



Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate.

The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America
- Acting as National Counsel on a mass tort in the US

KEY CONTACTS

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- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
- Devising a risk mitigation plan for a key product
- Negotiating a large vaccine contract with a global NGO
- Counselling on a multi-jurisdictional clinical trial
- Advising on the downsizing of employees in Europe
- Supporting global business conduct and compliance functions
- Outsourcing critical R&D or IT functions
- Devising an IP strategy for a promising new therapy
- Negotiating a worldwide licensing and collaboration deal
- Protecting a blockbuster drug in patent litigation

INSIGHTS

Publications

Major developments in class action litigation for 2018 – 2019

18 June 2019

A top-level look at class action litigation for 2018-2019 and a look at trends, issues, and strategies that businesses face in the months to come.

In *Albrecht*, US Supreme Court narrows implied preemption of failure-to-warn claims, finds preemption is legal issue for judge, not jury

21 MAY 2019

The *Albrecht* decision clarifies and substantially narrows the scope of preemption under the *Wyeth v. Levine* “clear evidence” standard.

Bellwether trials in MDL proceedings – guidance for transferee judges

16 MAY 2019

Practical considerations for transferee judges establishing and implementing bellwether protocols in MDL proceedings.

Intellectual Property and Technology News (Asia Pacific) May 2019

15 MAY 2019

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide development in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Israel Group News May 2019

9 MAY 2019

ISRAEL GROUP NEWS

In this issue, our global activities, latest publications, coming events and more.

First Circuit reverses course on its first-to-file rule

9 MAY 2019

First Circuit law on the first-to-file rule is evolving in a way that could have significant consequences for False Claims Act defendants.

The cybersecurity of digital medical devices: higher technological capabilities, higher likelihood of liability

8 MAY 2019

To prepare for potential new regulatory requirements, medical device manufacturers should take this opportunity to assess their compliance with HIPAA and FDA's Draft Guidance, then complete a Risk Management Plan.

EU Policy & Regulatory Alert - EU Publishes Artificial Intelligence Ethics Guidelines

12 APR 2019

On 8 April 2019, the EU's High-Level Expert Group ("AI HLEG") on Artificial Intelligence ("AI") published the much-anticipated "Ethics Guidelines for Trustworthy AI", setting out a horizontal framework for the development and deployment of ethical and robust AI systems across the EU

Supreme Court Corner Q1 2019

11 APR 2019

In celebration of the 10th anniversary of IPT News, we note that 10 years ago, in the first quarter of 2009, Bernard L. Bilski filed his petition in the landmark *Bilski v. Kappos*, 561 U.S. 593 (2010), forever shaping the patentability of business methods.

New Acting FDA Commissioner Sharpless: 4 policy issues to watch

9 APR 2019

A look at four pressing, high-profile issues facing the new acting FDA commissioner.

Significant preemption win for Bristol-Myers-Squibb and Pfizer in Eliquis product liability multi-district litigation

27 MAR 2019

The ruling significantly strengthens preemption law in two respects.

EU Policy & Regulatory Alert: EU Mechanism for Foreign Investment Screening to Enter into Force in April

21 MAR 2019

Today, on 21 March 2019, the new Regulation establishing a framework for the screening of foreign direct investments into the Union was published in the Official Journal of the European Union (EU).

March 2019 - Key issues in brand cross-licensing in China

20 MAR 2019

In recent years, Chinese brands have been increasingly gaining global recognition, especially in the technology, ecommerce, and consumer goods sectors. In this context, an increased number of foreign businesses are considering branded partnerships with a Chinese counterparty as a way of operating in China (e.g., co-branded joint venture). In recent years, Chinese brands have been increasingly gaining global recognition, especially in the technology, ecommerce, and consumer goods sectors. In this context, an increased number of foreign businesses are considering branded partnerships with a Chinese counterparty as a way of operating in China (e.g., co-branded joint venture).

Top of Mind: Litigation

20 MAR 2019

In this issue, our coverage of 10 big topics businesses have been thinking about this quarter.

Northern District of Illinois dismisses False Claims Act case against Pfizer and Hospira: key takeaways

19 MAR 2019

The DLA Piper team expects this case will be cited frequently by qui tam defendants in future cases.

Fifth Circuit Court of Appeals affirms CMS demand for return of \$8 million from failed care management demonstration project

12 MAR 2019

In a demonstration project, the provider's rights and remedies must be expressed in the grant agreement.

PFAS: in California, regulators put cleanup levels on hold, but announce major data hunt

7 MAR 2019

This data hunt will affect thousands of facilities, drinking water systems and private drinking water well owners.

Arizona Supreme Court's *Conklin* decision calls into question viability of *Stengel* claims

26 FEB 2019

The decision creates a promising foothold for defendants seeking to dismiss state-based failure-to-warn claims involving PMA devices.

Explainability: where AI and liability meet

25 FEB 2019

Makers and users of AI face a new and interesting problem: what is the acceptable tradeoff between explanation and accuracy?

Drug pricing week in review: Ways and Means hearing, new bipartisan legislation

19 FEB 2019

Members of Congress are increasingly addressing the drug pricing issue, sometimes in a bipartisan manner.

Israel Group News

12 FEB 2019

ISRAEL GROUP NEWS

In this issue, the rise of the Data Protection Officer, plus news and coming events.

False Claims Act – Year in Review: 2018

4 FEB 2019

In this handbook, we look back on 2018 as a year of shifting enforcement policies and continuing jurisprudential uncertainty in the wake of *Escobar*.

Congress begins new session with scrutiny of drug pricing near the top of the agenda

1 FEB 2019

The cost of prescription medications and therapies has quickly emerged as one of the top priorities of lawmakers on both sides of the Capitol.

Healthcare market proves strong with investors finding returns generally outweigh the risk

30 JAN 2019

Takeaways from the JPMorgan panel, "Healthcare M&A Exits: Who's Buying, What Are They Buying, and Why?"

EU Policy & Regulatory Update - EU Adds Three Iranian Persons to EU Terrorist List

14 JAN 2019

On 8 January 2019, the Council of the European Union (EU) adopted Decision (CFSP) 2019/25 amending and updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP.

Supreme Court hears oral argument in *Fosamax*: key takeaways

8 JAN 2019

None of the justices indicated a desire to upset the *Wyeth v. Levine* framework.

2018: the year in privacy

3 JAN 2019

A landmark year in state consumer privacy legislation.

Supporting the health of your health system

3 JAN 2019

Guidance to help tend to healthcare system wellness throughout the business life cycle.

Relying on "common sense" instead of prior art in evaluating the obviousness of pharmaceutical patents

21 DEC 2018

A one-time aberration, or the start of a trend?

***Alice* in Wonderland: navigating the strange world of patenting AI**

21 DEC 2018

Like the bottle labeled DRINK ME, certain techniques can make the trip through the AI-patent rabbit hole more scalable.

Leading life science patent litigators join DLA Piper in New York

21 DEC 2018

Michael Dougherty and Tony Pezzano have joined the firm's Intellectual Property and Technology practice as patent litigation partners in New York.

DOJ moves to dismiss 11 *qui tam* lawsuits filed by professional relator concerning patient-support programs

20 DEC 2018

The DOJ acts on its commitment to seek dismissal of *qui tam* suits it views as not serving the public interest.

A watershed moment for hemp and hemp-based CBD

14 DEC 2018

The 2018 Farm Bill creates a clear regulatory structure for the commercial development of industrial hemp, as well as stronger legal protections for hemp and hemp-based derivatives, like CBD.

