Asia, the US, Middle East, and Europe under the major institutional and ad hoc rules, such as those of the ICC, HKIAC, SIAC, CIETAC, LCIA, AAA, DIAC, CAS and UNCITRAL.

James was awarded the *Lexology* Client Choice Award for Construction in 2020. He is recognised in legal directories as "*best known for his tremendous skill in energy, infrastructure and construction disputes*" (Chambers Global 2011), "*'extremely good, quality lawyer', 'high profile', and 'a very fine practitioner'* " (Who's Who Legal UAE 2008), and "*singled out for his expertise in arbitration*", "*genuine arbitration specialist … he has a fine reputation.*" (Asia Pacific Legal 500 2010/2011/2012).

Chambers Asia-Pacific 2021 states that "James Kwan is singled out by a client who notes his '*awesome and acute business sense coupled with outstanding technicalknowledge and world-class client service.*'

Chambers Asia-Pacific 2020 states that "clients appreciate that James Kwan '*provides solid advice and recommends courses of action that are very effective in dealing with the issues,*' adding: '*He impressed us with his intelligent and structured approach to the case, his client focus and his hard work.*'

Legal 500 Asia Pacific 2020 endorses him as '*very hands-on*'…an '*expert in arbitration*' with '*great analytical skills*'.

According to Who's Who Legal 2018, he is "esteemed for his work in construction arbitration across the world where he provides '*an excellent service*' ", and his clients "consider him an expert on the tactical side of arbitration, drawing attention to his mindset of '*very good commercial thinking, insightful and strategic thinking, and analysis of the facts and dispute.*' " (Chambers Asia Pacific 2018). Named as one of the Hot 100 Lawyers of 2011 by Asian Legal Business, he was described as "*a world leader in arbitration and construction law*", "*has an intimate knowledge of the different arbitration models throughout the region*" and "*one of the finest international arbitration lawyers in Asia.*"

Chambers Asia Pacific 2017 states: "Clients recommend James Kwan for his '*thorough understanding of commercial disputes and arbitration,*' along with his '*strategic thinking, research into key issues and structuring of arguments.*' He has a focus on international commercial arbitration, with a track record of involvement in disputes relating to the infrastructure, energy and life sciences sectors."

James is the co-editor of *Construction Arbitration in Hong Kong: A Practical Guide* (Wolters Kluwer, 2015). He is the author of a chapter in *The Hong Kong Arbitration Ordinance Commentary and Annotations* (Sweet & Maxwell, 2011) and *Arbitration in China: A Practical Guide* (Sweet & Maxwell, 2004).

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Regularly serving as lead counsel in high-stakes, cutting-edge cases, Carolyn Lamm focuses her practice on resolving significant international arbitrations involving international corporates and sovereigns. Additionally, she serves as lead counsel in arbitration-related litigation matters.

Her practice concentrates on international dispute resolution through international arbitration, litigation and international trade proceedings, advising clients in matters with ICSID and its Additional Facility. She also advises on other international arbitral proceedings involving States, as well as commercial arbitral fora including AAA/CDR, ICC, Vienna Centre, Stockholm Chamber, Swiss Chamber and in federal court litigation.

Carolyn is the Distinguished Faculty Chair of the University Of Miami School Of Law, White & Case LLM Program in International Arbitration, where she teaches International Investment Arbitration.

Appointed by President Clinton to the US Panel of Arbitrators for ICSID arbitration, she later received appointment from the Government of Uzbekistan to the Uzbek Panel. Active in leading arbitration professional bodies, she is a former member of the American Arbitration Association Executive Committee and Board, and is a current member of the ICCA Governing Board, where she serves as Chair of the Cross Institutional Task Force on Gender Issues in International Arbitral Appointments and as a member of the Judiciary Committee. She also holds membership in the Council of the American Law Institute, serving on the Advisory Committee for the Restatement of International Arbitration and as a Counselor for the Restatement Fourth on Foreign Relations. Carolyn has served as an arbitrator in AAA International Rules, ICSID and NAFTA Chapter 11 disputes. She is also a founding member of the American Uzbekistan Chamber of Commerce and currently serves as Chairman of the Board.

Carolyn is a past President of both the District of Columbia Bar and the American Bar Association, serving two terms as the American Bar Association's Representative to the International Bar Association. Additionally, she is President of the American Bar Endowment.

Prior to joining White & Case, Carolyn was employed by the US Department of Justice under the Attorney General's Program for Honor Law Graduates. During her career with the Department of Justice, she served as a trial attorney in the Fraud Section, Civil Division, before obtaining the position of Assistant Director, Commercial Litigation Branch, Civil Division.

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Makoto Igarashi is a partner of Nishimura & Asahi, specialising in investment funds, asset management, banking, securities regulations, derivatives, and other related industries. Mr Igarashi plays a vital senior role within the firm's private equity practice group.

With the resources of Japan's largest law firm, Mr Igarashi and his colleagues are able to assist clients in all aspects of large-scale private equity transactions, including due diligence, financing and tax matters, strategy and compliance issues, and regulatory filings. Mr Igarashi has extensive experience as counsel to fund promoters, investment managers, placement agents, and various other financial institutions providing specialist advice in respect of fund raising and placement of buyout funds and turnaround or mezzanine types of private equity funds. He also serves as counsel to investment fund institutions and advisers, financial advisers, banks and other senior lenders advising on buyout loans and other debt and equity financing matters.

Mr Igarashi is a 1987 LLB graduate of the University of Tokyo and received an LLM from Harvard Law School in 1994. He has been a member of the Japanese and New York Bars since 1989 and 1995 respectively, and is fluent in both English and Japanese. Mr Igarashi joined the firm in 1989 and has been a partner since 1998. He spent one year on secondment at Cravath, Swaine & Moore, New York (1994 to 1995), and served as lecturer on finance law at Keio Law School, Tokyo (2004 to 2013).

He has written articles for various legal periodicals, such as "Private Equity Fund Regulations in Japan" (The American Lawyer, October 2009), "Legal Schemes for Private Equity Funds" in Private Equity for Institutional Investors (Kinzai, February 2013), "Investment Scheme for Pension Funds to Invest in Private Equity" in Private Equity for Pension Funds (Kinzai, October 2014), "Asset Management Business" in Corpus Juris Finance - Completely Revised Edition (first volume) (Shojihomu, August 2017) and "Fund Formation in Japan" (Getting the Deal Through 'Private Equity 202019', March 202019).

As the largest and one of the oldest law firms in Japan, covering all aspects of domestic and international business and corporate activity, Nishimura & Asahi currently has over 7600 Japanese and foreign lawyers - employing over 1,0700 support staff, including tax accountants, patent attorneys, senior Japanese and foreign business support professionals, and paralegals.

With the continued expansion of Nishimura & Asahi's international presence and clientele, the firm has overseas offices in Bangkok, Beijing, Shanghai, Dubai, Düsseldorf, Frankfurt, Hanoi, Ho Chi Minh City, Jakarta*1, New York, Singapore, Taipei, Yangon, and Hong Kong*2, and domestic offices in Tokyo, Nagoya, Osaka, and Fukuoka. With the expansion of the firm's domestic and global network, Nishimura & Asahi is ideally placed to provide clients with a borderless one-stop service, from Japan to the world.

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Christopher Hilditch joined the firm in 2002 to establish the London office, of which he is co-head. With over 25 years of experience advising many of the highest profile hedge funds, Chris focuses his practice on entrepreneurial and institutional investment managers, other financial services firms and investment funds, especially hedge funds, hybrid funds, co-investment funds and distressed funds. He provides practical and strategic advice on the structuring and operation of funds and investment managers, including fundraising, investor issues, investment transactions and financing as well as regulatory and compliance matters.

Chris is named in the "Hall of Fame" by *The Legal 500 UK* having previously received an "Outstanding Contribution" award for his services to the hedge fund industry (*The Hedge Fund Journal* Awards). Chris is also named as a leading funds lawyer in *Chambers UK*, *Chambers Europe*, *Expert Guide to the Best of the Best* (which named him as one of the top funds lawyers worldwide), *Expert Guide to the World's Leading Banking, Finance and Transactional Law Lawyers*, *IFLR1000*, *PLC Cross-Border Investment Funds Handbook*, *Who's Who Legal: The International Who's Who of Private Funds Lawyers* and *Who's Who of Professionals*. Chris has been described by interviewees in *Chambers UK* as "fantastic — practical, commercial and knows his stuff" and as a "go to lawyer for dealing with a complicated hedge fund" and in *The Legal 500 UK* as "excellent" and "knows the industry inside out." Clients praise his "very strong technical knowledge and commercial awareness" as well as his "deep knowledge and experience in the fund industry." Chris has participated in the UK Financial Services Authority's Legal Experts Group in respect of AIFMD and has been an active participant on various AIMA and other industry committees on matters relating to the hedge fund industry. Chris is a frequent speaker at industry conferences and seminars, including invitation-only conferences for clients of prime brokers and other industry participants. He has also written on a wide range of hedge fund and regulatory topics. Chris is the general editor of the *Chambers Alternative Funds Guide* — a guide examining key industry trends and regulatory and tax matters impacting funds, managers and investors. Chris attended law school at the College of Law, Guildford and holds an MA, with honours, from the University of Oxford.

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Stephanie R Breslow is co-head of the Investment Management Group and a member of the firm's Executive Committee. She maintains a diverse practice that includes liquid funds, private equity funds and the structuring of investment management businesses. She focuses her practice on the formation of private equity funds (including LBO, mezzanine, distressed, real estate and venture) and liquid-securities funds (including hedge funds, hybrid funds, credit funds and activist funds) as well as providing regulatory advice to investment managers. She also represents fund sponsors and institutional investors in connection with seed-capital investments in fund managers and acquisitions of interests in investment management businesses and funds of funds and other institutional investors in connection with their investment activities, including blockchain technology and virtual currency offerings and transactions.

Recently serving as chair of the Private Investment Funds Subcommittee of the International Bar Association, Stephanie is a founding member and former chair of the Private Investment Fund Forum, a former member of the Advisory Board of former Third Way Capital Markets Initiative, a former member of the Board of Directors and current member of 100 Women in Finance, a member of the Board of Visitors of Columbia Law School and a member of the Board of Directors of the Girl Scouts of Greater New York. Stephanie has received the highest industry honors. She was named to the inaugural Legal 500 US Hall of Fame in the category of "Investment Fund Formation and Management: Alternative/Hedge Funds." Stephanie is also listed in Chambers USA: America's Leading Lawyers, Chambers Global: The World's Leading Lawyers, Crain's Notable Women in Law, IFLR1000 Women Leaders, Best Lawyers in America, Who's Who Legal: The International Who's Who of Business Lawyers (which ranked her one of the world's "Top Ten Private Equity Lawyers"), Who's Who Legal: The International Who's Who of Private Funds Lawyers (which ranked her at the top of the world's "Most Highly Regarded Individuals" list), Who's Who Legal: Thought Leaders: Global Elite, Who's Who Legal: Thought Leaders: Private Funds, Expert Guide to the Best of the Best USA, Expert Guide to the World's Leading Banking, Finance and Transactional Law Lawyers, Expert Guide to the World's Leading Women in Business Law and PLC Cross-border Private Equity Handbook, among other leading directories. Stephanie was named the "Private Funds Lawyer of the Year" at the Who's Who Legal Awards 2014 and the Euromoney Legal Media Group's "Best in Investment Funds" and "Outstanding Practitioner," both at the Americas Women in Business Law Awards. She is also recognized as one of The Hedge Fund Journal's 50 Leading Women in Hedge Funds and was named one of the 2012 Women of Distinction by the Girl Scouts of Greater New York. Stephanie's representation of leading private investment funds has won numerous awards, including most recently Law360's Asset Management Practice Group of the Year. She is a much sought-after speaker on fund formation and operation and compliance issues, and she regularly publishes articles on the latest trends in these areas.

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Legal Education: LLB (Hons), LLM (Hons), King's College London
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Deepak's experience includes banking work such as capital market financing, security documentation and straight financing. He is particularly experienced in structuring and documenting Islamic financing transactions which include the world's first exchangeable Sukuk, Malaysia's first Islamic stapled securities transaction, Malaysia's first municipal bonds, and the world's first Green SRI Sukuk (2018). Deepak has also advised on the financing of significant Malaysian infrastructure and energy projects, including the privatisation of water supply, independent power plants and the construction of expressways.

