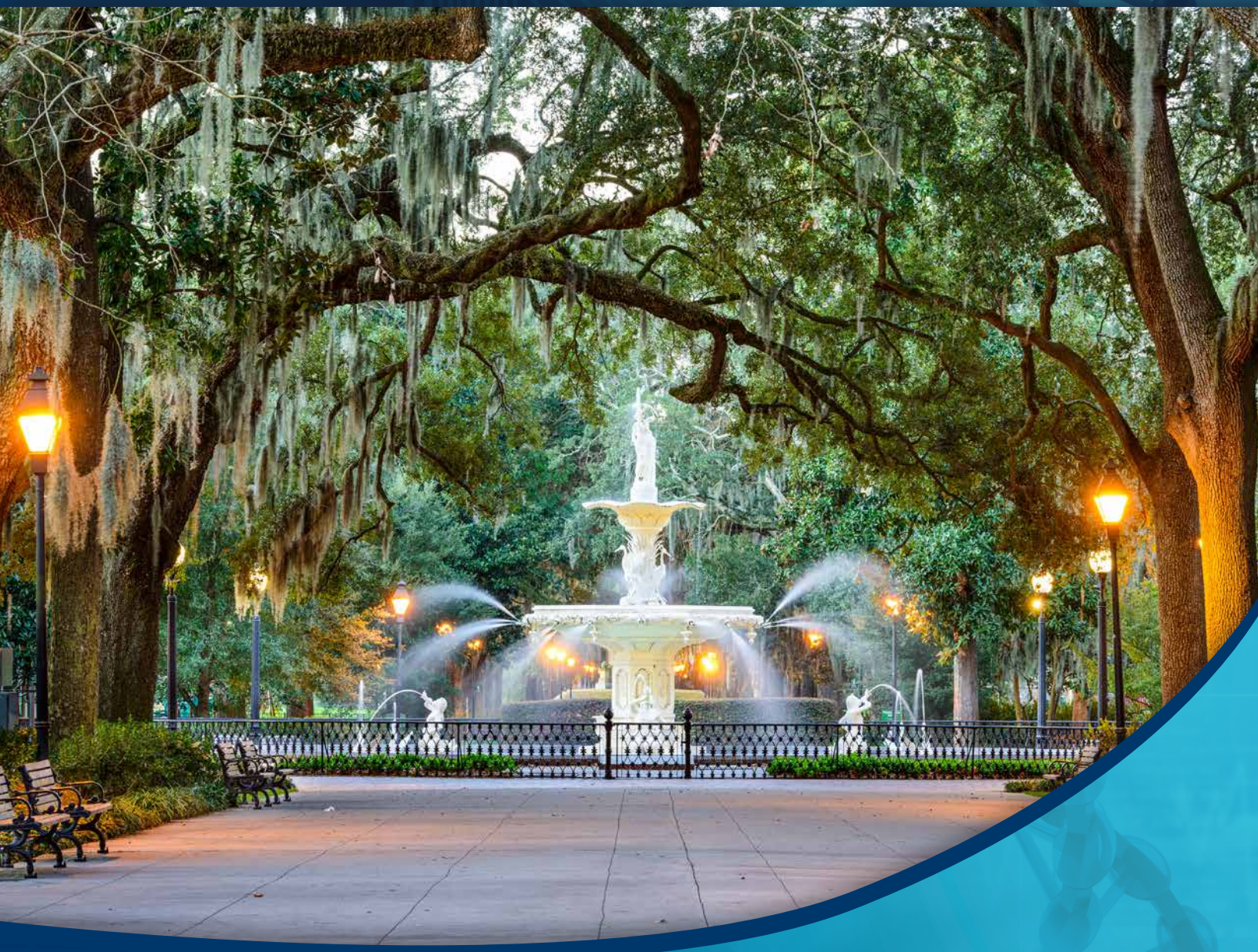
FINAL PROGRAM

IP Counsels Committee Conference



2016 FALL CONFERENCE

SAVANNAH, GA | NOVEMBER 14-16, 2016

Program Guide sponsored by

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IP Counsels Committee Conference

TABLE OF CONTENTS

CLE CREDIT INFORMATION

BIO will be offering continuing legal education credit at the 2016 IPCC-Fall Conference. Application for CLE credit will be submitted in California, Virginia, and Georgia. Attorneys will be notified if BIO receives credit approval. Attorneys needing CLE credit from other states are welcome to sign in, pick up the CLE forms and apply to their jurisdictions on their own. BIO will provide you with all the materials and documentation required to apply with your individual state CLE Boards.