Federal circuit judges disagree on proper standard for evaluating patent validity under 35 U.S.C. § 103

13 DEC 2018

The *prima facie* framework has become so common that two lines of cases are developing in both district courts and the Federal Circuit: the traditional *Graham* approach and the *prima facie* – rebuttal approach.

California Proposition 65 lists two chemicals, PFOA and PFOS, found in a number of consumer products

12 DEC 2018

Given Prop 65's active and litigious enforcers, companies doing business in California that suspect their products may cause an exposure to PFOA/PFOS should consider compliance options now.

Top of mind: Litigation

10 DEC 2018

Our coverage of big compliance, enforcement and litigation issues that businesses are thinking about this quarter.

DOJ tells SCOTUS it plans to seek to dismiss a major *qui tam* action because burdensome FCA discovery would not be in the public interest

6 DEC 2018

The DOJ's filing is a significant development for FCA defendants and may portend more dismissals to come.

EU Policy & Regulatory Alert: New Regulation on Foreign Direct Investment Screening in the EU

22 NOV 2018

The European Union is moving fast towards establishing a joint regulatory and policy framework for Europeans to seize the opportunities provided by Artificial Intelligence (AI) and to reinforce Europe's competitiveness in this field.

Food and Beverage News and Trends

19 NOV 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA plans new restrictions on e-cigarettes, FDA and USDA announce details on joint regulation of cell-cultured meats, Chicago voters say yes to plastic straw ban, more.

Improving class action notice and settlement procedures – new amendments to Rule 23

16 NOV 2018

As a whole, the amendments both modernize and streamline current procedures.

Exploring ways to improve MDL management: key takeaways from the MDL Subcommittee biannual session

5 NOV 2018

The MDL Subcommittee of the Advisory Committee on Civil Rules has held a number of public hearings regarding ways to improve the management of multi-district litigation.

Israel Group News

24 OCT 2018

[ISRAEL GROUP NEWS](#)

In this issue, legal developments worldwide that affect this dynamic ecosystem.

Artificial Intelligence: from diagnostic programs to sex robots - unresolved liability questions

24 OCT 2018

Could AI develop to a point where a jury can be persuaded to blame the product, but not the manufacturer?

CFIUS pilot program mandates declarations for certain non-controlling investments in critical technologies

17 OCT 2018

The pilot program covers critical technologies in 27 industries.

USPTO issues final rule on claim construction standard

15 OCT 2018

For all petitions filed after November 13, 2018, the PTAB will apply the same *Phillips* standard used by the district courts and the ITC.

Section 301 additional tariffs on imports of Chinese products: options for high tech and manufacturing companies

3 OCT 2018

Additional tariffs of 10 percent or 25 percent have been imposed on three different lists of thousands of imports from China. Companies can request exclusion from these tariffs.

Food and Beverage News and Trends

1 OCT 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, the FDA ponders releasing retailer names during food recalls and takes major steps against e-cigarettes.

Supreme Court Corner Q3 2018

27 SEP 2018

The court rules on recovery of lost foreign profits and ponders patentability issues in an invention's sale to a third party that is obligated to keep the invention confidential.

Intellectual Property and Technology News (Asia Pacific) September 2018

27 SEP 2018

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our annual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Are you a smaller reporting company? Why you should care

19 SEP 2018

The SEC has amended its definition of the smaller reporting company. Are you eligible to take advantage of these changes?

California amends Consumer Privacy Act to clarify exemptions and fix some technical deficiencies, but significant work remains

10 SEP 2018

SB 1121 clarifies only a handful of the dozens of drafting ambiguities and drafting errors in the CCPA.

Food and Beverage News and Trends

7 SEP 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA chief Gottlieb speaks out against kratom, plus kids' meals, milk, and meat in the news

Top of Mind: Litigation

6 SEP 2018

Here is a look at big topics that businesses have been thinking about this quarter, and how DLA Piper has been covering those stories.

Food and Beverage News and Trends

20 AUG 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA to provide more info on food packaging terms, plus raw milk, lab meat, GMOs, and a cattle feedlot becomes a suspect.

CRISPR technology and evolving scientific data: how biotechnology and pharmaceutical companies can mitigate potential product safety risks

16 AUG 2018

How may product safety issues impact those who develop, license or evaluate the potential of innovative gene therapies like CRISPR?

Food and Beverage News and Trends

27 JUL 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA says it will begin to take action against nondairy milk products.

The tide turns: If your company is doing business in the US, it may soon be required to collect state sales taxes

24 JUL 2018

Companies selling online products and services to customers in US states may soon be required to register, collect and remit taxes in those states.

PFOA/PFOS: California nods to New Jersey and moves closer to strict MCLs

23 JUL 2018

Indications that OEHHA may be well on the way to establishing public health goals for PFOA and PFOS.

eSignature and ePayment News and Trends

23 JUL 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

This regular publication from DLA Piper aims to help companies identify significant news and legal developments impacting digital transactions.

Ready or not? Product liability and regulatory implications for digital health products

2 JUL 2018

As laws and regulations catch up with digital health innovation, there remains an open question: how will traditional product liability case law apply?

Supreme Court agrees to hear *Fosamax*

29 JUN 2018

The grant of certiorari comes on the heels of Justice Anthony Kennedy's retirement announcement.

eSignature and ePayment News and Trends

29 JUN 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

In this issue, is your website ADA compliant? Plus news on federal and state law, federal and state regulatory activities, fresh judicial precedent and more.

Is your website ADA compliant? A brief look at the current legal status

29 JUN 2018

Websites too face regulatory issues around compliance with the Americans with Disabilities Act and other rules involving accessibility and accommodation.

***In re Fosamax*: Solicitor General recommends US Supreme Court review impossibility-preemption defense**

5 JUN 2018

The Solicitor General's recommendation substantially increases the chances that the Court will grant certiorari.

PFAS: Pruitt declares EPA will "take action" and sets four "critical steps" in motion

23 MAY 2018

Pruitt says the EPA intends to "take action" on what he calls four "critical steps" to address the growing concern over PFAS.

CPSC enforcement of Poison Prevention Packaging standards: a recent action – the first of many?

26 APR 2018

In addition to potential civil penalties, PPPA violations could also lead to costly recalls.

Proposition 65's glyphosate listing survives challenge despite numerous dissenting studies

26 APR 2018

Glyphosate's Prop 65 listing, and the World Health Organization's research, have become increasingly controversial.

ONC guide for accessing and using medical records breaks no new ground, instead doubles down on old processes

16 APR 2018

The ONC Guide to Getting and Using your Health Records educates patients on their rights of access and provides detailed instructions on how patients should request their records.

California court's narrow Prop 65 coffee ruling should not be misinterpreted

9 APR 2018

A careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

Section 301 trade action against Chinese products: time for quick action

4 APR 2018

Companies wishing to seek removal of a product from the final list have the opportunity to present their views, but less than two months remain before the window completely closes.

Massachusetts Supreme Court recognizes brand-name pharmaceutical makers owe duty to consumers of generic medications

19 MAR 2018

In an opinion with significant implications, the Massachusetts Supreme Court has recognized a narrow window of innovator liability against manufacturers of brand-name pharmaceuticals.

Regulation of medical devices - what is changing?

13 MAR 2018

After four years of deliberations, the new Medical Devices Regulation finally came into effect on 25 May 2017. This marks the commencement of a three-year transitional period for manufacturers of medical devices to update their policies and processes in order to distribute products in the EU market.

New glyphosate decision forces Prop 65 to reckon with federally accepted science

7 MAR 2018

This outcome will likely put wind in the sails of industry groups and individual companies challenging the science behind other Prop 65 listings.