He has been managing partner of the firm for over a decade and was awarded the Managing Partner of the Year Award at the Asian Legal Business (ALB) Malaysia Law Awards 2016. The firm is privileged to have received the following recognition for its Banking and Finance, Islamic Finance and Capital Markets practice during Deepak's tenure as managing partner:

Notable Awards & Accolades

- National Law Firm of The Year – International Financial Law Review Asia Awards, 2007 and 2014
- Malaysian Law Firm of The Year – ALB Malaysia Law Awards 2016 and 2020
- West Malaysia Law Firm of The Year – ALB Malaysia Law Awards 2017, 2018, 2019 and 2020
- Islamic Finance Law Firm of The Year – ALB Malaysia Law Awards 2016, 2017 and 2018
- Banking and Financial Services Law Firm of the Year - ALB Malaysia Law Awards 2014, 2015, 2016, 2017, 2018, 2019 and 2020
- Islamic Finance News (IFN) Law Awards 2018 – ESG, Green, SRI Law Firm of the Year
- IFN Law Awards 2019 – ESG, Green, SRI Law Firm of the Year; Energy & Natural Resources Law Firm of The Year
- Malaysia Capital Markets Firm of The Year – Asian-Mena Counsel Awards 2018 and 2019
- Malaysia Projects & Project Financing Firm of The Year – Asian-Mena Counsel Awards 2018 and 2019
- Malaysia Project Finance Law Firm of The Year – The Asset Triple A Asia Infrastructure Awards 2019
- Client Service Award, Malaysia – AsiaLaw Regional Awards 2019
- IFLR Asia-Pacific Awards 2020 – Most Innovative National Law Firm (Malaysia)
- In-House Community Malaysia Law Firm of the Year 2021 for Banking and Finance, Capital Markets, Corporate and M&A, Islamic Finance, Projects and Project Financing practice areas

Rankings / Publications

- Chambers & Partners, Chambers Asia-Pacific – Ranked Band 1, Banking & Finance, Islamic Finance;
- Legal 500 2021 – Hall Of Fame Lawyer, Ranked Tier 1 for Banking & Finance, Capital Markets and Islamic Finance;
- Asialaw Profiles 2021 – Elite Practitioner, Banking & Finance.

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Abradat Kamalpour is a Partner and Global Head of the Ashurst Islamic Finance practice. He is also the founder and architect of FinTech Legal Labs (the Ashurst FinTech accelerator programme). He has extensive experience in debt capital markets, FinTech and structured finance transactions. Abradat has been at the forefront of structuring Islamic-compliant capital markets and FinTech transactions, transforming non-compliant structures into instruments acceptable to Islamic investors. He is involved in some of the most high profile transactions in the Islamic finance market and capital market transactions using Blockchain and other innovative technologies.

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LABOUR AND EMPLOYMENT

LABOUR AND EMPLOYMENT

Covid-19 pandemic and labour market

Angelo Zambelli
Grimaldi Studio Legale
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Ban on dismissals and case-law precedents hereof

In order to keep the employment rate the same as before the spread of Covid-19 pandemic in Italy, a prohibition on dismissals relying on either collective or individual redundancy being served applies until 30 June 2021 (or until 31 October 2021, as far as employers meeting certain requirements are concerned).

On 11 November 2021, the Labour Court of Mantova has declared the invalidity of the dismissal for individual redundancy served to an employee upon the ground that the shop at which she was employed would have been shut down: according to such Court, albeit this dismissal would have fallen out the scope of the prohibition (which does not apply in case of shutdown of the business following the subjection of the employer to the winding-up or the bankruptcy procedure), the employer was not able to demonstrate the actual shutdown of the shop since it has not filed with any defences in the relevant proceedings.

The Labour Court of Trento (ruling issued on 21 January 2021) has declared the fairness of the dismissal for cause served to an employee who had been absent from work for a 14-day period as quarantined, since disciplinary dismissals are not included within the scope of the ban on dismissals. Moreover, according to such Court, the seriousness of the employee's breach was as such as to ground her dismissal with immediate effect since – when she had decided to go on holidays in a foreign Country – she was aware that, once back in Italy, she would have been prevented from going to work over the quarantine term.

Conflicts have arisen with respect to dismissals owing to the relevant employee's physical unsuitability as, albeit these use to be included within the "general" category of dismissals for individual redundancy, in these dismissals the redundancy does not qualify as a direct consequence of the decrease in the employer's revenues following to the drop in consumption associated with the spread of Covid-19 (as happens in those dismissals which the prohibition is aimed at preventing). According to the ruling issued on 7 January 2021 by the Labour Court of Ravenna, also these dismissals are prevented from being served over the term of the prohibition as adversely impacted by the spread of the pandemic: indeed, since the employer's organizational structure is deeply changed due to the current economic crisis, this affects the assessment about the existence of vacant positions which may be assigned to employees in order to avoid their dismissal, that employers must carry out before serving dismissals for individual redundancy, including those owing to the relevant employee's physical unsuitability.

> THE ECONOMIC CRISIS ARISING FROM THE SPREAD OF COVID-19 HAS DEEPLY AFFECTED THE LABOUR MARKET

Lastly, albeit such prohibition should not apply to those categories of employees – including executive status one – whose employment relationship is not governed by the "general" regulations on dismissals which are expressly recalled by the statutory provisions setting forth the ban, the Labour Court of Rome has (surprisingly) declared the invalidity of the dismissal served to an executive, upon the legal argument that reference made by the above statutory provisions is meant to identify those dismissals which fall within the scope of the ban (namely, all those arising from an individual redundancy) but not also the categories of employees who are "protected" by the same prohibition (ruling issued on 26 February 2021).

What if employees refuse to get vaccinated against Covid-19?

According to the national vaccination plan against Covid-19 established by the Italian Government, health workers have been enti-

LABOUR AND EMPLOYMENT

tled to receive preference over any other persons (including people over the age of 80 and those with health problems) during the first months of the implementation of such vaccination plan.

Issues have arisen as several out of them refused to get vaccinated, thus exposing both themselves and patients with whom they get in contact to the risk of Covid-19 infections: in particular, it was debated where health workers who did not get vaccinated would qualify as unsuitable to the work performance, thus being their employers entitled to suspend them from both the work performance and the salary as long as the ban on dismissals referred to above is effective (as a matter of fact, dismissals owing to the relevant employee's professional unsuitability are to be included within the "general" category of dismissals for individual redundancy, so they fall within the scope of the statutory prohibition) and to dismiss them once this ban is over.

At first, the Labour Court of Belluno (ruling issued on 19 March 2021, which – to our knowledge – is the sole case-law precedent about this issue) stated that the employer is entitled to unilaterally put health workers who have refused to get vaccinated on (paid) holidays, as it has the obligation to protect its employees' health and safety at work (otherwise, where health workers who refused to get vaccinated would be allowed to access its premises, such obligation would be breached).

Afterwards, these issues have been definitely solved by Law Decree no. 79/2021: indeed, pursuant to section 4 hereof, where health workers who perform their duties in both private and public hospitals, hospices, residential care homes, pharmacies, drugstores and firms refuse to get vaccinated, their employer is entitled to unilaterally change their tasks and, where these qualify as lower ones, to reduce the amount of their wages or, alternatively, where no other positions are available, to suspend them from both the work performance and the wage (these measures will cease to be available once health workers agree to get vaccinated or the national vaccination plan is fully implemented and, in any case, by 31 December 2021).

However, similar issues will arise once employees other than health workers will be allowed to get vaccinated according to the national vaccination plan.

Measure aimed at increasing the recourse to fixed-term employment contracts

Albeit the above ban on dismissals is effective in Italy as of 17 March 2020, the overall number of unemployed workers in Italy is significantly increased in the first three quarters of 2020: indeed, 470,000 jobs have been lost and the employment rate is decreased by 2% with respect to the first three quarters of 2019.

Reasons for these figures may be identified in the fact that the ban on dismissals only applies to employees hired under a "regular" open-term contract, so employers are permitted to terminate the so-called "flexible" contractual patterns and not to renew fixed-term employment contracts or extend their term upon its expiry: as a matter of fact, the overall number of fixed-term employment contracts decreased by 677,000 units in the second quarter of 2020 and by 449,000 units in the third one.

Therefore, in order to reduce the risk that the spread of Covid-19 pandemic may adversely impact fixed-term workers, until 31 March 2021 recourse to this contractual pattern (as any extensions and/or renewals hereof) has been allowed even in the absence of those reasons allowing the hiring under a fixed-term contract rather than on an open-term basis (indeed, according to the "ordinary" regulations, fixed-term contracts whose duration exceed 12 months are permitted to be executed only upon occurrence of objective and temporary needs, which are to be other than those relating to the company's ordinary business; the need to replace employees who are absent from work and are entitled to keep their position during their absence; or needs arising from a temporary and significant increase in the ordinary business of the company that could not be planned in advance).

Smart working: the new "ordinary" modalities of the work performance

As per statutory "emergency" regulations enacted by the Italian Government following the spread of Covid-19 pandemic in Italy, there is no legal requirement for employers to implement smart working, albeit this is strongly "recommended".

In order to promote the actual recourse to smart working, until 30 April 2021 (such term is likely to be postponed) this is allowed even in the event that the individual agreement whereby rules governing smart working – and, in particular, the relevant employee's right to disconnection and the powers of verification granted to the employer – are set out is not executed in advance between the employer and the relevant employee, as required in case of "ordinary" smart working pursuant to the relevant statutory regulations.

Moreover, until such term, the recourse to smart working is to be communicated to public bodies through a simplified IT procedure (otherwise, in case of "ordinary" smart working public bodies must be also provided with copy of the above individual agreement).

This has led to a significant increase in the recourse to smart working: indeed, the 41.9% of employees who perform duties which may be carried out by remote have carried out their tasks with smart working modalities during the second quarter of 2020, while this percentage was lower than 10% in 2019.

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Angelo Zambelli is co-managing partner, member of the executive committee and head of the employment and industrial relations department of Grimaldi Studio Legale.

He amassed an outstanding reputation in employment and labour law, industrial relations and issues relating employment-related litigation. He has acquired in-depth knowledge in the planning and implementation of extraordinary finance operations and restructuring plans, including the reorganisation and downsizing of either domestic companies or the Italian subsidiaries of international groups. Angelo works side by side with clients advising them on handling complicated industrial relations matters and often represents companies during negotiations.

He is an established lecturer at many conferences organised by Il Sole 24 Ore, AIDP (Italian Association of Personnel Management), AGI (Italian Labour Lawyers Association), EELA (European Employment Lawyers Association), IBA (International Bar Association), ELA (Employment Law Alliance) and ABA (American Bar Association).

He's the exclusive Italian representative for ELA and member of AGI, AIDP, EELA, IBA and ABA.

Angelo is author of several books on employment law and trade union issues, the latest of which are *Manuale di Diritto del Lavoro* (Employment and Labour Law Handbook) – Il Sole 24 Ore, 2019; *Crisi Aziendale e Rapporto di Lavoro* (Company Crisis and Employment Relationship) (Collection of five books) – Il Sole 24 Ore, 2018, awarded in June 2019 as the Best Book on Employment Law by the Labour Consultants Association of Milan; the International Labour and Employment Compliance Handbook (Italian Section) – IBA and Wolters Kluwer, first to eighth edition (2013 – 2020).

He won the award for Best Lawyer of the Year at the *Legalcommunity* Labour Awards in 2017, 2015 and 2014, as well as the award for Best Lawyer of the Year for Industrial Relations and Trade Unions in 2012 and 2013 and that for Best Lawyer of the Year for Restructuring in 2020. Angelo has received the *Le Fonti* award as Employment Lawyer of the Year 2018.

He's ranked in tier/band 1 in all the international legal directories.

Among others, he has been ranked among the top 30 leader lawyers in Italy, according to *Legalcommunity* and *GQ* magazine – which have listed professionals who stand out for managerial skills, strategic vision and media impact.

Moreover, according to a survey made by *Legalcommunity*, Angelo is one of the five employment lawyers to have been classified as a "star" in the Italian labour market in the last seven years, having been one of the lawyers who obtained the highest number of positive comments and referrals from important stakeholders in the market.

Angelo has been also included by both Who's Who Legal among the four "Most Highly Regarded" Italian employment lawyers in 2018, 2019 and 2020 and by The Legal 500 in its "Hall of Fame".