NOTICE AND DISCLAIMER

PROGRAM AGENDA

SAVANNAH, GA | NOVEMBER 14–16, 2016

All sessions will be in the Viennese Ballroom.

MONDAY | NOVEMBER 14

11:30 am – 4:30 pm — **REGISTRATION OPEN**

12:00 pm – 3:15 pm — **IPCC BUSINESS MEETING & WORKING LUNCHEON**

**Open to IP Counsels Committee company members only*

3:15 pm – 3:30 pm — **REFRESHMENT BREAK**

Sponsored by: **Marshall, Gerstein & Borun LLP**

3:30 pm – 4:30 pm — **PRE-CONFERENCE WORKSHOP: GOLIATH VS. GOLIATH PATENT WARS**

Sponsored by: **O'Melveny & Meyers, LLP**

This expert panel will address the changing landscape in pharma/biotech patent litigation that now sees the titans of the industry engaged in turf wars. Topics to be addressed include: the evolution of platform patents from methods of manufacture to molecular targets; analysis of several recent battles between big pharma, including *Gilead v. Merck and Amgen v. Sanofi/Regeneron*; offensive and defensive strategies involved; and possible implications on damages and injunctive relief.

Speakers: **Lisa Barons Pensabene,** *Partner & Head of Life Sciences Litigation*, O'Melveny & Myers, LLP
Filko Prugo, *Partner*, O'Melveny & Myers, LLP

5:30 pm – 7:30 pm — **WELCOME RECEPTION AT SAVANNAH CHART HOUSE**

Join us for cocktails and hor d'oeuvres overlooking the waterfront before exploring Savannah's historical River Street.

Sponsored by: **Finnegan, Henderson, Farabow, Garrett & Dunner, LLP**

TUESDAY | NOVEMBER 15

7:30 am – 4:30 pm — **REGISTRATION OPEN**

8:00 am – 9:15 am — **BREAKFAST SESSION**

Sponsored by: **Brinks Gilson & Lione**

What drives innovation? How can we fund the discovery of new life-saving therapies while improving access to medicines for existing patients? Have patents enhanced or hindered innovation in healthcare?

These are some of the questions at the heart of the biotechnology industry. In this breakfast session, Jennifer Fox of Brinks Gilson & Lione will lead a discussion with

TUESDAY | NOVEMBER 15 *continued*

Ed Miseta, Chief Editor & Clinical Leader of Outsourced Pharma, on the effects of patents on innovation and how capitalism in drug discovery can affect the availability of lifesaving drugs to patients.

Guest Speaker: **Ed Miseta,** *Chief Editor & Clinical Leader,* Outsourced Pharma
With: **Jennifer Fox,** *Shareholder,* Brinks Gilson & Lione

9:30 am – 10:45 am

SESSION 1: 101 UPDATE AND INDUSTRY PERSPECTIVES—BIOINFORMATICS AND DIAGNOSTICS

Sponsored by: **Choate Hall & Stewart LLP**

On June 27, 2016, the U.S. Supreme Court denied cert. in *Sequenom v. Ariosa*, letting stand the Fed. Cir. decision that ruled an admittedly revolutionary medical test for detecting fetal genetic conditions in early pregnancy to be patent ineligible.

While there is support within the industry for a legislative fix to amend 35 USC 101, there is significant uncertainty how much support it would receive from a new administration and how long it would take to pass.

This panel will discuss how diagnostics companies are coping with the uncertainty brought about by recent 35 USC 101 rulings, whether/how this is changing the way they protect and enforce their IP, whether and how they are relying on trade secret protection, and other issues.