Healthcare investment charges ahead in spite of lingering regulatory uncertainty

30 JAN 2018

Takeaways from our JP Morgan panel, "Healthcare M&A Exits, Who's Buying, What Are They Buying, and Why?"

2018 outlook for drugs and medical devices in China: regulatory reform fueled by innovation

18 JAN 2018

The year 2017 ended with a central government directive to reform the regulatory approval system for drugs and medical devices and a subsequent flood of CFDA changes and proposed changes to the system, and we should see further regulatory reform in 2018 as the Chinese government continues to encourage domestic innovation in this sector.

Supporting the health of your health system - our most popular guidance

2 JAN 2018

[HEALTH SYSTEMS ALERT SERIES](#)

Treat the health of your entire healthcare system. DLA Piper's lawyers provide guidance to help you tend to your system's wellness throughout the business life cycle.

Glyphosate not likely to be carcinogenic to humans, EPA says

22 DEC 2017

The EPA's decision will likely provide strong evidence to support efforts to challenge glyphosate's listing as a carcinogen.

California Supreme Court endorses innovator liability against manufacturers of brand-name pharmaceuticals

22 DEC 2017

California Supreme Court: brand-name manufacturers owe a duty of reasonable care to ensure that product labeling includes adequate warnings.

Intellectual Property and Technology News (Asia Pacific) December 2017

7 DEC 2017

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Product liability implications in the digital health industry

4 DEC 2017

As digital health products become commercialized and their use becomes more mainstream, companies face a higher likelihood of product liability litigation and regulatory scrutiny.

Ontario introduces bill to promote transparency in healthcare industry

4 OCT 2017

On September 27, 2017, Ontario introduced proposed legislation that aims to add transparency to certain marketing practices employed by the medical industry, in particular the provision of payments such as meals, hospitality, and financial grants from the medical industry to healthcare professionals.

Trade secrets are more important, and trade secret litigation is more common

29 SEP 2017

What do you need to be considering to protect your company in this environment?

FDA announces major regulatory overhaul initiative

8 SEP 2017

This initiative will be a massive undertaking given the breadth of FDA's regulatory authority over a vast array of products and industries.

Coming soon from FDA? Streamlined safety information in prescription drug television ads

7 SEP 2017

If FDA proceeds, TV may feature even more drug ads, and the advice to "talk to your doctor" will become even more important.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Supreme Court Corner: Q1 2016

29 MAR 2016

Two cases to watch.

Are IPRs impacting the pharmaceutical industry?

9 JUN 2015

Choosing between IPRs and district court litigation

Supreme Court Corner - Q1 2015

24 MAR 2015

Recent decisions and cases to watch

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014

Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

Supreme Court Corner - Q3 2014

10 SEP 2014

A review of cases relevant to IPT decided or argued before the Court during Q3

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

New guidance for lawyers advising clients on human rights risks

19 JUL 2017

On 17 July 2017, the International Bar Association Legal Policy and Research Unit (LPRU) released a *Handbook for Lawyers on Business and Human Rights* to provide guidance for business lawyers and their corporate clients on how to address human rights risks in corporate and commercial transactions.

Amendments to Canada's patent linkage provisions relating to generic and biosimilar market approval

17 JUL 2017

Long-awaited amendments to Canada's patent linkage provisions relating to generic and biosimilar market approval have been published.

A broken promise – The Supreme Court of Canada reverses Canada's "promise of the patent" doctrine

4 JUL 2017

The Supreme Court of Canada has dealt a significant blow to the "promise of the patent" doctrine—a controversial judge-made approach to the question of patent utility in Canada that has been heavily criticized over the past decade.

US Supreme Court strikes death blow against forum shopping in mass actions by limiting personal jurisdiction

21 JUN 2017

The Court's opinion continues the trend of limiting personal jurisdiction.

DOJ dismisses last of the drug trafficking charges against FedEx: two key takeaways

5 JUL 2016

A sudden about-face from the DOJ.

Ten tips for generating a life sciences brand name

19 NOV 2015

The proliferation of brands, combined with the PR and financial consequences of a potential rebrand in the event of infringement, has made selecting a trademark trickier than ever. Christina Martini and Virginia Wolk Marino report.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

HEALTH SYSTEMS ALERT SERIES

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

Revenue pressure climbs for skilled nursing facilities – what does this mean for healthcare REITs?

3 JUN 2015

Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

SEC begins Dodd-Frank rulemaking with new open process

28 Jul 2010

EVENTS

Upcoming

TopCo liability panel

25 JUN 2019

London

Previous

BIO's 2019 International Convention

3 - 6 JUN 2019

Philadelphia

Medical Device Happy Hour

15 MAY 2019
San Diego

DLA Piper luncheon during the 37th annual JP Morgan Healthcare Conference

8 JAN 2019

NJIPLA's 32nd Annual Pharmaceutical/Chemical Patent Practice Update

7 NOV 2018

The More Things Change: Improvement Patents, Drug Modifications, and the FDA

19 OCT 2018

Promotional Compliance and Liability Risks Beyond FDA

17 OCT 2018

Clarifying the Clinical Trial Process for Drugs and Biologics

27 SEP 2018
Boston

New frontiers on the abuse of dominance

18 JUN 2018
Webinar

Enforcement and compliance trends in today's life sciences environment

26 APR 2018
Webinar

NEWS

DLA Piper represents Locana in US\$55 million Series A financing

23 MAY 2019

DLA Piper represented Locana, Inc. in a US\$55 million round of Series A financing led by ARCH Venture Partners, with participation from existing investors Temasek and Lightstone Ventures.

DLA Piper announces launch of Artificial Intelligence practice

14 MAY 2019

DLA Piper announced today the launch of its Artificial Intelligence practice, which will focus on assisting companies as they navigate the legal landscape of emerging and disruptive technologies, while helping them understand the legal and compliance risks arising from the creation and deployment of AI systems.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA's* 2019 guide.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA's* 2019 guide.

Carl Wessel joins DLA Piper's Litigation practice in Washington, DC

22 APR 2019

DLA Piper announced today that Carl Wessel has joined the firm's Litigation practice as a partner in Washington, DC.

K. Randolph Peak joins DLA Piper's Healthcare sector and Corporate practice in Dallas

17 APR 2019

DLA Piper announced today that K. Randolph Peak has joined the firm's Healthcare sector and Corporate practice as a partner in Dallas.

DLA Piper advises Vivo Capital as lead investor in Series D financing for MacuLogix

8 APR 2019

DLA Piper represented Vivo Capital, LLC as the lead investor in US\$38.7 million Series D financing for MacuLogix, Inc., a Harrisburg, Pennsylvania-based company providing eye care professionals with tools to diagnose and treat patients with age-related macular degeneration (AMD).

DLA Piper announces partnership promotions for 2019

1 APR 2019

DLA Piper is proud to announce that 77 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2019 in the United States and May 1, 2019 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 43 different offices throughout 20 countries.

Patrick Anding joins DLA Piper's Corporate practice in Los Angeles and San Diego

20 MAR 2019

DLA Piper announced today that Patrick Anding has joined the firm's Corporate practice as a partner in Los Angeles and San Diego.

DLA Piper enhances cross-border tax capability with new partner hire in Dublin

26 FEB 2019

DLA Piper today announces the appointment of Maura Dineen as a Tax partner in the firm's newly opened Dublin office. This is the fifth partner hire for DLA Piper in Dublin in a month, following the announcements in January of Conor Houlihan (Finance & Projects), Éanna Mellett (Corporate), Mark Rasdale (Intellectual Property & Technology) and Ciara McLoughlin (Employment).