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Top 10 Patent and Regulatory Things You Need to Know when Bringing a Biopharma Product to Canada

Nancy Pei, Alice Tseng, and Daphne Lainson (pictured L-R)
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Canada is an attractive market for pharmaceutical manufacturers. While universal healthcare does not currently extend to drugs in an outpatient setting, most Canadian consumers have some form of drug coverage through government programs and/or private insurance. Further, Health Canada, the regulatory body for drug approvals, is well-respected globally, and approval in Canada may be recognized favourably in other jurisdictions. Below are ten patent and regulatory topics that in-house counsel need to know before bringing an innovative product to Canada.

1. Regulatory pathways: generics, biosimilars, submissions based on literature and market experience, drugs for rare diseases

Canada's Food and Drug Regulations[1] define four broad types of submissions leading to marketing approval (notice of compliance or NOC) of a new drug: (1) a new drug submission (typically for innovative drugs); (2) an extraordinary new drug submission; (3) an abbreviated new drug submission (for generic drugs); and (4) supplements.

Biosimilars are approved by way of a new drug submission, with information and submission requirements set out in a Guidance document[2]. If the biosimilar demonstrates similarity with a reference drug, Health Canada will accept a reduced non-clinical and clinical data package for the biosimilar. Innovators should be aware that if you decide not to seek regulatory approval in Canada, while not common, Health Canada may still approve another company's new drug submission relying on third-party literature and market experience (see Guidance)[3]. Drugs for rare diseases are approved under the standard pathways (see Health Canada's description[4] of its regulatory approach to drugs for rare diseases). Orphan drug exclusivity is not available in Canada.

2. Eight year data exclusivity for new biologic and pharmaceutical drugs

The only form of regulatory exclusivity available in Canada is data protection. If your drug is an innovative drug, it will be granted eight years of market exclusivity from first Notice of Compliance (NOC) (8.5 years with the pediatric extension) pursuant to C.08.004.1 of the Food and Drug Regulations[5]. Further, a submission for a biosimilar or generic drug cannot be filed until six years from first NOC of the innovative drug. An innovative drug, which can be a biologic, is defined as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph". No application is required to obtain data protection (see Guidance)[6]. Once granted, the drug is listed on the Register of Innovative Drugs[7].

HEALTH CANADA IS WELL-RESPECTED GLOBALLY, AND APPROVAL IN CANADA MAY BE RECOGNIZED FAVOURABLY IN OTHER JURISDICTIONS

3. Certificates of supplementary protection

A certificate of supplementary protection (CSP) is similar to a European supplementary protection certificate (SPC) (see comparison[8]; Patent Act Sections 104-134[9], CSP Regulations[10]). It grants an additional patent-like term calculated by subtracting the patent filing date from the NOC date, minus five years, to a maximum of two years. You will need to take careful note of the application requirements (see Guidance[11]), including two deadlines. First, your Canadian new drug submission must be filed within twelve months of the filing of the first application for marketing approval of the medicinal ingredient or combination of medicinal ingredients in the United States, Europe or any member country thereof, Japan, Switzerland and Australia. Second, the CSP application must be filed with Health Canada within 120 days of the later of the date of grant of the NOC and patent grant date. A CSP application may be filed by the drug manufacturer or any patentee of an eligible patent (e.g., a patent claiming the medicinal ingredient or combination of medicinal ingredients, or a use thereof).

Applicants may wish to have the patent grant before the NOC issues as this may govern entitlement in the event of a conflict with a competing CSP application. Pending CSP applications and granted and rejected CSP applications are listed on the CSP Register[12]. If a CSP is granted, it will be automatically reviewed for Patent Register eligibility (see #5 below). If the corresponding patent is listed on the Patent Register, the CSP will also be listed.

4. Patents

Patents are granted a 20-year term from the Canadian (Patent Cooperation Treaty) filing date. Other than the sui generis protection

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granted by a CSP, there are no other term extensions in Canada at this time. Canada has agreed to a Patent Term Adjustment (PTA) for Patent Office delays under the *Canada-United States-Mexico Agreement* (CUSMA), but with a long transition window giving Canada 4.5 years from the July 1, 2020 date of CUSMA to introduce Patent Term Adjustment (PTA).

The standards for patentability are very similar in Canada to many other jurisdictions, and typically an invention patentable in the US is also patentable in Canada. One exception relates to the scope of patent- eligible subject matter, as methods of medical treatment cannot be patented at this time. It is generally possible, however, to protect this subject matter by alternative claim formats.

5. Listing patents on Patent Register

The linkage Regulations (Patented Medicines (Notice of Compliance) Regulations[13]) are similar to the US Hatch-Waxman regime, see comparison[14]. The litigation aspects are described in: 10 Things You Need to Know about Life Sciences Patent Litigation in Canada[15]. This regime, you will need to ensure that patent lists are submitted (1) together with the regulatory submission (e.g., NDS or supplemental NDS) or (2) for any later-granting patents, within 30 days of issuance, provided the patent application was filed before the regulatory submission is filed (see Regulations[16] and Guidance[17]). Because a generic or biosimilar filer need only address patents listed on the Patent Register[18] by the date they file their regulatory submission, you should try to ensure all patents that you wish to be listed issue and are listed by expiry of the six-year no-filing period provided by data protection (see # 2 above). However, if a patent is not listed before a generic or biosimilar filing or at all, if the generic or biosimilar manufacturer addresses any other patents listed on the Patent Register and serves a notice of allegation, you will have the opportunity to bring an action regarding such other patent. In general, patents cannot be listed unless they claim the medicinal ingredient, formulation, dosage form, or use approved by the regulatory submission.

6. Price controls over patented medicines

While patents are of course a valuable way to protect your inventions, in Canada, they also attract the jurisdiction of the Patented Medicine Prices Review Board (PMPRB) which sets limits on the prices set by patentees (Patent Act, sections 79-103[19]). The jurisdiction extends to patents that would not be eligible for Patent Register listing (see #5 above) including, for example, process patents and patents that do not claim the approved drug (e.g., patents claiming a non-approved use or alternative formulation). Once a patent issues, the PMPRB asserts jurisdiction retroactively to the laid-open date of the patent application, provided there was a sale in Canada as of that date. More patents do not increase the PMPRB's jurisdiction, except as regards to the term of jurisdiction. The PMPRB loses jurisdiction over a drug once all related patents expire. Significant changes to the factors used to assess whether a price is excessive and the reporting requirements under the Patented Medicines Regulations[20] will come into force on July 1, 2021 (see amendments here[21] and here[22], and here[23], and applicable Guidelines[24]).

7. Transparency: submission filings and clinical trial data

Once your regulatory submission is accepted into review by Health Canada, certain details will be posted by Health Canada: see submissions currently under review[25]: New drug submissions and submissions currently under review: Supplemental new drug submissions for new uses and once approved, your approved drug will be listed in the NOC database[26] and Drug Product Database[27]. You will also be able to track generic submissions accepted into review here[28] (although sponsors are not identified) and biosimilar / submissions relying on third-party data (see #1 above) here[29].

Once your regulatory submission is authorized, a Summary Basis of Decision, including a regularly updated Post-Authorization Activity Table (PAAT), will be available[30]. The PAAT will include brief summaries of activities such as submissions for new uses of the product and whether Health Canada's decisions[31] were negative or positive. Regulatory Decision Summaries will also be posted not just after a positive regulatory decision, but also for certain final negative decisions and cancellations.

There is also the recent Public Release of Clinical Information[32] regime that requires sponsors to disclose the clinical information in their submission with the exception of personal information (which the sponsor must anonymize) and information meeting a very strict definition of confidential business information. Not only is this regime very onerous and time-consuming for sponsors to comply with, but sponsors are often very concerned regarding the extent of information released under this regime. The information released may go beyond the release of information in other jurisdictions, and potentially provide a disclosure that may impact on patentability. When considering whether an invention may be new and non-obvious over a prior disclosure, the information released by Health Canada should also be considered.

8. Special Access Program

Pursuant to the Special Access Program (SAP) (see Overview[33] and Guidance[34]), health care professionals can request access to certain drugs not available in Canada. SAP only considers permitting access to such drugs for patients with serious or life-threatening conditions, and only when conventional therapies have failed, are unsuitable or are unavailable. If the SAP request is approved and the drug manufacturer wishes to supply the drug, the drug will be sent by the drug manufacturer directly to a practitioner or pharmacist to receive (e.g., the practitioner who made the request, a hospital or community pharmacy). "Pre- positioning" is also allowed, meaning a manufacturer may submit a request for a letter of authorization allowing the drug's import by a drug establishment licence holder for storage until a letter of authorization is issued permitting sale. When considering providing drugs through SAP, you should also consider PMPRB implications.

9. How to calculate Loss of Exclusivity (LOE) date

Your estimated loss exclusivity date should take into account the expiry of data protection (see #2 above) and the expiry date of any patents / CSPs on the Patent Register (see #5 above), taking into account the likelihood that the patent(s) will be infringed and will withstand validity attacks.

10. Marketing the Drug

Once your drug is approved, numerous other regimes and requirements must also be considered. For example, since Canada restricts advertising of prescription drugs to the general public (Direct-to-Consumer Advertising restriction), drug manufacturers must ensure their activities are not considered "advertising" nor otherwise run afoul of advertising laws. Press releases / press conferences intended to inform shareholders, "formulary kits", as well as medical condition focused (versus product focused) communications are some of the activities that, assuming certain conditions are met, do not run afoul of the Direct-to-Consumer Advertising restriction and can therefore be permitted.

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Patient support programs are ubiquitous now for various classes of drugs. There are numerous privacy laws in Canada and one privacy issue that needs to be remembered is that transferring / storing personal information outside of Canada can, depending on the privacy legislation that applies, trigger various requirements and potential challenges, in addition to being objectionable for certain patients and health care professionals.

As a result of certain provincial laws which restrict drug manufacturers from providing rebates or other benefits to pharmacies, it is particularly important to ensure any arrangement in this regard is considered carefully and structured appropriately. Though rebate laws are just one healthcare compliance regime that must be taken into account when structuring commercial arrangements, non-compliance in this respect is particularly important since it can result in a drug being disqualified for reimbursement by the provincial payer.

Though this section highlights only three issues, a myriad number of regimes must be considered when marketing a product.

Summary

As you will have noted, Canada mirrors the regulatory/patent regimes in other jurisdictions in many respects but has key differences. Pre-planning by co-ordinating between regulatory and patent groups before bringing any drug to Canada is critical to ensure all necessary decisions are taken well in advance of critical deadlines.

1 https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html
2 https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/information-submission-requirements-biosimilar-biologic-drugs-1.html
3 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/drug-submissions-relying-third-party-data-literature-market-experience.html
4 https://www.canada.ca/en/health-canada/services/licences-authorizations-registrations-drug-health-products/regulatory-approach-drugs-rare-diseases.html
5 https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-142.html
6 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-data-protection-under-08-004-1-food-drug-regulations.html
7 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs/register.html
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10 https://laws-lois.justice.gc.ca/eng/regulations/SOR-2017-165/FullText.html
11 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates/certificate-supplementary-protection-regulations.html
12 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html
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17 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html
18 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/patent-register.html
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30 https://hpr-rps.hres.ca/reg-content/summary-basis-decision-detailTwo.php
31 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/regulatory-decision-summary.html
32 https://www.smartbiggar.ca/insights/publication/final-regulations-addressing-the-public-release-of-clinical-information-now-in-force
33 https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access.html
34 https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/guidance.html

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Nancy Pei is a partner in Smart & Biggar's Toronto office. With hands-on experience as a pharmacist and over 20 years of patent litigation expertise, Nancy has established a successful IP practice focused exclusively in the field of life sciences—including pharmaceuticals and biologics.

As a patent litigator, Nancy advocates on behalf of innovative life sciences companies in cases relating to the *PM(NOC) Regulations*, in patent infringement/impeachment actions, s. 8 cases, related quantification reference proceedings and judicial review applications. She has represented clients before the Federal Court of Canada, the Federal Court of Appeal, the Supreme Court of Canada and the Ontario Superior Court of Justice. She also provides advice on matters relating to patent listing, data protection, Certificates of Supplementary Protection, the Patented Medicine Prices Review Board and access to information requests.

Nancy's clients benefit not only from the depth and breadth of her experience but also from her unique insights on broader patenting, regulatory and business issues, helping them manage the life cycles of their products and remain competitive in an ever-changing industry.