Moderator: **William Haulbrook, Ph.D.,** *Partner,* Choate Hall & Stewart LLP
Speakers: **Charles Lyon,** *Partner,* Choate Hall & Stewart LLP
Noam Pollack, *General Counsel,* Point of Care Diagnostics of Siemens
Mark Shtilerman, *Senior Counsel,* Deerfield Management

10:45 am – 11:00 am

REFRESHMENT BREAK

Sponsored by: **Marshall, Gerstein & Borun LLP**

11:00 am – 12:15 pm

SESSION 2: LICENSING & COLLABORATION AGREEMENTS—TRAPS FOR THE UNWARY

Sponsored by: **Choate Hall & Stewart LLP**

In an increasing integrated world where more and more R&D is done by collaboration, in licensing and acquisition, agreement structure can have a profound impact on the strength of IP protection. This panel will explore key issues and problems that commonly arise in license and collaboration agreements including, for example, know-how transfer provisions, common representations and warranties, change of control, diligence limitations and other issues.

Moderator: **Eric Marandett,** *Partner,* Choate Hall & Stewart LLP
Speakers: **Christine Bellon,** *Senior Vice President, Legal Affairs,* Relay Therapeutics, Inc.
Randall Morin, *Assistant Chief IP Counsel,* Vertex Pharmaceuticals
Gerald Quirk, *Chief Legal Officer,* Syros Pharmaceuticals

TUESDAY | NOVEMBER 15 *continued*

12:30 pm – 1:45 pm

[LUNCHEON] FIRESIDE CHAT: STANDING ON THE FRONT LINES: TRIALS AND TRIBULATIONS OF POST GRANT PROCEEDINGS

Sponsored by: **Goodwin Procter**

The U.S. patent system has changed dramatically in the five years since the passage of the American Invents Act. One of the biggest impacts on the biotechnology sector has been changes to post-grant proceedings, which have significantly increased the opportunities to challenge and invalidate a patent. Given these changes, how have patent holders and challengers adjusted to the new dynamic? What have been their experiences within the system, and how have patent holders dealt with these changes?

Nick Mitrokostas of Goodwin Procter will lead an informal discussion between in-house counsel on the challenges they're companies have faced in their proceedings, expectations vs. reality, and broader speculation about the impact these proceedings will have on the life sciences.

Moderator: **Nicholas K. Mitrokostas,** *Partner*, Goodwin Procter

Speakers: **Willem F.C. de Weerd,** *Corporate Patent Counsel,* Merck Serono

Julia Pike, *Vice President of IP, North America,* Sandoz Inc.

-2:00 pm – 3:15 pm

SESSION 3: FIVE YEARS OF LIVING WITH THE AIA: THE IMPACT OF IPR ON PHARMACEUTICAL PATENTS

Sponsored by: **Finnegan, Henderson, Farabow, Garrett & Dunner, LLP**

When Congress enacted the AIA five years ago, very few anticipated the significant effect post grant proceedings would have on life sciences. This panel will analyze the impact of IPR proceedings on pharmaceutical patents and litigation, considering:

- Statistical trends and future implications
- Complicating issues with joinder, time-barred parties, and finality
- Effects of panel dependency and lack of precedential decisions
- Estoppel effects and strategic considerations

Moderator: **Robert F. Shaffer,** *Attorney,* Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Speakers: **Nicole A. Conlon, Ph.D.,** *Attorney,* Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

David Hoffman, Ph.D., *Executive Director,* Intellectual Property, Parker Institute for Cancer Immunotherapy

3:15 pm – 3:30 pm

REFRESHMENT BREAK

Sponsored by: **Marshall, Gerstein & Borun LLP**

3:30 pm – 4:45 pm

SESSION 4: BIOSIMILARS—INSIGHTS INTO THE PATENT DANCE

Sponsored by: **Finnegan, Henderson, Farabow, Garrett & Dunner, LLP**

This panel will present an update on biosimilars at the FDA and the federal courts, including a detailed analysis of recent case law.