Michael Furrow and Brian O'Reilly join DLA Piper's Intellectual Property and Technology practice in New York

20 FEB 2019

DLA Piper announced today that Michael Enzo Furrow, Ph.D., and Brian David O'Reilly have joined the firm's Intellectual Property and Technology practice as partners in New York.

DLA Piper recognized as a leading private equity, venture capital and M&A firm in *PitchBook's* league tables

19 FEB 2019

For the second consecutive year, DLA Piper was the only firm to rank as one of the top five most active law firms for private equity, venture capital and M&A deal volume in *PitchBook's* 2018 global league tables report.

DLA Piper advises Qualcomm in sale of Qualcomm Life to Francisco Partners

12 FEB 2019

DLA Piper represented Qualcomm in the sale of Qualcomm Life, Inc., a wholly owned subsidiary of Qualcomm Incorporated that offers end-to-end medical device connectivity, to private equity firm Francisco Partners.

DLA Piper advises SoftBank Vision Fund in investment in Zymergen

15 DEC 2018

The DLA Piper team representing SoftBank Vision Fund was led by partner Louis Lehot and included partner Craig Lang and associate Evan Youngstrom (all of Silicon Valley).

Christine Walchuk joins DLA Piper's Corporate practice in Northern Virginia

19 NOV 2018

DLA Piper announced today that Christine Walchuk has joined the firm's Corporate practice as a partner in Northern Virginia.

DLA Piper advises Gener8 in its acquisition by Sverica Capital Management

21 SEP 2018

DLA Piper represented Gener8, LLC, a designer and manufacturer of life science instrumentations and medical devices headquartered in Sunnyvale, California, in its acquisition by private equity firm Sverica Capital Management LP.

Daniel Tobey joins DLA Piper's Litigation practice in Dallas

19 SEP 2018

DLA Piper announced today that Daniel Tobey has joined the firm's Litigation practice as a partner in Dallas.

DLA Piper adds Michael Dougherty and Tony Pezzano to Intellectual Property and Technology practice in New York

19 SEP 2018

DLA Piper announced today that Michael Dougherty and Tony Pezzano have joined the firm's Intellectual Property and Technology practice as partners in New York.

DLA Piper advises BTG in acquisition of Novate Medical

10 SEP 2018

DLA Piper represented BTG plc, a global specialist healthcare company, in its acquisition of Novate Medical Ltd.

DLA Piper advises Maryland Proton Treatment Center in US\$277.4 million tax-exempt municipal bond financing

6 SEP 2018

DLA Piper represented Maryland Proton Therapy Center (MPTC) in its US\$277.4 million tax-exempt municipal bond financing.

Tami Howie to join DLA Piper's Corporate practice in Washington, DC

15 AUG 2018

DLA Piper announced today that Tami Howie will join the firm's Corporate practice as a partner in Washington, DC.

DLA Piper advises Liquidia Technologies in its US\$50 million IPO

3 AUG 2018

DLA Piper advised Liquidia Technologies, Inc. in its US\$50 million initial public offering.

DLA Piper advises Olive in US\$32.8 million Series D financing

31 JUL 2018

DLA Piper represented Olive, a technology company applying artificial intelligence to healthcare administration, in its US\$32.8 million Series D financing.

DLA Piper recognized again as a Top Global Outsourcing Advisor

28 JUN 2018

DLA Piper is pleased to announce that the firm has been selected for the 2018 World's Best Outsourcing Advisors list by the International Association of Outsourcing Professionals (IAOP).

DLA Piper advises Immunomedics in US\$276 million follow-on public offering

18 JUN 2018

DLA Piper advised Immunomedics, Inc. in its follow-on public offering of common stock valued at approximately US\$276 million.

DLA Piper advises ADMA Biologics' follow-on public offering

12 JUN 2018

DLA Piper advised ADMA Biologics, Inc. (Nasdaq: ADMA) in its underwritten follow-on public offering of common stock valued at approximately US\$40 million.

DLA Piper advises Insilico Medicine in Series A financing

12 JUN 2018

DLA Piper represented Insilico Medicine Inc. in the completion of Series A financing led by WuXi AppTec's Corporate Venture Fund.

DLA Piper named International Law Firm of the Year in Ukraine for fifth year running at The Legal Awards 2018

24 MAY 2018

DLA Piper has been named International Law Firm of the Year in Ukraine at the 2018 Legal Awards, held by Yuridicheskaya Practika Publishing House. This is the fifth time the office has won the award.

DLA Piper announces partnership promotions for 2018

3 APR 2018

DLA Piper is proud to announce that 62 lawyers have been promoted to its partnership. The promotions are effective as of 1 April 2018 in the United States and 1 May 2018 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 42 different offices throughout 20 countries.

Businesses still not fully aware of Data Protection issues

31 JAN 2018

DLA Piper has released its second Data Privacy Snapshot report, finding that once again, company global privacy programs have gaps in meeting increasingly demanding global privacy principles. Significantly, it appears that many companies are falling short of data protection obligations under the General Data Protection Regulation (GDPR), which will start to apply from 25 May 2018.

Stephen Matthews joins DLA Piper's Litigation practice in New Jersey

17 JAN 2018

DLA Piper announced today that Stephen Matthews has joined the firm's Litigation practice as a partner in the Short Hills, New Jersey, office.

DLA Piper advises Immunomedics on royalty funding and stock purchase agreements with Royalty Pharma which raised an aggregate of US\$250 million

9 JAN 2018

DLA Piper represented Immunomedics, Inc., in the sale of tiered, sales-based royalty rights on global net sales of sacituzumab govitecan (IMMU-132) to Royalty Pharma for US\$175 million. Royalty Pharma has also purchased US\$75 million in common stock of Immunomedics, at US\$17.15 per share.

DLA Piper represents Vivo Capital in equity financing of Harmony Biosciences, LLC

13 OCT 2017

DLA Piper represented healthcare-focused investment firm Vivo Capital as the lead investor in a US\$270 million equity financing of Harmony Biosciences, LLC, a biopharmaceutical company that develops orphan and rare disease therapies.

DLA Piper successfully represents NuVasive in shareholder derivative suit victory

4 OCT 2017

DLA Piper successfully defended NuVasive, its board of directors and three officers of the company in a shareholder derivative suit.

Lisa Haile and Gina Durham named *Daily Journal* Top Intellectual Property Lawyers in California

16 AUG 2017

DLA Piper is pleased to announce that the *Daily Journal* has named Lisa Haile and Gina Durham to its 2017 list of Top Intellectual Property Lawyers in California. The award recognizes attorneys who successfully argued a novel theory of law, saved a client's business by winning a case or protected a client's portfolio.

DLA Piper recognized for strong client relationships in *BTI Industry Power Rankings*

18 JUL 2017

DLA Piper has been recognized for the strength of its client relationships across a broad spectrum of industries in BTI Consulting Group's 2017 *BTI Industry Power Rankings*.



Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate.

The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational

risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America
- Acting as National Counsel on a mass tort in the US
- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
- Devising a risk mitigation plan for a key product
- Negotiating a large vaccine contract with a global NGO
- Counselling on a multi-jurisdictional clinical trial
- Advising on the downsizing of employees in Europe
- Supporting global business conduct and compliance functions
- Outsourcing critical R&D or IT functions
- Devising an IP strategy for a promising new therapy
- Negotiating a worldwide licensing and collaboration deal
- Protecting a blockbuster drug in patent litigation

INSIGHTS

Publications

Major developments in class action litigation for 2018 – 2019

18 June 2019

A top-level look at class action litigation for 2018-2019 and a look at trends, issues, and strategies that businesses face in the months to come.