Nancy is named as a leading Life Sciences legal practitioner in *Expert Guides: Women in Business Law*, *LMG Life Sciences*, *The Best Lawyers in Canada*, *Who's Who Legal: Life Sciences* and MIP's *IP Stars Handbook: Patents*. She is a pharmacist, patent and trademark agent and lawyer. She was called to the Ontario bar in 1997.

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Peter is co-chair of Quinn Emanuel's Global Life Sciences Practice. Peter focuses his practice on patent infringement and inventorship litigation and counseling matters regarding pharmaceuticals, biologics, DNA sequencing technologies, and medical devices, but has also served as lead counsel for both plaintiffs and defendants in a wide range of patent and general commercial matters in courts across the country and in national and international arbitrations.

Peter has been recognized by *Chambers USA* as a leading lawyer in intellectual property every year since 2007, and has been similarly recognized by *Chambers Global* every year since 2013. *Chambers* has noted in various years that Peter is "a fantastic trial lawyer," "one of the brightest ANDA litigators out there today," "tremendously strategic in setting up a case," and has a "track record of winning."

Managing Intellectual Property magazine named Peter one of "America's Best Life Sciences Litigators," including him in its Top 10 list for 2012. The *LMG Life Sciences* rankings echo this praise, listing Peter as a top performer in every edition.

Peter has also been listed in a number of other guides and rankings, including the *IAM Life Sciences 250*, the *IAM Patent Litigation 250*, and the *IAM Patent 1000*. *IAM* has reported client comments that "he is one of the smartest lawyers out there and handles cases expertly and efficiently, obtaining great results at a reasonable cost – often through facilitating early wins."

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William Savitt is the co-chair of the Litigation Department of Wachtell, Lipton, Rosen & Katz. His practice focuses on representing corporations and directors in litigation involving mergers and acquisitions, proxy contests, corporate governance disputes, class actions involving allegations of breach of fiduciary duty, and regulatory enforcement actions relating to corporate transactions. Mr Savitt writes and speaks extensively on corporate and securities law topics and is an adjunct law professor at Columbia Law School in the field of transactional litigation.

Mr Savitt has played a leading role in high-stakes corporate governance and merger-and-acquisitions litigation in the Delaware Court of Chancery and in courts around the country. Among recent examples, Mr Savitt successfully litigated the landmark case of *Corwin* v. *KKR Financial* in the Court of Chancery and the Delaware Supreme Court; defended Allergan in response to a hostile bid from Pershing Square and Valeant; defended Sothebys' shareholder rights plan against an activist investor attack; was lead trial counsel in the successful and unprecedented litigation effort of Vulcan Materials Company to obtain a court order enjoining an attempted hostile takeover by an industry rival; has defended corporate bylaw and charter provisions in courts around the country; has tried numerous M&A cases to successful verdict; and was lead attorney in the United States and Canada in Lions Gate Entertainment's successful multi-national defense of Carl Icahn's takeover attempt. Mr Savitt is a recognized authority on multi-jurisdictional corporate litigation and has defended numerous corporate merger and class action fiduciary challenges in Delaware, New York, California and elsewhere, including recent successful defenses of the New York Stock Exchange's merger with the InterContinental Exchange, the going-private sale of Dell, Inc., and the merger between Saks Fifth Avenue and Hudson's Bay Company.

Mr Savitt graduated *magna cum laude* from Brown University and received a M.Phil. from Columbia University in European legal history. He graduated from Columbia Law School in 1997, where he was editor-in-chief of the *Columbia Law Review.* Upon graduation from law school, Mr Savitt served as a law clerk to the Honorable Pierre N. Leval of the United States Court of Appeals for the Second Circuit for the 1997 term and to the Honorable Ruth Bader Ginsburg of the Supreme Court of the United States for the October 1998 term. Among other professional recognitions, Mr Savitt has been named by *Chambers USA: America's Leading Lawyers for Business* as a leading securities litigator, by *Lawdragon* as one of the 500 leading lawyers in the United States, by Benchmark Litigation as a "litigation star" and as a leading authority in the *International Who's Who of Corporate Governance.* He is a member of the American Law Institute, the Board of Directors of the New York Legal Aid Society and the Board of Trustees of the *Columbia Law Review,* Inc., and is a past executive director of Interfaith Hunger Appeal, a New York-based international hunger relief organization.

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Executive Chairman and Managing Partner of Garrigues since September 2014.

Fernando Vives has more than thirty years' experience at Garrigues and has been a partner since 1998.

Between 2001 and 2009 he headed Garrigues' Corporate/Commercial Law practice, encompassing the securities market, financial services, real estate,energy and telecommunications, EU and competition and M&A areas.

He practices in the areas of securities market law, corporate law, M&A, private equity, banking & finance law and insurance law, with particular emphasis on capital markets and financial services.

He specializes in major transactions involving mergers, reorganizations, tender offers, corporate LBOs, securities issues and public offerings, and regulatory matters concerning listed companies. He regularly advises on major M&A deals and is actively involved in private equity transactions,working on related tasks and on raising outside financing. He also has a wealth of experience in the insurance industry, where he advises numerous insurance groups operating in Spain.

He also acts as adviser to the shareholders' meetings and boards of directors of some of the largest listed companies in Spain on corporate governance related matters: Telefónica, SA, Banco Bilbao Vizcaya Argentaria, SA, Iberdrola, SA, to name but a few.

Fernando has acted as lead lawyer in a host of high-profile Spanish and international M&A and corporate finance deals in recent years, including for instance: advising Telefónica in the sale of Telxius tower division to American Towers Corporation at record multiples for 7.7 billion euros (2021), advising Bankia on its merger by absorption with Caixabank for €4.3Bn (2020), advising Iberdrola in the merger by its US subsidiary, Avangrid, of PNM Resources for €3.6Bn (2020), advising Bankinter in the spin-off of its subsidiary Línea Directa Aseguradora for €1.4Bn (2019), advising International Airlines Group on the acquisition of Air Europa from Globalia for €1Bn (2019), advising Allianz on the sale to Banco Santander of 60% of Allianz Popular and on the termination of its bancassurance alliance with Banco Popular for €937 million (2019). He also gave advice to Blackstone on the €2 billion tender offer for 100% of Hispania SOCIMI (2018). Advice to Bankia on the €825 million merger by absorption of Banco Mare Nostrum (BMN), (2018). Advice on the €3.6 billion merger of Elektro Holding, S.A. and Neoenergia, S.A. (2017). Advice to Telefónica on the €1.3 billion deal to sell up to a 40 percent stake in its telecom masts subsidiary Telxius to private equity firm KKR (2017). €740 million acquisition by Telefónica of an additional 6% stake in Germany-based Telefónica Deutschland from Netherlands-based KPN (2017). Advice on the €3.2 million IPO of Gestamp Automoción (2017). Advice to the selling shareholder and the company on all legal aspects of the €3 Bn IPO of Prosegur Cash, a spin-off of Prosegur (2017). amongst many others.

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David A Katz is a partner at Wachtell, Lipton, Rosen & Katz in New York City, an adjunct professor at New York University School of Law, and co-chair of the Board of Advisors of the NYU Law Institute for Corporate Governance and Finance. Previously, he was an adjunct professor at Vanderbilt University Law School and at the Owen Graduate School of Management. Mr Katz is a corporate attorney focusing on mergers and acquisitions, corporate governance, shareholder activism and complex securities transactions, has been involved in many major domestic and international merger, acquisition and buyout transactions, strategic defense assignments and proxy contests, and has been involved in a number of complex public and private offerings and corporate restructurings. He frequently counsels boards of directors and board committees on corporate governance matters and crisis management.

Mr Katz taught *Mergers and Acquisitions* at New York University School of Law for over 15 years and previously co-taught a joint law and business short course on mergers and acquisitions at Vanderbilt University Law School with Delaware Chief Justice Leo Strine. He is co-chair of the Tulane Corporate Law Institute.

In 2004, he was chosen by *The American Lawyer* as one of the 45 highest performing members of the private bar under the age of 45; in 2005, 2012 and 2015, he was selected by *The American Lawyer* as a Dealmaker of the Year; in 2016, he was named by NACD Directorship as one of the 100 most influential players in corporate governance for the seventh time; in 2013 he was named Lawyer of the Year by Global M&A Network; in 2014 and each of the five prior years he was named *Who's Who Legal*'s Mergers and Acquisitions Lawyer of the Year, in 2014 was also named *Who's Who Legal*'s Corporate Governance Lawyer of the Year and in 2015 and 2016 was named Who's Who Legal's Corporate Governance and M&A Lawyer of the Year; and in 2015 he was elected by The American College of Governance Counsel as an Inaugural Class Fellow.

Mr Katz is a member of the American Bar Association, Section on Business Law, where he founded the Committee on Mergers and Acquisitions Task Force on the Dictionary of M&A Terms and a member of the Committee on Mergers and Acquisitions Subcommittee for Acquisitions of Public Companies. Mr Katz is also a member of the Federal Securities Laws Committee, the New York State Bar Association and the Association of the Bar of the City of New York. Mr Katz is a member of the Society for Corporate Governance and the National Association of Corporate Directors. Mr Katz serves as a member of the Board of Trustees at New York University and at New York University School of Law. He sits on the Board of Directors of The Partnership for Drug-Free Kids and is a member of the Advisory Board at the John L. Weinberg Center for Corporate Governance at the University of Delaware. He writes a bi-monthly column on corporate governance for the New York Law Journal with his colleague Laura McIntosh.

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John Reiss is the Global Head of White & Case's Mergers & Acquisitions Group. He has more than 30 years of experience representing parties in virtually all manner of M&A transactions in all industries.

John's practice focuses on complex, multijurisdictional transactions, some of which have set new market precedents, and many of which have been recognized with national and international awards.

A diverse range of US and international clients has benefited from John's experience. His clients, from a range of industries, include Anthem, DISH Network Corporation, Fortis, Hess, ICBC, Mobile Mini, Pernod Ricard, Pilot Flying J, Regal Beloit, SodaStream, SSAB Svenskt Stål AB, Toyota Industries and Ahold NV; as well as a variety of Private Equity firms such as Cobepa, CVC Capital Partners, Dominus Capital, Harvest Partners, Quad-C Management Inc. and Roark Capital.

John received his JD from the University of Pennsylvania Law School in 1984. He also received his MBA and his BS, *summa cum laude*, from the Wharton School of Finance and Commerce at the University of Pennsylvania in 1984 and 1981.

John is recognized in the fields of M&A, Private Equity, and Corporate Governance by many highly respected professional publications, including *Chambers Global* (2020), *Chambers USA* (2020) and *Euromoney* (2020). John has also appeared on a number of media outlets, including Bloomberg TV, Bloomberg Radio and CNBC.

Recent matters include the representation of:

- The Independent Directors of Mobile Mini, Inc. (NASDAQ: MINI) in its US$6.6 billion merger of equals with WillScot Corp. (NASDAQ: WSC).
- SodaStream International Ltd. (NASDAQ/TLV: SODA) in its US$3.2 billion sale to PepsiCo, Inc. (NASDAQ: PEP).
- Harvest Partners on numerous acquisitions, including its investment in MRI Software, a leading provider of real estate management software solutions globally.
- Roark Capital Group and Inspire Brands, Inc. on numerous acquisitions, including its US$2.3 billion acquisition of Sonic Corp. (NASDAQ: SONC) and its acquisition of Jimmy John's LLC.
- DIC Corporation, a Japanese fine chemicals company, and its US subsidiary Sun Chemical Corporation, in its €1.15 billion acquisition of BASF's global pigments business, known as BASF Colors & Effects.
- Pernod Ricard SA, the world's second largest producer of wines and spirits, in its acquisition of Firestone & Robertson Distilling; and in its acquisition of a majority interest in Rabbit Hole Spirits, LLC.

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Reed Freeman Jr. is an authority on privacy, cybersecurity, and the privacy aspects of advertising online, on mobile devices, in social media, and on connected devices such as smart TVs. Reed has extensive experience defending clients in Federal Trade Commission (FTC) and state consumer protection investigations and data breach responses. He also counsels clients on compliance with FTC and state trade regulation issues, state privacy and data security laws, including counseling on compliance with California's Privacy Protection Act (CCPA) and the implementing regulations by the California General, the California Consumer Protection Act ("CPRA"), the Virginia Consumer Data Protection Act ("VCDPA"), privacy and data security compliance around the globe, and advertising and privacy self-regulatory codes.