Moderator: **Howard W. Levine,** Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Speakers: **Brian P. Barrett,** *R.Ph., Senior Director - Assistant General Patent Counsel,* Eli Lilly and Company

Jonathan R. Davies, *Ph.D., Attorney, Finnegan,* Henderson, Farabow, Garrett & Dunner, LLP

5:30 pm – 8:30 pm

ACTIVITY & DINNER RECEPTION WITH SAVANNAH TROLLEY TOUR

Our haunted-history trolley tour of Downtown Savannah (complete with pub stop!) will depart promptly at 5:30 pm from the hotel lobby, and end with dinner at the landmark Old Pink House on Reynolds Square.

Dinner Sponsored by: **McDonnell Boehnen Hulbert & Berghoff LLP**

WEDNESDAY | NOVEMBER 16

8:00 am – 9:15 am

[BREAKFAST] STRATEGIC DECISION MAKING IN DUAL PTAB AND DISTRICT COURT PROCEEDINGS

Sponsored by: **Proskauer**

Inter partes reviews have transformed the relationship between Article III patent litigation and administrative patent actions. Originally intended as a substitute for district court litigation, *inter partes* reviews have proven popular as well as controversial. Yet scholarly and other analyses of litigant behavior in these proceedings has been limited thus far to descriptive data summaries or specific policy perspectives on these types of post-grant challenges, such as their impact on the well-rehearsed patent troll debate.

At this breakfast session, we will explore the impact of dual PTAB and district court proceedings in the biopharma industry through an informal discussion with two in-house counsels from leading biopharma companies and Prof. Saurabh Vishnubhakat, who conducted original research of how litigants use *inter partes* reviews relative to Article III litigation, and the implications of these latest findings for the U.S. system for adjudicating patent validity, generally, and for the biotech sector in particular.

Introduction: **Fangli Chen,** Proskauer Rose LLP

Interviewer: **Siegmund "Sige" Gutman,** Proskauer Rose LLP

Interviewees: **Henry Gu,** *Assistant General Counsel, Head of Intellectual Property,* ARIAD Pharmaceuticals

Karen Martin, *In-house counsel,* Shire

Prof. Saurabh Vishnubhakat, *Associate Professor of Law,* Texas A&M University School of Law / Postdoctoral Associate, Duke Law

WEDNESDAY | NOVEMBER 16 *continued*

9:30 am – 10:45 am

SESSION 5:
THE EFFECT OF BREXIT ON THE UNIFIED PATENT SYSTEM, THE U.K. AND GLOBAL PATENT STRATEGY

Sponsored by: **Fitzpatrick, Cella, Harper & Scinto**

This panel will discuss the ramifications of Brexit on the implementation and realization of the European Unitary Patent, Unified Patent System and Unified Patent Court, and how it may affect U.K. patent practice and global patent strategy.

Moderator: **Robert S. Schwartz, Ph.D.,** *Partner,* Fitzpatrick, Cella, Harper & Scinto

Speakers: **Dominic Adair, Ph.D.,** *Partner,* Bristows
Christopher P. Borello, *Partner,* Fitzpatrick, Cella, Harper & Scinto
Dirk Bühler, Ph.D., *Partner,* Maiwald
Larry Coury, Ph.D., Regeneron

10:45 am – 11:00 am

REFRESHMENT BREAK

Sponsored by: **Marshall, Gerstein & Borun LLP**

11:00 am – 12:15 pm

SESSION 6:
UNIQUE ISSUES FOR METHOD OF TREATMENT PATENTS

Sponsored by: **Fitzpatrick, Cella, Harper & Scinto**

This panel will discuss the state of law regarding validity, patentability and infringement of method of treatment patents. This will include looking at section 101 under the Supreme Court's Mayo analysis (such as with *BMS v. Merck, Ariosa Diagnostics v. Sequenom and Vanda v. Roxane*), unique section 112 issues and other potential legal issues that may, in the future, lead to Post Grant Review, particularly in light of the broader range of bases available for challenge as compared to *Inter Partes* Review. This will also include a look at recent decisions on indirect infringement and the impact of claim construction on the outcome of these cases.