In *Albrecht*, US Supreme Court narrows implied preemption of failure-to-warn claims, finds preemption is legal issue for judge, not jury

21 MAY 2019

The *Albrecht* decision clarifies and substantially narrows the scope of preemption under the *Wyeth v. Levine* “clear evidence” standard.

Bellwether trials in MDL proceedings – guidance for transferee judges

16 MAY 2019

Practical considerations for transferee judges establishing and implementing bellwether protocols in MDL proceedings.

Intellectual Property and Technology News (Asia Pacific) May 2019

15 MAY 2019

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide development in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Israel Group News May 2019

9 MAY 2019

[ISRAEL GROUP NEWS](#)

In this issue, our global activities, latest publications, coming events and more.

First Circuit reverses course on its first-to-file rule

9 MAY 2019

First Circuit law on the first-to-file rule is evolving in a way that could have significant consequences for False Claims Act defendants.

The cybersecurity of digital medical devices: higher technological capabilities, higher likelihood of liability

8 MAY 2019

To prepare for potential new regulatory requirements, medical device manufacturers should take this opportunity to assess their compliance with HIPAA and FDA's Draft Guidance, then complete a Risk Management Plan.

EU Policy & Regulatory Alert - EU Publishes Artificial Intelligence Ethics Guidelines

12 APR 2019

On 8 April 2019, the EU's High-Level Expert Group ("AI HLEG") on Artificial Intelligence ("AI") published the much-anticipated "Ethics Guidelines for Trustworthy AI", setting out a horizontal framework for the development and deployment of ethical and robust AI systems across the EU

Supreme Court Corner Q1 2019

11 APR 2019

In celebration of the 10th anniversary of IPT News, we note that 10 years ago, in the first quarter of 2009, Bernard L. Bilski filed his petition in the landmark *Bilski v. Kappos*, 561 U.S. 593 (2010), forever shaping the patentability of business methods.

New Acting FDA Commissioner Sharpless: 4 policy issues to watch

9 APR 2019

A look at four pressing, high-profile issues facing the new acting FDA commissioner.

Significant preemption win for Bristol-Myers-Squibb and Pfizer in Eliquis product liability multi-district litigation

27 MAR 2019

The ruling significantly strengthens preemption law in two respects.

EU Policy & Regulatory Alert: EU Mechanism for Foreign Investment Screening to Enter into Force in April

21 MAR 2019

Today, on 21 March 2019, the new Regulation establishing a framework for the screening of foreign direct investments into the Union was published in the Official Journal of the European Union (EU).

March 2019 - Key issues in brand cross-licensing in China

20 MAR 2019

In recent years, Chinese brands have been increasingly gaining global recognition, especially in the technology, ecommerce, and consumer goods sectors. In this context, an increased number of foreign businesses are considering branded partnerships with a Chinese counterparty as a way of operating in China (e.g., co-branded joint venture). In recent years, Chinese brands have been increasingly gaining global recognition, especially in the technology, ecommerce, and consumer goods sectors. In this context, an increased number of foreign businesses are considering branded partnerships with a Chinese counterparty as a way of operating in China (e.g., co-branded joint venture).

Top of Mind: Litigation

20 MAR 2019

In this issue, our coverage of 10 big topics businesses have been thinking about this quarter.

Northern District of Illinois dismisses False Claims Act case against Pfizer and Hospira: key takeaways

19 MAR 2019

The DLA Piper team expects this case will be cited frequently by qui tam defendants in future cases.

Fifth Circuit Court of Appeals affirms CMS demand for return of \$8 million from failed care management demonstration project

12 MAR 2019

In a demonstration project, the provider's rights and remedies must be expressed in the grant agreement.

PFAS: in California, regulators put cleanup levels on hold, but announce major data hunt

7 MAR 2019

This data hunt will affect thousands of facilities, drinking water systems and private drinking water well owners.

Arizona Supreme Court's *Conklin* decision calls into question viability of *Stengel* claims

26 FEB 2019

The decision creates a promising foothold for defendants seeking to dismiss state-based failure-to-warn claims involving PMA devices.

Explainability: where AI and liability meet

25 FEB 2019

Makers and users of AI face a new and interesting problem: what is the acceptable tradeoff between explanation and accuracy?

Drug pricing week in review: Ways and Means hearing, new bipartisan legislation

19 FEB 2019

Members of Congress are increasingly addressing the drug pricing issue, sometimes in a bipartisan manner.

Israel Group News

12 FEB 2019

[ISRAEL GROUP NEWS](#)

In this issue, the rise of the Data Protection Officer, plus news and coming events.

False Claims Act – Year in Review: 2018

4 FEB 2019

In this handbook, we look back on 2018 as a year of shifting enforcement policies and continuing jurisprudential uncertainty in the wake of *Escobar*.

Congress begins new session with scrutiny of drug pricing near the top of the agenda

1 FEB 2019

The cost of prescription medications and therapies has quickly emerged as one of the top priorities of lawmakers on both sides of the Capitol.

Healthcare market proves strong with investors finding returns generally outweigh the risk

30 JAN 2019

Takeaways from the JPMorgan panel, "Healthcare M&A Exits: Who's Buying, What Are They Buying, and Why?"

EU Policy & Regulatory Update - EU Adds Three Iranian Persons to EU Terrorist List

14 JAN 2019

On 8 January 2019, the Council of the European Union (EU) adopted Decision (CFSP) 2019/25 amending and updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP.

Supreme Court hears oral argument in *Fosamax*: key takeaways

8 JAN 2019

None of the justices indicated a desire to upset the *Wyeth v. Levine* framework.

2018: the year in privacy

3 JAN 2019

A landmark year in state consumer privacy legislation.

Supporting the health of your health system

3 JAN 2019

Guidance to help tend to healthcare system wellness throughout the business life cycle.

Relying on "common sense" instead of prior art in evaluating the obviousness of pharmaceutical patents

21 DEC 2018

A one-time aberration, or the start of a trend?

***Alice* in Wonderland: navigating the strange world of patenting AI**

21 DEC 2018

Like the bottle labeled DRINK ME, certain techniques can make the trip through the AI-patent rabbit hole more scalable.

Leading life science patent litigators join DLA Piper in New York

21 DEC 2018

Michael Dougherty and Tony Pezzano have joined the firm's Intellectual Property and Technology practice as patent litigation partners in New York.

DOJ moves to dismiss 11 qui tam lawsuits filed by professional relator concerning patient-support programs

20 DEC 2018

The DOJ acts on its commitment to seek dismissal of *qui tam* suits it views as not serving the public interest.

A watershed moment for hemp and hemp-based CBD

14 DEC 2018

The 2018 Farm Bill creates a clear regulatory structure for the commercial development of industrial hemp, as well as stronger legal protections for hemp and hemp-based derivatives, like CBD.

Federal circuit judges disagree on proper standard for evaluating patent validity under 35 U.S.C. § 103

13 DEC 2018

The *prima facie* framework has become so common that two lines of cases are developing in both district courts and the Federal Circuit: the traditional *Graham* approach and the *prima facie* – rebuttal approach.

California Proposition 65 lists two chemicals, PFOA and PFOS, found in a number of consumer products

12 DEC 2018

Given Prop 65's active and litigious enforcers, companies doing business in California that suspect their products may cause an exposure to PFOA/PFOS should consider compliance options now.

Top of mind: Litigation

10 DEC 2018

Our coverage of big compliance, enforcement and litigation issues that businesses are thinking about this quarter.

DOJ tells SCOTUS it plans to seek to dismiss a major *qui tam* action because burdensome FCA discovery would not be in the public interest

6 DEC 2018

The DOJ's filing is a significant development for FCA defendants and may portend more dismissals to come.