In addition to working with clients to develop globally compliant privacy policies and programs, Reed assists clients in connection with privacy and data security involved in transactional matters, such as mergers and acquisitions, asset sales and asset purchases, in contract negotiations, and in connection with applications for membership in industry trade groups.

Reed's clients include retailers; hospitality companies; financial institutions; software companies; hardware manufacturers; online, mobile, and social media publishers and advertisers; online, mobile, and social media application developers; data aggregators; advertising technology companies; advertising trade associations; industry coalitions; and social media-based advertising service companies.

Prior to joining Venable, Reed served as the co-chair of the cyber security and privacy and big data practices at an international law firm. He previously worked in the FTC's Bureau of Consumer Protection as a staff attorney, and as chief privacy officer and vice president for legislative and regulatory affairs for an online advertising software company.

Honors and Recognitions

Reed Freeman "is smart, practical, and understands business in a way that many lawyers do not; he is a calming influence and provides invaluable advice," according to clients. "He is a privacy savant," says a source. "He has things committed to memory that I couldn't possibly recall. He gives thoughtful answers and he understands the business aspect of my questions as well." Sources also say he is a "strong lawyer" who has "breathtaking knowledge" of offline and online privacy issues.

- ***Legal 500***
  - Hall of Fame, 2017
  - Media, Technology and Telecoms: Cyber Law (including Data Privacy and Data Protection)
- ***Chambers USA,*** Privacy and Data Security (Band 1), Nationwide
- ***Chambers Global,*** Privacy and Data Security (Band 1), USA
- ***Best Lawyers in America***, Lawyer of the Year, Privacy and Data Security Law, Washington, DC, 2021
- ***National Law Journal,*** Trailblazer, Regulatory & Compliance, 2015
- ***Washingtonian,*** Top Attorney, Cybersecurity, 2015

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EXPERTGUIDES

THE WORLD'S LEADING LAWYERS CHOSEN BY THEIR PEERS

PROJECT FINANCE

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PROJECT FINANCE

Financing Rail Infrastructure in Nigeria – Future Outlook

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Introduction

The critical need to develop Nigeria's rail infrastructure has been a burning issue over the last 30 years. The topography of Nigeria as well as the structure of its economy necessitate an efficient and sustainable rail infrastructure; yet since the decline and obsolecy of the rail infrastructure built during the colonial era, the Nigerian Railway Corporation has been largely moribund and ineffective, existing mainly as a property leasing agency in respect of the landed property owned by the corporation. Since the mid1980s, successive governments in Nigeria have paid scant attention to infrastructure development either by direct investment or by creating an environment or law that encourage private sector participation in infrastructural development. The narrative has only recently begun to change with the construction and commencement of operations of the Abuja Light Rail, the Abuja – Kaduna Rail and the Lagos – Ibadan Rail. Funding however continues to be a critical challenge to the development of Nigeria's rail infrastructure, with even the lines which have commenced service being significantly de-scoped to save on cost and suffering significant completion delays due to funding.

Completed, Ongoing and Proposed Railway Projects in Nigeria, in the Last Five Years

A review of all the railway projects above show that all are (or will be) substantially funded through external borrowings. This funding structure is not sustainable to finance the vast rail infrastructure which Nigeria needs to build to support its growth plan.

Last year alone, the senate approved nearly $23 billion in foreign loans for infrastructure projects. As at 31st December 2020, Nigeria's public debt stood in excess of $86 billion with 38% of this sum being external debt. The government cannot continue to borrow the large sums of money required to finance rail (or other) infrastructure, particularly where the projected revenues do not support repayment.

Additionally, over-exposure to foreign loans exposes the projects to exchange rate risks, since project revenues are in Naira, invariably leading to defaults, extended tenors and abandoned projects. A look at the commencement / completion timelines for most of the projects clearly shows a trend of delays, largely attributable to funding. Such delays typically lead to cost overruns and thus set up a cycle of failure invariably ending in abandonment or significant de-scoping of the project.

Private Financing of Railway Projects – a Viable Option?

Private capital available to traditional private equity, infrastructure and pension funds is significant, with assets under management of pension funds alone, standing in excess of NGN 12.2 trillion as at November 2020. Admittedly, there has been an increase in deployment of such capital to infrastructure projects in the last few years, particularly following the updates to the investment guidelines for pension fund managers. (Such capital is however largely focused on projects such as real estate and power, due to demand and turnaround time). The capital available to be matched with "suitable" projects is significant, and it is worth exploring how the rail sector can benefit.

Challenges of Private Financing of Railway Projects

Disproportionate Risk and Returns

Private financing of infrastructure projects is relatively straightforward where the revenues and cash flows are expected to adequately repay financing and associated costs. This explains why private funding of power infrastructure projects has been so successful in recent years once a credible offtaker is identified. The private sector ultimately invests in these projects to make a profit (which is expected to be higher, where higher risks are associated with the investment). The challenge with rail projects is that by their nature, they are considered to be more of social impact investments. Rail fares are almost always subsidized to compete with other modes of transport and the revenue returns seldom compensate for the risks involved.

Cherry Picking

Flowing from the focus on matching risks to returns, project precedence has shown that where private funds are involved in transport infrastructure projects, there is a tendency for sponsors to cherry pick, and cover the more lucrative routes; leaving the government to fi-

PROJECT FINANCE

Rail Line	Cost (US$)	Funding Model	Description
Abuja – Kaduna	$876million	500 million in loans from the Exim Bank of China; balance funded by the Federal Government of Nigeria (FGN).	187km from Abuja to Kaduna (part of the 2,700km Lagos – Kano line).
Lagos – Ibadan	$2.53 billion	Loan from the Export-Import (Exim) Bank of China.	156 km from Lagos to Ibadan (part of the 2,700km Lagos – Kano line).
Ibadan – Kano	$5.3 billion	FGN to provide an equity stake of 15% with the remaining 75% funded by from China's Exim Bank.	Comprised of 4 sections - the 200km Ibadan-Ilorin section, the Ilorin-Minna section a distance of 270km and then the Abuja, Kaduna and finally Kano a distance of 300km. (part of the 2,700km Lagos – Kano line).
Abuja – Warri	$3.9billion	FGN to provide an equity stake of 15%, China Railway Construction Corporation Limited (CRCC), an equity stake of 10%, and the remaining 75% borrowed from China's Exim Bank. The CRCC will operate the railway and the port to recover its investment.	Originally commenced as the Itakpe – Ajaokuta cargo line in 1987, it was extended to link the capital Abuja to the port city of Warri, a distance by air of approximately 440km.
Kano-Maradi	$1.959 billion	To be financed by bilateral loan arrangements.	To link Kano–Danbatta–Kazaure–Daura–Mashi– Katsina–Jibiya–Maradi (Niger Republic) with a branch line from Kano to Dutse.
Lagos-Calabar	The project is valued at $11bn	Originally intended to be funded from loans from China's Exim Bank; however following indications that the funding is not available and continuous delays to the commencement of the project (which was expected to be completed in 2018), the FGN is currently exploring other funding options.	1402 km (871 mi) to be developed in two phases. The first phase will run between Calabar and Port Harcourt; while the second phase will run between Port Harcourt and Lagos via Onitsha.
Port Harcourt-Maiduguri	$3 billion	FGN to provide about 15% of the $3 billion rehabilitation and reconstruction cost, while the balance will be provided by a syndicate of Chinese financiers.	Rehabilitation and reconstruction of the 1,443-kilometer (897-mile) Eastern Railway line that starts from the southeastern oil hub of Port Harcourt and terminates at the northeastern city of Maiduguri.

nance infrastructure on the less lucrative routes. This then leads to issues of sustainability and integration, with the government, more often than not, unable to efficiently complete, at value, the rest of the infrastructure.

Integration of National Infrastructure

Another issue is the challenge of integrating the national railway infrastructure where various portions are privately financed by different entities. Generally, the sponsorship and financing of a complete national rail infrastructure is unattractive to private funders who do not have the capacity or appetite for such projects, occasioning a mix of financing options, and therefore competing interests on various portions of the infrastructure.

Security

Furthermore, the fragmented nature of the interests in the assets will create issues in relation to security over the said assets. The extent to which a private financier can have recourse to assets if a project fails is also a material consideration. Fixed rail infrastructure such as tracks are immoveable assets and have limited resale value outside the rest of the infrastructure, whilst the civil works such as tunnels have no resale value. Other than perhaps the project land (where substantial portions are located in urban areas, which is not typically the case in Nigeria); the viability of the project assets as security is therefore dependent on the financier being able to sell the entire project. Even where joint security arrangements are entered into and parties agree to sell, this will only be feasible if the project as a whole was economically viable in the first instance. Recourse must therefore be made to sovereign guarantees, or bank guarantees/ insurance (which then make the project prohibitively expensive).

It is therefore more typical for private investors to invest in rail assets such as rolling stock (over which security can be more easily taken), rather than the railway infrastructure.

Revisiting the PPP Model – InfraCo

Private financing on its own, cannot be viable for rail infrastructure projects where there is a funding gap i.e the project revenues cannot effectively carry the project cost over a reasonable project life cycle. The financing of railway infrastructure can therefore not be done in isolation of public sector funding or support in the form of subsidies, grants, sovereign guarantees, waivers, tax exemptions or government borrowings or a mix of all or some of such support.

The proposed Infrastructure Company of Nigeria Limited ("**InfraCo**") when established, properly structured and efficiently resourced, can create a viable midpoint between public funding and private finance for major infrastructure projects in Nigeria, including future rail projects.

InfraCo will be established by the FGN to replicate Infraco Asia (on a domestic scale), and focus on critical infrastructure investments. It will be a dedicated privately-managed infrastructure and industrial vehicle that will harness opportunities for Nigeria's infrastructure development by originating, structuring, executing and managing end-to-end bankable projects in that space. Its Initial seed capital of NGN1 trillion is expected to come from the Central Bank of Nigeria ("**CBN**"), the Nigerian Sovereign Investment Authority ("**NSIA**"), and the Africa Finance Corporation ("**AFC**") (identified as the promoters). (The President has also intimated that part of the seed capital is expected to come from pension fund assets; there has however been significant push back in this regard, and it is unclear whether pension funds will still be required to provide seed capital).The company is expected to grow to NGN15 trillion in assets and capital over time (raising capital from local and foreign private sector development financiers and markets), which will be managed by an experienced and reputable asset management firm. The firm will also be responsible for capital raising, and revenue generation. The board of the company will be chaired by the CBN Governor, and will include the MD of NSIA, President of AFC, representatives of Nigerian Governors Forum and Ministry of Finance, and three independent directors from the private sector.

Viability – Can InfraCo really be the Catalyst for Future Rail Infrastructure Financing

Nigeria has previously explored and failed with the PPP Model of financing infrastructure. For instance, the Abuja Light Rail Project was initiated in 1997 under a PPP Model. Following years of delay due to funding issues, the Project was re-awarded to China Civil Engineering Construction Corporation at a cost of $824 million, with 60% of the cost funded by foreign loans. As at today, only the first phase – line between the city center and the airport with no stops in between, has been commissioned.

The challenges of misalignment of interests, political risk, policy reversals, bureaucracy and challenging and unstable regulatory environment caused private capital to shy away from infrastructure projects, under the PPP regime. All of these problems still exist. How do we assure a clear and certain statutory and regulatory framework? How do we ensure transparency, appropriate governance, non-interference by government and first-class management selected on merit? How do we confirm an attractive and viable security structure? How do the promoters of InfraCo intend to ensure sufficiency of capital, capacity for efficient project completion, and sustainable returns on investment? There must be a clear plan for a systemic shift to resolve historical challenges.

In addition, there must also be a strategy to close the funding gap created between the pillars of commercial viability and impact development. Moodys has predicted that Nigeria will need to invest at least $3 trillion over the next 30 years to close the country's infrastructure gap. A well structured, well funded and efficiently managed InfraCo established and empowered under the right statutory and regulatory framework can catalyse infrastructure development in Nigeria and possible attract part of the $17trillion negative interest yielding funds sterilized in the international capital markets.

Conclusion

There will be tremendous pressure on InfraCo and competing interests for its resources. Accordingly, its contributions to the financing of raill projects may be focused on rolling stock, ticketing and operations, as well as other more commercially viable infrastructure, and thereby free up Government borrowing for core rail infrastructure.