Moderators: **Christina Schwarz,** Fitzpatrick, Cella, Harper & Scinto
Ha Kung Wong, Fitzpatrick, Cella, Harper & Scinto

Speakers: **Claire M. Vasios, Ph.D.,** *Vice President,* Alkermes, Inc.
Peter J. Waibel, Esq., *Executive Director—Patent Litigation,* Novartis


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MISSION AND GUIDELINES

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Committee Chair

Chair: **Kenneth Dow,** *Vice President, Patents & Assistant Patent Counsel,* Johnson & Johnson

Subcommittees and Working Groups

If you are interested in joining any of the following subcommittees, please contact Austin Donohue at adonohue@bio.org.

Amicus Subcommittee

Chair: **Brian P. Barrett,** *Associate General Patent Counsel,* Eli Lilly

PTO Working Group

Chair: **Jason Ferrone,** *Vice President, Patents & Corporate Development,* ISIS Pharmaceuticals, Inc.

International IP Working Group

Chair: **Li Westerlund,** *Vice President of Global Intellectual Property,* Bavarian Nordic Group

MISSION

To promote strong, predictable intellectual property protection and efficient transfer of IP rights for the biotechnology industry domestically and internationally.

ELIGIBILITY FOR PARTICIPATION

In order to be eligible for membership, the interested party MUST be a member if BIO. Unless otherwise directed by the chair of the IPCC, committee members MUST represent a member biotechnology company either as in-house patent counsel or outside patent counsel. While a law degree is not required, many committee activities require detailed knowledge of patent law.

PARTICIPATION

The committee meets bi-annually in-person. There are also opportunities for working groups to meet on an ad hoc basis or to give comments throughout the year on papers, letters, and other correspondence sent out on behalf of BIO's members.

RESPONSIBILITIES

- The Intellectual Property Counsels Committee (IPCC) is responsible for developing domestic and international intellectual property policy that benefits the biotechnology industry.
- The committee is responsible for reviewing and commenting on proposed intellectual property legislation.
- The committee is responsible got reviewing and commenting on IP-related regulations from Federal agencies, including the United States Patent and Trademark Office (PTO) and the National Institutes of Health (NIH).

- The committee works with BIO staff to brief Members of Congress and officials of the governmental agencies such as the PTO, the U.S. State Department, the Federal Trade Commission, the U.S. Trade Representative, and the NIH on intellectual property matters.
- The committee actively participates in efforts to influence legislation, treaties, jurisprudence and practice in a manner most beneficial to the continued positive development of the biotechnology industry.
- The committee, from time to time, approves the filing of amicus briefs in cases that have an impact on the biotechnology industry.
- Committee members may be asked to help develop IP-related position papers, white papers and educational materials.
- Committee members may be asked to formulate comments and testimony on various IP-related guidelines and regulations.

POLICY APPROVAL PROCESS

Substantive matters designed to become the official position of BIO are sent as recommendations of the IPCC to the Board of Directors Standing Committee on Intellectual Property for first review. The Standing Committee on Intellectual Property will discuss and, as appropriate, determine changes in the recommendations. The Standing Committee will then either return substantive matter to the IPCC for further comment and revision or refer the matter to the full Board of Directors for consideration.

PAST ACCOMPLISHMENTS

The IPCC has helped develop and pass the American Inventor Protection Act of 1999 and the America Invents Act of 2011; developed BIO's positions on patent reform; and engaged in Patent Reform negotiations on the Hill. The committee has developed BIO's position and testimony on patenting genetic materials, university and industry partnerships/technology transfer and intellectual property and competition policy. The committee has also filed comments to relevant PTO proposed rule-making notices most notably the PTO's utility and written description guidelines; PTO claims and continuation rules, "three track" examination, the PTO's "Patents for Humanity" program, and implementing regulations for the America Invents Act. The committee has also filed numerous amicus briefs in cases of relevance to the biotechnology industry, including *Monsanto v. Bowman, Prometheus v. Mayo, Therasense v. Becton Dickinson, AMP v. Myriad Genetics, Stanford v. Roche, and Microsoft v. i4i,* among others. The committee also files annual comments to, and participates in the Special 301 process highlighting countries with IP concerns, at the Office of the United States Trade Representative. Also, on the international front, the committee has developed BIO's position on substantive patent law harmonization, intellectual property in global health, and intellectual property and access to genetic resources.