EU Policy & Regulatory Alert: New Regulation on Foreign Direct Investment Screening in the EU

22 NOV 2018

The European Union is moving fast towards establishing a joint regulatory and policy framework for Europeans to seize the opportunities provided by Artificial Intelligence (AI) and to reinforce Europe's competitiveness in this field.

Food and Beverage News and Trends

19 NOV 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA plans new restrictions on e-cigarettes, FDA and USDA announce details on joint regulation of cell-cultured meats, Chicago voters say yes to plastic straw ban, more.

Improving class action notice and settlement procedures – new amendments to Rule 23

16 NOV 2018

As a whole, the amendments both modernize and streamline current procedures.

Exploring ways to improve MDL management: key takeaways from the MDL Subcommittee biannual session

5 NOV 2018

The MDL Subcommittee of the Advisory Committee on Civil Rules has held a number of public hearings regarding ways to improve the management of multi-district litigation.

Israel Group News

24 OCT 2018

[ISRAEL GROUP NEWS](#)

In this issue, legal developments worldwide that affect this dynamic ecosystem.

Artificial Intelligence: from diagnostic programs to sex robots - unresolved liability questions

24 OCT 2018

Could AI develop to a point where a jury can be persuaded to blame the product, but not the manufacturer?

CFIUS pilot program mandates declarations for certain non-controlling investments in critical technologies

17 OCT 2018

The pilot program covers critical technologies in 27 industries.

USPTO issues final rule on claim construction standard

15 OCT 2018

For all petitions filed after November 13, 2018, the PTAB will apply the same *Phillips* standard used by the district courts and the ITC.

Section 301 additional tariffs on imports of Chinese products: options for high tech and manufacturing companies

3 OCT 2018

Additional tariffs of 10 percent or 25 percent have been imposed on three different lists of thousands of imports from China. Companies can request exclusion from these tariffs.

Food and Beverage News and Trends

1 OCT 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, the FDA ponders releasing retailer names during food recalls and takes major steps against e-cigarettes.

Supreme Court Corner Q3 2018

27 SEP 2018

The court rules on recovery of lost foreign profits and ponders patentability issues in an invention's sale to a third party that is obligated to keep the invention confidential.

Intellectual Property and Technology News (Asia Pacific) September 2018

27 SEP 2018

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our annual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Are you a smaller reporting company? Why you should care

19 SEP 2018

The SEC has amended its definition of the smaller reporting company. Are you eligible to take advantage of these changes?

California amends Consumer Privacy Act to clarify exemptions and fix some technical deficiencies, but significant work remains

10 SEP 2018

SB 1121 clarifies only a handful of the dozens of drafting ambiguities and drafting errors in the CCPA.

Food and Beverage News and Trends

7 SEP 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA chief Gottlieb speaks out against kratom, plus kids' meals, milk, and meat in the news

Top of Mind: Litigation

6 SEP 2018

Here is a look at big topics that businesses have been thinking about this quarter, and how DLA Piper has been covering those stories.

Food and Beverage News and Trends

20 AUG 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA to provide more info on food packaging terms, plus raw milk, lab meat, GMOs, and a cattle feedlot becomes a suspect.

CRISPR technology and evolving scientific data: how biotechnology and pharmaceutical companies can mitigate potential product safety risks

16 AUG 2018

How may product safety issues impact those who develop, license or evaluate the potential of innovative gene therapies like CRISPR?

Food and Beverage News and Trends

27 JUL 2018

[FOOD AND BEVERAGE NEWS AND TRENDS SERIES](#)

In this issue, FDA says it will begin to take action against nondairy milk products.

The tide turns: If your company is doing business in the US, it may soon be required to collect state sales taxes

24 JUL 2018

Companies selling online products and services to customers in US states may soon be required to register, collect and remit taxes in those states.

PFOA/PFOS: California nods to New Jersey and moves closer to strict MCLs

23 JUL 2018

Indications that OEHHA may be well on the way to establishing public health goals for PFOA and PFOS.

eSignature and ePayment News and Trends

23 JUL 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

This regular publication from DLA Piper aims to help companies identify significant news and legal developments impacting digital transactions.

Ready or not? Product liability and regulatory implications for digital health products

2 JUL 2018

As laws and regulations catch up with digital health innovation, there remains an open question: how will traditional product liability case law apply?

Supreme Court agrees to hear *Fosamax*

29 JUN 2018

The grant of certiorari comes on the heels of Justice Anthony Kennedy's retirement announcement.

eSignature and ePayment News and Trends

29 JUN 2018

[ESIGNATURE AND EPAYMENT NEWS AND TRENDS](#)

In this issue, is your website ADA compliant? Plus news on federal and state law, federal and state regulatory activities, fresh judicial precedent and more.

Is your website ADA compliant? A brief look at the current legal status

29 JUN 2018

Websites too face regulatory issues around compliance with the Americans with Disabilities Act and other rules involving accessibility and accommodation.

***In re Fosamax*: Solicitor General recommends US Supreme Court review impossibility-preemption defense**

5 JUN 2018

The Solicitor General's recommendation substantially increases the chances that the Court will grant certiorari.

PFAS: Pruitt declares EPA will "take action" and sets four "critical steps" in motion

23 MAY 2018

Pruitt says the EPA intends to "take action" on what he calls four "critical steps" to address the growing concern over PFAS.

CPSC enforcement of Poison Prevention Packaging standards: a recent action – the first of many?

26 APR 2018

In addition to potential civil penalties, PPPA violations could also lead to costly recalls.

Proposition 65's glyphosate listing survives challenge despite numerous dissenting studies

26 APR 2018

Glyphosate's Prop 65 listing, and the World Health Organization's research, have become increasingly controversial.

ONC guide for accessing and using medical records breaks no new ground, instead doubles down on old processes

16 APR 2018

The ONC Guide to Getting and Using your Health Records educates patients on their rights of access and provides detailed instructions on how patients should request their records.

California court's narrow Prop 65 coffee ruling should not be misinterpreted

9 APR 2018

A careful understanding of the narrow basis of the ruling is important for coffee consumers and for all manner of product-based companies doing business in California.

Section 301 trade action against Chinese products: time for quick action

4 APR 2018

Companies wishing to seek removal of a product from the final list have the opportunity to present their views, but less than two months remain before the window completely closes.

Massachusetts Supreme Court recognizes brand-name pharmaceutical makers owe duty to consumers of generic medications

19 MAR 2018

In an opinion with significant implications, the Massachusetts Supreme Court has recognized a narrow window of innovator liability against manufacturers of brand-name pharmaceuticals.

Regulation of medical devices - what is changing?

13 MAR 2018

After four years of deliberations, the new Medical Devices Regulation finally came into effect on 25 May 2017. This marks the commencement of a three-year transitional period for manufacturers of medical devices to update their policies and processes in order to distribute products in the EU market.

New glyphosate decision forces Prop 65 to reckon with federally accepted science

7 MAR 2018

This outcome will likely put wind in the sails of industry groups and individual companies challenging the science behind other Prop 65 listings.

Healthcare investment charges ahead in spite of lingering regulatory uncertainty

30 JAN 2018

Takeaways from our JP Morgan panel, "Healthcare M&A Exits, Who's Buying, What Are They Buying, and Why?"

2018 outlook for drugs and medical devices in China: regulatory reform fueled by innovation

18 JAN 2018

The year 2017 ended with a central government directive to reform the regulatory approval system for drugs and medical devices and a subsequent flood of CFDA changes and proposed changes to the system, and we should see further regulatory reform in 2018 as the Chinese government continues to encourage domestic innovation in this sector.