In order for rail projects to attract private sector investors, the way in which such projects are developed must change; incorporating/ integrating wider strategic goals on a whole city level- and thus ensuring that people will want to use the service, it will have a positive social impact and it can be funded and operate sustainably. For instance, the success of many European rail models lies in the active involvement of the operator with businesses that are not directly connected to transport. The right planning of shops and offices within and around stations will contribute to increasing the revenue that can be extracted not just from the rail users, but people living and passing through surrounding areas and will help make the project more commercially viable. Until then, Nigeria's fledgling rail reform, will likely continue to be dependent on government borrowing.

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Brian Kelsall's practice is focused on project finance and development, banking and corporate finance and public private partnerships. Brian has considerable experience in infrastructure development and finance, spanning Canada, the US and emerging markets. Regularly advising lenders, developers and contractors, Brian has acted for clients across the telecom, infrastructure, energy, oil and gas, and mining sectors.

Brian is recognised as one of the top projects and project finance practitioners in Canada, and has one of the leading international projects and project finance practices in Canada. He is independently ranked by leading legal publications including, The Lexpert/American Lawyer Guide to the Leading 500 Lawyers in Canada, Best Lawyers, Who's Who Legal, Euromoney's "Best of the Best", Chambers Canada and the International Financial Law Review. Brian is also relationship partner for many of the firm's top projects clients.

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Asue Ighodalo is a founding partner of Banwo & Ighodalo, one of the foremost commercial law firms in Nigeria. He obtained his first degree in Economics from the University of Ibadan, a law degree from the London School of Economics and Political Science; and was admitted into the Nigerian Bar in July 1985.

His core areas of practice are Corporate and Project Finance, Securities and Capital Markets, Energy & Natural Resources, and Mergers & Acquisitions.

Asue is a member of the Nigerian Bar Association (past Chairman of the Section on Business Law), International Bar Association (Energy, Environment, Natural Resources and Infrastructure Law Section (SEERIL)), Association of International Petroleum Negotiators, Institute of Directors Nigeria, Commercial Law and Taxation Committee of the Lagos Chamber of Commerce and Industry and Chartered Institute of Taxation of Nigeria.

Asue is the Chairman, Board of Directors, the Nigeria Economic Summit Group (NESG), Sterling Bank Plc, Levene Energy Group and Edo State Investment Summit. He also sits on the boards of Mainstreet Technologies Limited, Cardinal Stone Partners, Okomu Oil Palm Plc, Christopher Kolade Foundation, and the Nigeria Sovereign Investment Authority (NSIA).

Asue has been consistently ranked as a "Tier 1" or "Leading lawyer" in all of his areas of practice by the leading legal directories. He has authored many articles in leading law publications and also delivered several presentations on diverse subjects.

His hobbies include golfing, watching football, reading, traveling and participating in political discourse. He is married and has a daughter.

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Mrs Erika Åslund has significant experience and is widely regarded as an accomplished real estate M&A practitioner. She has consistently over the years represented both Swedish and international investors in the largest and most complex real estate M&A transactions in Sweden.

Mrs Erika Åslund has been awarded several domestic and international recognitions and she is also ranked in the Hall of Fame for Real Estate work in the *Legal 500 EMEA*.

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Daniel Aquilina heads Ganado Advocates' banking ship finance and aviation teams, assisting leading international banks and financial institutions involved in the financing of Maltese registered vessels and aircraft by perfecting the registration of mortgages and security interests.

Daniel has considerable experience in the drafting of Maltese law regulated security and has been involved in complex multi-vessel and aircraft transactions including advice relating to alternative ship finance mechanisms and structures under Maltese law. He has been involved in major Maltese ship finance deals for several years, advising major multinational and providers/arrangers of finance with loan restructuring and mortgage enforcement matters. He also advises on ship sale and purchase, shipbuilding contracts, ship registration and all other aspects of ship purchase, chartering and operation.

Daniel was the Secretary of the Malta Maritime Law Association and Council Member of the Maritime Legislative Advisory Council for many years and now continues to give his contribution as a member of the Association. He also served on the board of governors of the International Propeller Club, Port of Valletta. Between 2016 and 2019, Daniel served as Chairman of Malta Marittima Agency – the Maltese Government's Agency which aimed to enhance co-operation between the maritime industry and Government stakeholders, in order to continue developing the Maltese maritime industry.

Daniel is recognised for his shipping expertise in Chambers Europe and The Legal 500.

"Daniel Aquilina regularly assists international banks with shipping finance matters. An interviewee considers that Aquilina is *efficient, commercial and has very good knowledge and experience in all Maltese ship registration and finance matters.*", Chambers Europe, 2021

"'Every time I have a complex legal matter pertaining to Maltese law, Daniel Aquilina is the lawyer to reach out to – succinct advice taking into account the commercial parameters.", The Legal 500, 2021

"Daniel Aquilina is the partner that I have been working with for the last 15 years. He is always on the top of a transaction, he is very knowledgeable and his work is of top quality. Daniel is very committed to his clients and contactable at all times especially when we need help to overcome issues and problems with a transaction.", The Legal 500, 2021

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Johannes Bürgi, partner with Walder Wyss since 2005, advises clients on matters involving real estate, finance, structured finance, restructuring, and capital markets.

In real estate, Johannes advised a large sovereign wealth fund on an important investment in a real estate development in Switzerland and a UK based international banking institution on the restructuring of various large real estate financings in Switzerland. He also advised the Norges Bank Investment Management (NBIM) in its 1 billion Swiss franc landmark acquisition of the Uetlihof office complex in Zurich from Credit Suisse AG in a sale-leaseback transaction, Blackstone Group with respect to the Swiss part of the acquisition of assets of GE Capital Real Estate in a transaction valued at US$23 billion globally, a Middle-Eastern sovereign wealth fund on its acquisition of a portfolio of hotel properties in Switzerland and an international commercial bank on a large development financing of hotel residences in Switzerland. Other work highlights include acting on behalf of a consortium of lenders with respect to the rescue operation of a major German Pfandbriefbank, acting on behalf of UBS AG with respect to its novel covered bond program backed by Swiss residential mortgages, acting on the first public private partnership financing transaction in Switzerland, acting on behalf of Apollo International in its trade receivables factoring and inventory based financing to fund Apollo's acquisition of Rio Tinto's Alcan business as well as acting on a large restructuring transaction with respect to a pan-European hotel financing.

Who's Who Legal says: Johannes Bürgi is "in high demand" due to his "relaxed manner" and "sharp intellect". Chambers Global praises his "strong client skills and pragmatic approach," his "excellent strategic oversight" and his "wealth of experience."

Born in 1972, Johannes Bürgi was educated at Lausanne and Berne universities (state exam, 1998; Dr iur, 2001, summa cum laude) and at Stanford Law School (LLM in corporate governance and practice, 2003). He has working experience as a District Court law clerk, trainee at a Berne law firm, research assistant at the University of Berne and secondee to UBS Investment Bank in Zurich. He is fluent in German, English and French; he is registered with the Zurich Bar Registry and admitted to practice in all Switzerland.

With approximately 150 lawyers, Walder Wyss is one of the largest Swiss law firms, with offices in Zurich, Geneva, Basel, Berne, Lausanne and Lugano. It offers a full range of services for the business community in Switzerland, as well as public, private and international clients. Its practice teams handle business transactions, banking and finance matters, taxes, arbitration and litigation as well as IP/IT and competition matters.

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TAX

TAX

A Period of Great Tax Uncertainty

James P Fuller and Larissa Neumann
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International tax planners today live in a period of great uncertainty. In the US, in particular, we expect soon to have significant changes made to our international tax rules. Non-US tax planners also soon will have changes with which to deal if implementation of the proposed OECD changes takes place.

President Biden's tax proposals would increase the corporate tax rate to 28%. The Global Intangible Low-Tax Income ("GILTI") rules would be "strengthened" and the tax rate on GILTI would be 21%. The Foreign-Derived Intangible Income ("FDII" an export benefit) would be repealed and the Base Erosion and Anti-Abuse Tax ("BEAT") provisions would be replaced by "an under-tax payments rule" to bring the US rules more in line with the OECD's Pillar 2.

The President's proposals also involve "achieving global agreement on a strong corporate minimum tax through multilateral negotiations." Obviously, this reflects a new US approach to the OECD's Pillar 2. The apparent reason for this change is that the President would increase US corporate tax rates and without a global minimum tax, foreign-owned businesses operating internationally could be significantly more profitable than US-owned businesses.

Biden has suggested that his plan may eliminate BEAT and replace it with a new anti-abuse erosion regime more akin to the undertaxed payment rule being developed by the OECD as a backstop to the global minimum tax. His new plan is called SHIELD – Stopping Harmful Inversions and Ending Low-tax Developments. SHEILD appears to be similar to the OECD undertaxed payment rule proposal. SHIELD would seem to provide a strong incentive for other jurisdictions to implement a similar Pillar 2 minimum tax, because if they did not, they would effectively be losing tax revenue to the US.

To make matters more uncertain, a number of US Senators and House members have introduced their own legislation that would require multinational corporations to pay tax at the same rate on profits earned offshore as they do on US profits. One of the bills would also disallow interest deductions for US corporations that are part of the multinational corporate group in situations in which a disproportionate share of the worldwide group's debt is in the US. The other bill would require detailed country-by-country disclosure regarding revenues, profits, tax, employees, and so forth and would be publicly available. Numerous other changes are proposed by these bills as well.

THE VIEWS OF MODERATE DEMOCRATS IN BOTH THE HOUSE AND SENATE WILL BE IMPORTANT

The views of moderate Democrats in both the House and Senate will be important. In the House, Democrats have a thin margin and can only afford to lose the votes of 3 members. In the Senate, there is exactly a 50 – 50 Democrat – Republican split. While the Vice President can break a tie vote in the Senate, this means that Senate Democrats cannot afford to lose any votes if all Republicans were to vote against a tax bill. Some moderate Senate Democrats have already indicated that they prefer less onerous changes than those proposed by President Biden. For example, some Senate Democrats would prefer a 25% corporate tax rate or to retain the FDII rules. The Democrats that are pushing for a 25% rate instead of a 28% rate, note that 25% is more in line with the global average. They don't disagree with the President's general direction, just regarding some important details.

The 28% would increase the combined federal and state average top tax rate on corporate income to 32.4%, which is the highest in the OECD, reducing US competitiveness. The combined rate can be higher or lower depending on which state or states a company operates in. For example, a lot of companies are looking to get out of California because the state tax rate is so high at 8.84%. At the current 21% federal rate the combined California corporate income tax rate is already 28%. If the federal rate goes up to 28% the combined rate in California will be close to 35%.

The elimination of FDII is a big issue. FDII was implemented in the US by the Trump administration to encourage domestic manufacturing and exports. There has always been concern about the fact that the FDII benefit could be eliminated or significantly reduced.

Internationally, the OECD has proposed significant changes in the form of well-known Pillars 1 and 2. How Pillar 1 is implemented by various countries could be far reaching

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and go beyond initial discussions concerning sales made digitally. In addition, Pillar 2's minimum tax could materially change tax planning in the international community. Already, there has been some indication that if the US were to tax GILTI at 21% that would be too high a tax rate to be compatible with Pillar 2.

All of this makes it nearly impossible to do rationale international tax planning at the current time. It is impossible to know how all of these rules ultimately will evolve.

Finally, to complicate matters further, whatever tax rules are implemented this year can be expected to change in the future. This can be a result of politics (the Trump Administration's changes lasted only four years) or further OECD action. Anyone who thought the BEPS changes of 5 years ago were final or even semi-final probably never expected the full effects of the OECD's Pillar 1 and Pillar 2. In fact, we do not yet even know what those full effects will be.

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Vik is an international tax partner and the leader of the international tax practice in Australia. Vik has 32 years' experience in the profession and has been a partner for 21 years at Deloitte and at another Big 4 accounting firm. Vik has extensive experience in advising multinational corporations and leading financial institutions on cross-border transactions, profit repatriation, acquisitions and restructures, on tax due diligence assignments and on financing issues.

Vik also has substantial practical experience in advising on the taxation aspects of private equity investment, cross border real estate investments, mergers and acquisitions, and on cross-border and domestic investment generally. As an international tax/mergers and acquisitions tax specialist, Vik has advised on numerous, significant mergers and acquisitions transactions in Australia and overseas.

Vik has also been heavily involved in cross-border capital raising, structured finance transactions and hybrid capital structures and has advised on a number of market-leading publicly-listed issues.