BIO STAFF CONTACTS

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Austin Donohue, *Coordinator, Legal and Intellectual Property, adonohue@bio.org*

BIO ANTITRUST STATEMENT

All BIO meeting activities shall be conducted to abide strictly by all applicable antitrust laws. The antitrust principles discussed below apply to every meeting or conference call, no matter how informal, in which BIO members and staff gather under BIO's auspices.

Antitrust violations do not require proof of a formal agreement. A violation may be alleged based upon the mere appearance of unlawful activity. For example, discussion of a sensitive topic, such as price, followed by parallel action by those involved or present at the discussion, may be sufficient to show a price-fixing conspiracy. It is therefore important for speakers and attendees at BIO meetings to avoid discussing confidential business plans or information that is competitively sensitive, including the following:

- **Company-specific current or future prices**, including discounts, rebates, and pricing plans or policies;
- **Sales or research in particular markets or sales to particular customers**, including whether or how to sell in specific markets, whether to bid for specific business or participate in specific programs, conditions (such as resale restrictions) applicable to particular private or governmental customers, and whether to conduct research in particular areas;
- **Advertising and promotion plans**, including expected levels of advertising, which products to advertise, content of advertising, and future plans for the number of sales representatives and levels of expenditure on sales activities; and
- **How companies might or should respond in the marketplace** (such as by changing pricing, sales, distribution, or advertising policies) in light of existing or pending laws or regulations or current business or policy climates, including the suggestion of boycotts, or refusals to deal with, particular markets or customers.

This list of generally prohibited topics is not exhaustive. By the same token, it is generally fine to discuss the nature of government regulations or policies on pricing, advertising and other aspects of pharmaceutical or biotechnology company business and advocacy efforts to address these government regulations or policies, as long as the discussions are limited to matters of public policy and government advocacy.

Criminal prosecution by federal or state authorities is a very real possibility for violations of the antitrust laws. Imprisonment, fines or treble damages may ensue. BIO, its members and guests must conduct themselves in a manner that avoids even the perception or slightest suspicion that antitrust laws are being violated. Whenever uncertainty exists as to the legality or propriety of conduct, including during any meeting or discussion, obtain legal advice by contacting Tom DiLenge, BIO's Vice President & General Counsel, at (202) 962-6671.

The antitrust laws do not prohibit meetings among members of a trade association in order to petition government or respond to government initiatives, to educate and inform the public, or to suggest quality and safety standards, thereby promoting economic welfare and the vitality of our several industries. It is in this spirit that BIO conducts its meetings and conferences.

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CONFERENCE ORGANIZER

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world. BIOtechNOW is BIO's blog chronicling "innovations transforming our world" and the BIO Newsletter is the organization's bi-weekly email newsletter.

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Choate provides leading life sciences companies and institutions with integrated legal services that enable our clients to achieve success. Our team of life sciences attorneys, many with advanced degrees, use their scientific and strategic expertise to advise clients on IP protection and strategies, financings, M&A and strategic transactions.

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Finnegan is one of the largest IP law firms in the world. From offices in Atlanta, Boston, London, Palo Alto, Reston, Seoul, Shanghai, Taipei, Tokyo, and Washington, DC, the firm practices all aspects of patent, trademark, copyright, and trade secret law, including counseling, prosecution, licensing, and litigation. Finnegan also represents clients on IP issues related to European patents and trade marks, international trade, portfolio management, the Internet, e-commerce, government contracts, antitrust, and unfair competition.