Supporting the health of your health system - our most popular guidance

2 JAN 2018

HEALTH SYSTEMS ALERT SERIES

Treat the health of your entire healthcare system. DLA Piper's lawyers provide guidance to help you tend to your system's wellness throughout the business life cycle.

Glyphosate not likely to be carcinogenic to humans, EPA says

22 DEC 2017

The EPA's decision will likely provide strong evidence to support efforts to challenge glyphosate's listing as a carcinogen.

California Supreme Court endorses innovator liability against manufacturers of brand-name pharmaceuticals

22 DEC 2017

California Supreme Court: brand-name manufacturers owe a duty of reasonable care to ensure that product labeling includes adequate warnings.

Intellectual Property and Technology News (Asia Pacific) December 2017

7 DEC 2017

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Intellectual Property and Technology News (Asia Pacific) is our biannual publication designed to report on worldwide developments in intellectual property and technology law, offering perspectives, analysis and visionary ideas.

Product liability implications in the digital health industry

4 DEC 2017

As digital health products become commercialized and their use becomes more mainstream, companies face a higher likelihood of product liability litigation and regulatory scrutiny.

Ontario introduces bill to promote transparency in healthcare industry

4 OCT 2017

On September 27, 2017, Ontario introduced proposed legislation that aims to add transparency to certain marketing practices employed by the medical industry, in particular the provision of payments such as meals, hospitality, and financial grants from the medical industry to healthcare professionals.

Trade secrets are more important, and trade secret litigation is more common

29 SEP 2017

What do you need to be considering to protect your company in this environment?

FDA announces major regulatory overhaul initiative

8 SEP 2017

This initiative will be a massive undertaking given the breadth of FDA's regulatory authority over a vast array of products and

industries.

Coming soon from FDA? Streamlined safety information in prescription drug television ads

7 SEP 2017

If FDA proceeds, TV may feature even more drug ads, and the advice to “talk to your doctor” will become even more important.

Precarious steps: patent eligibility for healthcare IT

26 SEP 2016

Three recent Federal Circuit decisions, along with new updates from the USPTO, offer guidance on which steps to take in patenting healthcare IT-related inventions.

Stop them in their tracks: key points in seeking a preliminary injunction against medical device infringers

22 SEP 2016

Three considerations to bear in mind when bringing or defending a preliminary injunction motion in a medical device infringement case.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

Supreme Court Corner: Q1 2016

29 MAR 2016

Two cases to watch.

Are IPRs impacting the pharmaceutical industry?

9 JUN 2015

Choosing between IPRs and district court litigation

Supreme Court Corner - Q1 2015

24 MAR 2015

Recent decisions and cases to watch

Substitution allowed? State biosimilars laws are evolving

10 SEP 2014

Biosimilar products have not yet reached the US market, but debates on the laws and regulations that will govern them have been raging for some time

Supreme Court Corner - Q3 2014

10 SEP 2014

A review of cases relevant to IPT decided or argued before the Court during Q3

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

[INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS SERIES](#)

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

New guidance for lawyers advising clients on human rights risks

19 JUL 2017

On 17 July 2017, the International Bar Association Legal Policy and Research Unit (LPRU) released a *Handbook for Lawyers on Business and Human Rights* to provide guidance for business lawyers and their corporate clients on how to address human rights risks in corporate and commercial transactions.

Amendments to Canada's patent linkage provisions relating to generic and biosimilar market approval

17 JUL 2017

Long-awaited amendments to Canada's patent linkage provisions relating to generic and biosimilar market approval have been published.

A broken promise – The Supreme Court of Canada reverses Canada's "promise of the patent" doctrine

4 JUL 2017

The Supreme Court of Canada has dealt a significant blow to the "promise of the patent" doctrine—a controversial judge-made approach to the question of patent utility in Canada that has been heavily criticized over the past decade.

US Supreme Court strikes death blow against forum shopping in mass actions by limiting personal jurisdiction

21 JUN 2017

The Court's opinion continues the trend of limiting personal jurisdiction.

DOJ dismisses last of the drug trafficking charges against FedEx: two key takeaways

5 JUL 2016

A sudden about-face from the DOJ.

Ten tips for generating a life sciences brand name

19 NOV 2015

The proliferation of brands, combined with the PR and financial consequences of a potential rebrand in the event of infringement, has made selecting a trademark trickier than ever. Christina Martini and Virginia Wolk Marino report.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

Wellness innovators take note: FDA reveals risk-based approaches to the regulation of health IT and mobile medical apps

2 FEB 2015

HEALTH SYSTEMS ALERT SERIES

With these draft guidance documents, FDA indicates it will not take enforcement action in connection with low-risk general wellness products and establishes a new risk-based approach to medical device accessories

Revenue pressure climbs for skilled nursing facilities – what does this mean for healthcare REITs?

3 JUN 2015

Healthcare REITs must be mindful of the challenges they may face due to changes in the healthcare environment

SEC begins Dodd-Frank rulemaking with new open process

28 Jul 2010

EVENTS

Upcoming

TopCo liability panel

25 JUN 2019
London

[Previous](#)

BIO's 2019 International Convention

3 - 6 JUN 2019
Philadelphia

Medical Device Happy Hour

15 MAY 2019
San Diego

DLA Piper luncheon during the 37th annual JP Morgan Healthcare Conference

8 JAN 2019

NJIPLA's 32nd Annual Pharmaceutical/Chemical Patent Practice Update

7 NOV 2018

The More Things Change: Improvement Patents, Drug Modifications, and the FDA

19 OCT 2018

Promotional Compliance and Liability Risks Beyond FDA

17 OCT 2018

Clarifying the Clinical Trial Process for Drugs and Biologics

27 SEP 2018
Boston

New frontiers on the abuse of dominance

18 JUN 2018

Webinar

Enforcement and compliance trends in today's life sciences environment

26 APR 2018
Webinar

NEWS

DLA Piper represents Locana in US\$55 million Series A financing

23 MAY 2019

DLA Piper represented Locana, Inc. in a US\$55 million round of Series A financing led by ARCH Venture Partners, with participation from existing investors Temasek and Lightstone Ventures.

DLA Piper announces launch of Artificial Intelligence practice

14 MAY 2019

DLA Piper announced today the launch of its Artificial Intelligence practice, which will focus on assisting companies as they navigate the legal landscape of emerging and disruptive technologies, while helping them understand the legal and compliance risks arising from the creation and deployment of AI systems.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA's* 2019 guide.

DLA Piper lawyers and practices ranked in latest Chambers edition

30 APR 2019

DLA Piper today announced that 158 of the firm's lawyers and 64 of its practices were ranked in *Chambers USA's* 2019 guide.

Carl Wessel joins DLA Piper's Litigation practice in Washington, DC

22 APR 2019

DLA Piper announced today that Carl Wessel has joined the firm's Litigation practice as a partner in Washington, DC.

K. Randolph Peak joins DLA Piper's Healthcare sector and Corporate practice in Dallas

17 APR 2019

DLA Piper announced today that K. Randolph Peak has joined the firm's Healthcare sector and Corporate practice as a partner in Dallas.

DLA Piper advises Vivo Capital as lead investor in Series D financing for MacuLogix

8 APR 2019

DLA Piper represented Vivo Capital, LLC as the lead investor in US\$38.7 million Series D financing for MacuLogix, Inc., a Harrisburg, Pennsylvania-based company providing eye care professionals with tools to diagnose and treat patients with age-related macular degeneration (AMD).

DLA Piper announces partnership promotions for 2019

1 APR 2019

DLA Piper is proud to announce that 77 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2019 in the United States and May 1, 2019 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 43 different offices throughout 20 countries.