He is actively engaged in advising on the practical impact of the Base Erosion and Profit Shifting (BEPS) measures, and in relation to the related Australian measures including the Multinational Anti-avoidance legislation and the Diverted Profits Tax.

He is member of the Institute of Chartered Accountants of Scotland, an affiliate member of Chartered Accountants Australia and New Zealand, and a Chartered Taxation Adviser of the Taxation Institute of Australia.

Vik is a regular speaker at internal and external seminars.

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Wilbert brings over 25 years of experience working with large global companies, investors and governments on projects related to international tax, pan-European advice, cross-border reorganizations, mergers and acquisitions and strategic tax counseling.

Wilbert is since 2014 the managing partner and Chairman of KPMG Meijburg & Co in The Netherlands. He previously served as global leader of KPMG's International Tax Group and as president of the Dutch Association of Academic Tax Advisors.

He is a frequent speaker and moderator at international conferences, delivering insights on topics such as international tax, fiscal policy, European integration, globalization and economic developments. Over the last 25 years, he has also published and contributed to articles and books on business and tax.

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Prof Dr Stef van Weeghel is Global Tax Policy leader at PwC. He is also professor of international tax law at the University of Amsterdam and chair of the Board of Trustees at the International Bureau of Fiscal Documentation (IBFD).

Stef's primary focus is on tax policy, strategic tax advice and tax controversy. His experience covers cross-border transactions, structuring and tax controversy/litigation. He advises and renders second opinions to clients and their advisers on corporate income tax and tax treaty matters, is consulted by the Dutch government on a regular basis and participates in the work of the OECD. He acts as counsel and as expert witness on tax treaty interpretation (for taxpayers and for governments) before Dutch and foreign courts and in arbitration pursuant to bilateral investment treaties and in commercial arbitration.

Stef graduated from the University of Leiden in business law (1983) and tax law (1987) and obtained an LLM in Taxation from New York University (1990). In 1997, he received a doctorate in law from the University of Amsterdam (PhD thesis: Improper Use of Tax Treaties); in 2000 he was appointed a tenured professor of international tax law at that same university. He has authored and co-authored several books and many articles on Dutch and international taxation. He has lectured extensively in the Netherlands and internationally.

Before joining PwC, Stef was a partner at Linklaters and at Stibbe where his roles included membership of the executive committee, head of tax and resident partner in the New York office. He has acted as secretary and chair of the Dutch branch of the International Fiscal Association (IFA) and is immediate past chair of IFA's Permanent Scientific Committee. In 2010 he was the general reporter for Subject 1 (Tax treaties and tax avoidance: application of anti-avoidance provisions) at the IFA Congress in Rome.

In 2009/2010 Stef chaired the Study Group Tax System, a committee that advised the Dutch government on comprehensive tax reform. In 2000 he was a member of the Van Rooy-Committee that advised the Dutch government on corporate income tax reform. Prior thereto he was member of a working group at the Dutch Ministry of Finance that worked on revision of the Dutch ruling practice. He also worked on the review of administrative practices in taxation commissioned by the European Commission. On various occasions he appeared as expert before the Finance Committees of the Second and First Chamber of the Dutch Parliament and he also appeared before the TAXE-Committee and the PANA-Committee of the European Parliament.

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Lars Franck leads both the Deloitte Nordic and Deloitte Sweden Business Tax practices. With more than 25 years of Swedish and international tax experience, Lars has a broad depth of experience on complex tax issues relating to cross-border transactions, cash repatriation, financial and international tax planning. He specialises in planning, implementing and evaluating cross-border mergers & acquisitions and intra-group restructurings. In addition, Lars has a special interest and knowledge in EU related tax issues as well as extensive industry experience in the financial services industry. He is also regularly engaged by clients in connection with tax controversy. Lars works with both Swedish and foreign multinationals.

Lars earned his LLM from the University of Gothenburg in 1995, is a certified tax adviser by FAR, the institute for the accountancy profession in Sweden, and is a member of the International Fiscal Association. Before joining Deloitte Sweden in 2002, Lars was active as an attorney at the tax department of one of the leading Swedish law firms and member of the Swedish Bar Association.

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Jean-Blaise Eckert is considered as a leading lawyer in tax and private client matters in Switzerland. He is the co-head of the tax group of Lenz & Staehelin. He advises a number of multinational groups of companies as well as HNWIs. Jean-Blaise Eckert is a frequent speaker at professional conferences on tax matters. He is Secretary General of the International Fiscal Association (IFA). Jean-Blaise Eckert studied law at the University of Neuchâtel and was admitted to the Bar of Neuchâtel in 1989 and to the Bar of Geneva in 1991. He studied business administration in the US (Berkeley, Haas Business School) where he acquired an MBA in 1991. He acquired a diploma as a Certified Tax Expert in 1994. Since 2016, he is a Certified Specialist SBA in Inheritance Law.

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Jim Fuller is a partner in Fenwick's tax group. *Euromoney* named Jim nine times as one of the world's top 30 tax advisers, most recently in 2021.

He is the only U.S. tax adviser to receive a Star Performer rating (higher than first tier) in *Chambers USA* (2020), and *Chambers Global* ranks him tier one in corporate and international tax (2020). He also is one of the three "most highly regarded" U.S. tax practitioners according to *Who's Who Legal* (Law & Business Research Ltd). *Legal 500* has included Jim in its "Halls of Fame" for both Corporate Tax and International Tax. Jim also is one the U.S.'s top 30 transfer-pricing advisors, according to *Euromoney* (2019).

Fenwick is first tier in *International Tax Review*'s World Tax 2020 in Corporate Tax, Tax Controversy and International Tax, the only firm in California to be named first tier in all three categories, and one of only three firms in the US to be so named. *International Tax Review* named Fenwick & West "Tax Firm of the Year for the San Francisco Area" 10 times and "U.S. (or Americas) Tax Litigation Firm of the Year" five times. Fenwick also has received a Transfer Pricing Firm of the Year award, been named "Americas M&A Tax Firm of the Year" and received a number of *ITR*'s M&A and JV Tax Deal of the Year awards.

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Jodi J Schwartz focuses on the tax aspects of corporate transactions, including mergers and acquisitions, joint ventures, spin-offs and financial instruments. Ms Schwartz has been the principal tax lawyer on numerous domestic and cross-border transactions in a wide range of industries. She was elected partner in 1990.

Ms Schwartz received her B.S. in Economics *magna cum laude* from the University of Pennsylvania in 1981, her M.B.A. from the University of Pennsylvania (Wharton School) in 1984, her J.D. *magna cum laude* from the University of Pennsylvania Law School in 1984 and her LL.M. in taxation from the New York University Law School in 1987.

Ms Schwartz is recognized as one of the world's leading lawyers in the field of taxation, including being selected by *Chambers Global Guide to the World's Leading Lawyers, Chambers USA Guide to America's Leading Lawyers for Business, International Who's Who of Business Lawyers* and as a tax expert by *Euromoney Institutional Investor Expert Guides*. In addition, she is a member of the Executive Committee and past chair of the Tax Section of the New York State Bar Association and also is a member of the American College of Tax Counsel.

Ms Schwartz serves as an officer of both the UJA-Federation of NY and the Jewish Federations of North America, serves a member of the board of Steep Rock Association and serves on the Board of Overseers of the University of Pennsylvania Law School. Ms Schwartz lives in Manhattan with her husband, son and daughter.

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TRADEMARKS

Feature by:

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TRADEMARKS

Opportune Trademarks

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With the advent of digital advertisement, branding has evolved in numerous ways over the years. Now – more than ever, with consumers getting access to everything from global news, regular entertainment as well as social media directly in the comfort of their palms – it is only reasonable for brands to reach their target consumers digitally to keep with the times.

Increasingly, brand advertisements, initiatives and movements reach consumers through interactive marketing tools by using current events as a way of starting conversation about their brands. Over the years, certain brands have used political events, entertainment news and social movements as an opportunity to connect with their consumers as a shift from traditional marketing techniques.

An apt phrase for such usage would be 'Opportune trademarks' where brands use current events or news items by designing them as different versions of their original trademark such that it identifies with the same source. For example, the Google logo appears in different guises regularly, a phenomenon which has become known as the 'Google doodle'. As a new form of marketing a brand, it uses current events happening around the world, converts it into a piece of digital art all while keeping its logo intact.

https://icetoday.net/2018/10/google-doodle-collage/

While it has its pros and cons, social media is certainly a marketing strategy that brings in a lot of eyeballs on to the brand. With social media platforms becoming indispensable marketing channels for brand owners, using opportune trademarks on social media opens a plethora of options of advertising through photographs, videos and hashtags versions of an ad campaign. Since some years now, Amul – an Indian dairy giant which is more than 74 years old has been using giant hoardings, print media as well as social media for branding their products in different opportunistic ways. The concept of regular changes in branding and advertisements was introduced to the general public by Amul in India and it has been milking opportunities in India through their iconic Amul girl mascot. The mascot talks about current events in interestingly worded phrases which has nothing to do with the brand's product yet manages to make a story around it. Amul has over time emerged as a market leader, going beyond language barriers in India thereby creating a brand legacy that translates into brand equity. **Legally, this increase in brand equity translates into people's knowledge of the brand and often leads to affirmative and quick enforcement in the market thus protecting the brand against squatters and infringers.**

https://www.amul.com/files/hits/amul-hits-2433.jpg

TRADEMARKS

Trending videos, forwards and re-sharing posts on social media further enables consumers to share advertisements with their circle thereby leading to goodwill expansion. Endorsement on social media thus becomes more personal and comes with a consumers' brand of approval whether the 'like' or 're-sharing' is due to the quality of the content or the current value of the content. This works well for brands that may not be everyone's cup of tea – for instance, Zoom as a platform became popular during the pandemic despite existing market leaders such that one may not use Zoom every day but would still know of it.

With an aim to focus consumers' attention to the brand name, even if there is no interest in its particular product/service, such branding techniques work on making sustained efforts with a level of continuity in the minds of a consumer. In the case of Google, while the doodles are not consistent, the repeated act make it familiar to the consumer psyche thus advancing the goodwill and knowledge of the brand. On the other hand, Surf Excel, an Indian cloth detergent brand gains brand value by focussing on emotional aspects of a consumer psyche by using heartfelt videos as a medium to showcase their products. Yet another model of using opportune trademarks is followed by Durex, the sexual wellbeing brand wherein it uses witty innuendos and pictorial representation in their branding to increase awareness about an otherwise taboo topic. **From a legal standpoint, such branding techniques results in piqued curiosity of the consumer which directly results in steady flow of brand awareness. This leads to considerable goodwill of the brand thus helping in varied legal battles with the balance of convenience staying in favour of the brand.**

DurexIndia/photos/a.306244276143283/320639821370395/?type=3

In 2020, with the pandemic affecting commercial ventures around the globe, several brands came up with varying ways to invite attention to their products and services often by playing to the public sentiments, government guidelines and focussing on safe health during the pandemic. In order to keep up with the times, brands also follow an out of box, innovative thinking to ensure that the brand memory increases.

As such, apart from the pandemic brands use various global events which by their very nature convert into personalised branding techniques. Brands often use International Days such as Valentines' day, fathers' day and popular festivals in order to pique the consumers' curiosity into their brand thus focussing on the value of repetition and keep the customers guessing about what's next. The 2021 Suez Canal traffic caused by the stuck ship gained worldwide popularity and brands were quick to act on the opportunity by coming up with innovative and often wacky adverts on digital platforms.

Does it always work for the brand?

As has typically been the case, different models work for different brands and while using opportune trademarks as a way of branding can increase brand awareness multi folds, it may not always work in the brands' favour. Arguably, not all brands can rely on opportunistic marketing by using their trademarks in a fluid manner as there exists a very thin line between making it and breaking it. Oftentimes, renowned brands have to issue apologies with supposedly opportunistic branding strategies that end up backfiring on to the brand and leading to negative reviews.

For instance, in 1982, United Colours of Benetton, in an effort to focus on inclusivity despite race difference as a core brand value ended up facing immense backlash. The digital photograph in the advert showed two young girls embracing one another. Consumers questioned the brands' intention and noticed the stark imbalance right away. The girl on the left has the hair and cheeks of a cherub, of an angel. The other girl has her hair spiked up like devil horns and resists a smile. Although attempting a "uniting" effect, the ad fails in its racist shortcomings, separating colours into good and evil.