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Contact: Nicholas Mitrokostas, *Partner,* IP Litigation, **nmitrokostas@goodwinlaw.com**

Goodwin's Intellectual Property Litigation Practice, recently named by Law360 for the second consecutive year as one of its "Practice Groups of the Year," has worked with clients to secure preliminary injunctions, declaratory and summary judgments, favorable results in Markman proceedings, advantageous settlements, victories at trial and appellate relief. Goodwin attorneys routinely work with clients to take cases from pre-suit investigations through discovery and trials. Widely recognized as a leader in life sciences patent matters, Goodwin has been named for three consecutive years as "Biotechnology Law Firm of the Year" by *U.S. News Best Lawyers.* To learn more about our practice, go to goodwinlaw.com/IP.

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Professionals in Marshall Gerstein's biotechnology practice have intellectual property experience in a variety of disciplines, including DNA, RNA, protein and antibody therapeutics and diagnostics; plant biotechnology; industrial technology and research platforms; nanotechnology; and interdisciplinary inventions. We have procured, enforced and defended patents relating to billion-dollar biologic and pharmaceutical products and handled patents covering more than a dozen commercially marketed products and numerous clinical trial candidates.

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Proskauer's Life Sciences Patent practice partners with leading biologics, pharmaceutical, biotechnology, and medical device clients to meet their business objectives. We have extensive experience with patent litigation, contested patent office proceedings, FDA regulations, patent prosecution and transactions, including prior in-house counsel experience at Amgen and Wyeth.

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With 550 attorneys in the Mid-Atlantic, Southeast and Silicon Valley, Womble Carlyle is a full-service law firm that guides life sciences businesses in such core areas as Intellectual Property (including litigation, counseling and patent prosecution), Litigation, Corporate Transactions, Financing and Real Estate/Infrastructure. Our clients are varied and cover the continuum from university spin-offs and venture capital-backed start-ups to Fortune 100 multi-national corporations.

SPEAKER BIOGRAPHIES

Dominic Adair

Dominic specialises primarily in patent litigation with a focus on life sciences; his science background gives him an excellent grounding in the technical aspects of such disputes. He has experience before the Patent Office, High Court and Court of Appeal as well as experience of Opposition proceedings before the EPO.

Dominic has extensive experience of cross-border litigation in and beyond Europe. This has involved working closely with other lawyers, in-house and external, to ensure alignment with global strategic objectives concerning the defence and enforcement of several portfolios of patents.

In the pharmaceutical sector, Dominic has worked on all aspects of the drug life cycle, from freedom to operate analyses and early-stage risk assessment of generic competition to end-stage litigation, SPCs and anti-trust issues.

Outside patent litigation, Dominic has experience of conducting litigation concerning registered designs and copyright and the issues arising in the tobacco, publishing, gaming and computer gaming industries. He also has experience of other technology-related disputes such as product liability claims before the Technology and Construction Court and the International Court of Arbitration.

Dominic writes regularly on reported patent cases in the UK and at the EPO and is a member of the AIPPI. He is a regular conference speaker and presenter. See more at: http://www.bristows.com/our-people/dominic_adair/#sthash.cdHQhxK4.dpuf

Lisa Barons Pensabene

Lisa Barons Pensabene is the global head of O'Melveny's Life Sciences Litigation practice. Lisa handles high stakes patent litigation in the pharmaceutical and chemical industries. A first chair trial lawyer, she has led more than a dozen major pharmaceutical and chemical patent litigations, leading cases in bench and jury trials, arguing to the Federal Circuit, and leading briefing to the U.S. Supreme Court. Lisa is well-known as an expert on Hatch-Waxman and biosimilars litigation. The recipient of numerous accolades, Lisa was nominated as General Patent Litigator of the Year by LMG Life Sciences in 2015 and named a "Life Science Star" in the publication's 2015 edition. Lisa has also been repeatedly recognized as a leading attorney in *IAM Patent 1000*, and listed in *IAM 250: The World's Leading Patent Litigators*.