Patrick Anding joins DLA Piper's Corporate practice in Los Angeles and San Diego

20 MAR 2019

DLA Piper announced today that Patrick Anding has joined the firm's Corporate practice as a partner in Los Angeles and San Diego.

DLA Piper enhances cross-border tax capability with new partner hire in Dublin

26 FEB 2019

DLA Piper today announces the appointment of Maura Dineen as a Tax partner in the firm's newly opened Dublin office. This is the fifth partner hire for DLA Piper in Dublin in a month, following the announcements in January of Conor Houlihan (Finance & Projects), Éanna Mellett (Corporate), Mark Rasdale (Intellectual Property & Technology) and Ciara McLoughlin (Employment).

Michael Furrow and Brian O'Reilly join DLA Piper's Intellectual Property and Technology practice in New York

20 FEB 2019

DLA Piper announced today that Michael Enzo Furrow, Ph.D., and Brian David O'Reilly have joined the firm's Intellectual Property and Technology practice as partners in New York.

DLA Piper recognized as a leading private equity, venture capital and M&A firm in *PitchBook's* league tables

19 FEB 2019

For the second consecutive year, DLA Piper was the only firm to rank as one of the top five most active law firms for private equity, venture capital and M&A deal volume in *PitchBook's* 2018 global league tables report.

DLA Piper advises Qualcomm in sale of Qualcomm Life to Francisco Partners

12 FEB 2019

DLA Piper represented Qualcomm in the sale of Qualcomm Life, Inc., a wholly owned subsidiary of Qualcomm Incorporated that offers end-to-end medical device connectivity, to private equity firm Francisco Partners.

DLA Piper advises SoftBank Vision Fund in investment in Zymergen

15 DEC 2018

The DLA Piper team representing SoftBank Vision Fund was led by partner Louis Lehot and included partner Craig Lang and associate Evan Youngstrom (all of Silicon Valley).

Christine Walchuk joins DLA Piper's Corporate practice in Northern Virginia

19 NOV 2018

DLA Piper announced today that Christine Walchuk has joined the firm's Corporate practice as a partner in Northern Virginia.

DLA Piper advises Gener8 in its acquisition by Sverica Capital Management

21 SEP 2018

DLA Piper represented Gener8, LLC, a designer and manufacturer of life science instrumentations and medical devices headquartered in Sunnyvale, California, in its acquisition by private equity firm Sverica Capital Management LP.

Daniel Tobey joins DLA Piper's Litigation practice in Dallas

19 SEP 2018

DLA Piper announced today that Daniel Tobey has joined the firm's Litigation practice as a partner in Dallas.

DLA Piper adds Michael Dougherty and Tony Pezzano to Intellectual Property and Technology practice in New York

19 SEP 2018

DLA Piper announced today that Michael Dougherty and Tony Pezzano have joined the firm's Intellectual Property and Technology practice as partners in New York.

DLA Piper advises BTG in acquisition of Novate Medical

10 SEP 2018

DLA Piper represented BTG plc, a global specialist healthcare company, in its acquisition of Novate Medical Ltd.

DLA Piper advises Maryland Proton Treatment Center in US\$277.4 million tax-exempt municipal bond financing

6 SEP 2018

DLA Piper represented Maryland Proton Therapy Center (MPTC) in its US\$277.4 million tax-exempt municipal bond financing.

Tami Howie to join DLA Piper's Corporate practice in Washington, DC

15 AUG 2018

DLA Piper announced today that Tami Howie will join the firm's Corporate practice as a partner in Washington, DC.

DLA Piper advises Liquidia Technologies in its US\$50 million IPO

3 AUG 2018

DLA Piper advised Liquidia Technologies, Inc. in its US\$50 million initial public offering.

DLA Piper advises Olive in US\$32.8 million Series D financing

31 JUL 2018

DLA Piper represented Olive, a technology company applying artificial intelligence to healthcare administration, in its US\$32.8 million Series D financing.

DLA Piper recognized again as a Top Global Outsourcing Advisor

28 JUN 2018

DLA Piper is pleased to announce that the firm has been selected for the 2018 World's Best Outsourcing Advisors list by the International Association of Outsourcing Professionals (IAOP).

DLA Piper advises Immunomedics in US\$276 million follow-on public offering

18 JUN 2018

DLA Piper advised Immunomedics, Inc. in its follow-on public offering of common stock valued at approximately US\$276 million.

DLA Piper advises ADMA Biologics' follow-on public offering

12 JUN 2018

DLA Piper advised ADMA Biologics, Inc. (Nasdaq: ADMA) in its underwritten follow-on public offering of common stock valued at approximately US\$40 million.

DLA Piper advises Insilico Medicine in Series A financing

12 JUN 2018

DLA Piper represented Insilico Medicine Inc. in the completion of Series A financing led by WuXi AppTec's Corporate Venture Fund.

DLA Piper named International Law Firm of the Year in Ukraine for fifth year running at The Legal Awards 2018

24 MAY 2018

DLA Piper has been named International Law Firm of the Year in Ukraine at the 2018 Legal Awards, held by Yuridicheskaya Practika Publishing House. This is the fifth time the office has won the award.

DLA Piper announces partnership promotions for 2018

3 APR 2018

DLA Piper is proud to announce that 62 lawyers have been promoted to its partnership. The promotions are effective as of 1 April 2018 in the United States and 1 May 2018 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 42 different offices throughout 20 countries.

Businesses still not fully aware of Data Protection issues

31 JAN 2018

DLA Piper has released its second Data Privacy Snapshot report, finding that once again, company global privacy programs have gaps in meeting increasingly demanding global privacy principles. Significantly, it appears that many companies are falling short of data protection obligations under the General Data Protection Regulation (GDPR), which will start to apply from 25 May 2018.

Stephen Matthews joins DLA Piper's Litigation practice in New Jersey

17 JAN 2018

DLA Piper announced today that Stephen Matthews has joined the firm's Litigation practice as a partner in the Short Hills, New Jersey, office.

DLA Piper advises Immunomedics on royalty funding and stock purchase agreements with Royalty Pharma which raised an aggregate of US\$250 million

9 JAN 2018

DLA Piper represented Immunomedics, Inc., in the sale of tiered, sales-based royalty rights on global net sales of sacituzumab govitecan (IMMU-132) to Royalty Pharma for US\$175 million. Royalty Pharma has also purchased US\$75 million in common stock of Immunomedics, at US\$17.15 per share.

DLA Piper represents Vivo Capital in equity financing of Harmony Biosciences, LLC

13 OCT 2017

DLA Piper represented healthcare-focused investment firm Vivo Capital as the lead investor in a US\$270 million equity financing of Harmony Biosciences, LLC, a biopharmaceutical company that develops orphan and rare disease therapies.

DLA Piper successfully represents NuVasive in shareholder derivative suit victory

4 OCT 2017

DLA Piper successfully defended NuVasive, its board of directors and three officers of the company in a shareholder derivative suit.

Lisa Haile and Gina Durham named *Daily Journal* Top Intellectual Property Lawyers in California

16 AUG 2017

DLA Piper is pleased to announce that the *Daily Journal* has named Lisa Haile and Gina Durham to its 2017 list of Top Intellectual Property Lawyers in California. The award recognizes attorneys who successfully argued a novel theory of law, saved a client's business by winning a case or protected a client's portfolio.

DLA Piper recognized for strong client relationships in *BTI Industry Power Rankings*

18 JUL 2017

DLA Piper has been recognized for the strength of its client relationships across a broad spectrum of industries in BTI Consulting Group's 2017 *BTI Industry Power Rankings*.