With social media gaining popularity and being extensively used by brands as a platform to interact with customers, while brands are able to capture new markets and venture out to new avenues, it also makes them more accountable to the public at large. With such accountability, controversies and questions from the public come to the forefront. **As a result, legal consequences can often be injurious to a brand especially when a branding strategy adversely hurt the sentiments of a community protected under different set of laws on a global level.**

TRADEMARKS

An apt example would be Surf Excel's attempt to bring secularism in its ad campaign for the laundry detergent during festive season of Holi which saw a Hindu girl helping her Muslim friend. The friendship ad majorly backfired as the brand was accused of promoting hate and hurting religious sentiments.

In a similar case of hurt sentiments, renowned Indian jewellery brand – Tanishq's viral video was also taken down after an apology from the brand.

Another aspect that may not work well is the lack of focus on the brand item. When the product/service that the brands wants to advertise are not in focus enough and the 'opportunity' aspect is focussed on much more than the actual product, the **'Invisible Gorilla'** experiment, a psychology selective attention test done by the Harvard University several years ago, comes into play. This experiment reveals two things: that we are missing a lot of what goes on around us, and that we have no idea that we are missing so much. When put in context of opportune trademarks used for branding, it can lead to the consumer forgetting the brand behind an ad thus leading to loss of brand essence so much so that they forget what the brand was about.

Legal implications

Strategically, using varied forms of a trademark as a fluid marketing tool can work very well for increasing the awareness of a brand amongst the public. It does however takes a considerable amount of effort, time and marketing strategies to make such branding tools take off in the market. Thus, it is often seen as a way to re-invent brands often being the difference between a 'known brand' and a 'very well-known brand' in a way that consumers' desire to follow the brand increases.

Legally, if the 'use' of the trademark departs too far from the 'registration' of the mark, then the registrations can become vulnerable to attack. However, it undeniably makes enforcement of a brand easier for legal purposes owing to the common knowledge of the brand within the general public.

Further, with brands such as McDonalds and Burger King often getting into public competitive banter through such advertising tactics can come under the backlash of tip-toing around the lines of advertising standards in different jurisdictions as per its code and conduct followed. The risk of legal ramifications by way of misrepresentation such as Patanjali for its marketing about Coronil without due permission from the health authorities, may also be of reasonable consideration to brands that are new and starting out in the market so as to avoid negative publicity.

Furthermore, legal troubles by way of disparaging advertisements is another aspect that brands would invariably like to avoid. For instance, in 2017, Horlicks Limited sued Heinz India Pvt. Ltd. after Heinz published an advertisement for its 'Complan' branded health food drink which compared one cup of Complan with two cups of a competing brand, 'Horlicks' along with a tagline which stated "From Now On, Only Complan". Horlicks claimed that the advertisement was intentionally and deliberately disparaging its health food drink product Horlicks in India.

It is thus imperative to note that protection of intellectual property is absolutely essential not just for legal reasons but for marketing reasons as well, with trademarks playing an integral role in branding now more than ever.

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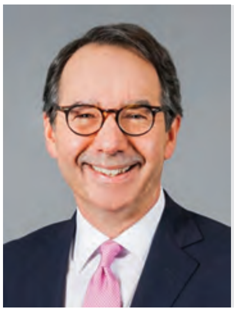

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Mark Evans, managing partner of Smart & Biggar's Toronto office, is widely recognized as one of Canada's leading trademark lawyers and litigators.

Representing many of the world's most famous brand owners and personalities, clients seek him out for his sophisticated expertise in trademark counselling, strategy, management, and enforcement/litigation services to help them strategically build and protect the value of their brands.

Mark has significant experience in all aspects of trademark law including trademark and trade-dress litigation, brand selection and clearance, trademark prosecution, oppositions and cancellations, and licensing and merchandising.

Mark has successfully litigated many commercially important and precedent-setting trademark cases, both at trial and on appeal, and he has twice been selected as "Trademark Litigator of the Year" by *Benchmark Canada*. At the forefront of the Canadian trademark profession, he was named in 2020 as Canada's Outstanding Trademark Practitioner' by *Managing IP* as well as a 'Global Elite Thought Leader in Trademarks' by *Who's Who Legal*. Mark is listed annually in *Acritas Stars*, *The Lexpert®/American Lawyer Guide to the Leading 500 Lawyers in Canada, The Best Lawyers in Canada*, *Chambers Global, Who's Who Legal: Canada, World Trademark Review 1000, The Best Lawyers in Canada*, *The Legal 500 Canada* and MIP's *IP Stars Handbook: Trademark & Copyright*. Surveys, clients and colleagues describe him as "The best bar none" and "The 'go-to' lawyer" for trademark law.

Mark has written extensively on IP law, is a frequent speaker and taught trademark law for several years at Osgoode Hall Law School. He is a registered patent and trademark agent and was called to the Ontario Bar in 1986.

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Safir Anand is the Senior Partner and Head of Trade Marks and Contractual & Commercial IP at Anand and Anand. He has been consistently recognized as one of India's top IP attorneys and has over 25 years of experience.

He is on the advisory board of International Facility Management Association, Fashion Design Council of India, Event and Entertainment Management Association as also on the Boards of companies like JHS Svendgaard Brands Limited, Brand Musiq Private Limited, Teamwork Arts Private Limited and My Rights LLP. He holds memberships in national and international organizations.

He was a member of the International Trademark Association's (INTA) Presidential Task force which examined complexities involved in brand valuation and currently serves on INTA's Commercialisation of Brands Committee (CBC) and the CBC leadership team, as well as the INTA Research Advisory council; and as Co-Chair of the global brand transactions and due diligence sub-committees.

Safir has received several awards and accolades. Below are some of his recent achievements:

- Recognized as Innovative Practitioners by Financial Times Innovative Lawyers Asia-Pacific 2020;
- Awarded the extremely prestigious "IAF-Atmanirbhar Bharat Award 2020-21";
- Awarded the Most Innovative Lawyer of the Year at BW Businessworld Global Legal Summit and India Legal Leaders Awards 2020;
- Under his leadership, the firm was awarded "Independent Luxury Law Firm of the Year 2020" by the Luxury Law Alliance.
- Enlisted in the Legal Powerlist 2020 as one of the Top Individual Lawyers
- India Business Law Journal ranked Safir among India's top 100 lawyers and featured him in the 2020 A-list

Safir frequently writes for financial dailies, international publications and is on the editorial panel of many leading journals and magazines focused on commercialization; licensing; Franchising; and Intellectual Property.

A few of his most recent published works are as follows:

- As a Member of INTA's Presidential Task Force contributed his insights on Business Environment Trends for INTA's "Brand Value Special Task Force Report"
- Asia IP Magazine sought Safir's inputs in its latest feature, CSR during Covid-19: The sincerity and brand loyalty factors.
- Article for Asia IP Magazine In its recent feature, "Law Firms in APAC pitch in to help address problems caused by Covid-19".
- "How to Avoid A 'Corona Moment' For Your Brand Name"- Businessworld

Safir's prudent insights into IP; licensing and franchising; packaging, advertising, labeling; and pharmaceutical laws; corporate governance; and Foreign Direct Investment have been widely covered by leading newspapers and business channels including Economic Times; Business Standard and CNBC.

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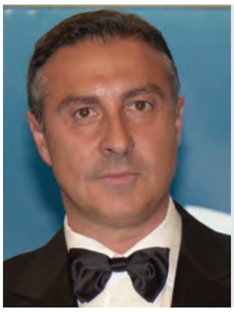

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Roberto Pisano is the founder and managing partner of Studio Legale Pisano, an Italian boutique firm which specializes in all areas of white-collar crime including corporate criminal responsibility, corruption, market abuse and false accounting, tax crimes, fraud and recovery of assets, bankruptcy crimes, environmental and health and safety crimes and money laundering. The firm provides assistance as well in the course of regulatory investigations and specializes on transnational investigations and related aspects of mutual legal assistance and extradition. The firm benefits from the expertise of specialists in criminal and international law and interacts daily with counsel of various jurisdictions to successfully represent defendants during white collar criminal and regulatory proceedings. The firm has a history of representing prominent individuals and entities in high-profile Italian criminal proceedings, and in the frame of foreign proceedings for judicial review of search and seizure orders, assets confiscation, extradition and surrender according to the European Arrest Warrant regulations.

In the course of his practice, Mr Pisano successfully represented prominent individuals and entities in high-profile Italian criminal proceeding with media impact, including: various cases of corruption involving international corporations and their top officials (including alleged corruption of foreign public officials, with multiple investigations in the US, the UK, France, etc.); various cases of extradition, including the recent FIFA investigation by the US authorities and representation of foreign States; three cases alleging international tax fraud involving the former Italian prime minister; a case involving a claim for restitution of antiquities by the Italian Ministry of Culture, in which Mr Pisano represented a prominent US museum; a case involving a major US bank in the bankruptcy of the Parmalat group; a case alleging multiple homicide of employees of a multinational company manufacturing hazardous products, in which Mr Pisano was a member of the defence team; various appeals in foreign jurisdictions (e.g., the US, Hong Kong, Switzerland, Monaco, etc.) against seizure and confiscation of assets; Italian criminal counsel for foreign multinationals conducting internal investigations. Mr Pisano also advises and represents relevant foreign governments.

Mr Pisano obtained a law degree, summa cum laude, from the state University of Milan in 1992, and a PhD from the University of Genoa in 1999. Between 1993 and 1997 he was a research associate at Bocconi University of Milan where he has subsequently worked for many years as a contract professor on Business and Tax Crimes. He is a regular speaker at conferences and seminars in Italy and abroad on the subject of white-collar crime and mutual legal assistance and extradition.

Mr Pisano was co-chair of the business crime committee of the IBA in 2007 and 2008 and vice-chair of the ECBA in 2008 and 2009. He is the author of several publications on the subject of business crime and mutual legal assistance, including: *Tax Crimes* (Cedam, 2002, co-author); *Criminal Responsibility from Asbestos* (Giuffré, 2003, contributor); *The Relations Between Domestic Law, Treaty Law and EC Law* (Egea, 1995); 'EU arrest warrant in action' (in *European Lawyer*, 2005, co-author); and *The Illegal Performance of Financial Intermediation* (Cedam, 2007).

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Stephen A Best, a former state and federal prosecutor, is Chair of Brown Rudnick's White Collar Defense & Government Investigations group. Steve's diverse practice focuses on representing clients in government investigations and enforcement proceedings, FCPA/anti-corruption compliance and defense, corporate governance, crisis management, and audit committee investigations.

Steve is regularly called upon and has developed a strong reputation for achieving successful outcomes for clients in high-profile FCPA and insider trading cases across the country. He served as lead counsel in the successful defense of Mark Cuban against the SEC's highly publicized claims of insider trading.

Steve is a skilled litigator and represents clients in both criminal and civil trials and he has been lead chair on approximately two hundred jury trials and hundreds of bench trials. A client in *Chambers & Partners* recently said that Steve is "a very aggressive litigator, he's no-nonsense and he will basically fight to the death for his clients, he's someone that you would want to hire if you wanted to fight the government." Steve's litigation acumen and skills, along with his deep understanding of government investigations have also been mentioned by clients in *Who's Who Legal: Business Crime Defence 2020*, stating, "Stephen Best is a 'bright and thorough litigator' who impresses with his 'complete and utter devotion to clients.' He is highlighted for his 'perfect judgement and analytical skill,' and his stellar track record in anti-corruption proceedings and investigations."

Over his extensive career, Steve has represented audit committees and independent special committees investigating whistleblower allegations of fraud and other corporate wrongdoing. He has a deep knowledge of complex accounting and SEC reporting issues, and anti-corruption compliance, with particular focus on government enforcement and regulatory matters, ethics, and compliance.

Before joining Brown Rudnick, Steve served as the Co-Chair of the White Collar Defense group at a large, multinational law firm based in New York and, prior to that, was a prosecutor for almost ten years serving as an Assistant United States Attorney in Washington, DC and an Assistant Commonwealth's attorney in Fairfax, Virginia.

Steve is a regular lecturer on criminal law and procedure to bar associations and state and federal law enforcement agencies. He was previously an instructor at the University of Virginia National Trial Advocacy Institute.

Steve is consistently selected by his peers for inclusion in *The Best Lawyers in America©* in the field of Criminal Defense: White Collar and recognised by *Super Lawyers* and *Chambers & Partners*, year after year, with a *Chambers & Partners* source noting that "[h]e cares more about client outcomes than any other lawyer I know – he will do anything from an effort, planning and tactical standpoint to deliver a result."

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