Christine Bellon

Chris is the Senior Vice President of Legal Affairs of Relay Therapeutics, Inc., a newly-launched company whose drug discovery engine is built on advances in detecting and characterizing dynamic interactions on proteins. Prior to Relay, she served as VP of Legal Affairs at Blueprint Medicines. As one of Blueprint's early employees, she played key roles in building Blueprint's global IP portfolio, securing strategic partnerships in rare genetic diseases and cancer immunotherapy, and in Blueprint's initial public offering. Before going to Blueprint, she served in legal leadership roles at Hydra Biosciences and Infinity Pharmaceuticals. Earlier in her career, she practiced law in the Boston office of Fish & Richardson P.C. Chris is the Chair of the Overseers and a Trustee of the Boston Museum of Science.

Chris holds a B.S. in Chemistry from Yale University; a Ph.D. in Organic Chemistry from the Massachusetts Institute of Technology, where she did research in the laboratory of K. Barry Sharpless; and a J.D. from Columbia Law School.

Christopher P. Borello

With Fitzpatrick since law school, Chris has learned from some of the most respected attorneys in the field of IP. He has experience asserting and defending patents, with domestic and foreign clients, with cases large and small ($ billions down to $ thousands in exposure), and with Fortune 500 companies and startups, from inception through trial. Chris has worked on cases involving pharmaceuticals (small molecules, formulations, and methods of treatment), biotechnology, mechanical devices, and computer technology. He recognizes the importance being responsive and efficient.

In addition to his work in the U.S. District Courts, Chris has experience with contested proceedings in the Patent and Trademark Office, with arbitrations, and in drafting complex settlement agreements.

Prior to joining Fitzpatrick, Chris was an environmental engineer for a national engineering firm, while in law school, he was an editor of the *Pace Environmental Law Review*.

Chris is the Administrative Partner of the Firm's New York Office and presently serves on the Firm's Management Committee.

Dr. Dirk Bühler

Dirk Bühler is a European and German Patent Attorney and has been a partner and managing director in the Munich office of Maiwald Patent Attorneys since 2007. His expertise focuses on contentious patent proceedings before the EPO and the German courts as well as due diligence advice on patent portfolios in the fields of biotechnology and pharmaceuticals.

Dirk has extensive experience in international and national patent infringement litigation, complex EPO opposition and appeal proceedings with multiple parties as well as nullity proceedings before the German Federal Patent and German Federal Supreme Court. Dirk is recommended by iam100 as "biochemical virtuoso".

Dirk has lectured in patent law at the Management Center Innsbruck. He is co-author of the "Handbuch des Patentrechts" (Handbook of Patent Law), published in both German and English and editor of the European handbook "Supplementary Protection Certificates". Dirk is a member of the Biochemistry and Molecular Biology Society. He has received scholarships from the "Studienstiftung des Deutschen Volkes" (German National Merit Foundation) and the "Boehringer Ingelheim Foundation for Basic Research in Biomedicine". He has lectured in patent law at the Management Center Innsbruck.

Prior to joining Maiwald, Dirk studied biochemistry at the Free University Berlin, the University of California at Berkeley and the Ruprecht-Karls-Universität Heidelberg, graduating in 1998. He subsequently carried out research at the Max-Planck-Institut for Biochemistry in Martinsried, Munich and obtained his doctorate 2001 with a thesis in the fields of molecular medicine and cellular biochemistry. Dirk Bühler passed the German patent bar examination in 2004 and since then is also admitted to practice as a European patent attorney at the European Patent Office.

Fangli Chen, Ph.D.

Dr. Fangli Chen is a partner in Proskauer's Litigation Department and vice chair of its Life Sciences Patent practice. She has deep scientific expertise and a strong business sense, and represents all types of companies in the biotech and pharmaceutical industries. She specializes in the strategic development of complex IP portfolios for companies that align with their business goals. The primary focus of her practice is intellectual property prosecution, which includes strategic development of complex patent portfolios for companies, universities and research institutions in the fields of biochemistry, molecular and cell biology, immunology, biochemical and molecular diagnostics, pharmaceuticals, microbiology, molecular genetics, pharmacogenomics, recombinant technologies, enzyme replacement therapy, messenger RNA therapy, gene therapy, bioinformatics, drug discovery, medical devices and chemistry.

She provides strategic IP counseling, prepares and prosecutes patent applications, performs due diligence investigations, and provides freedom-to-operate studies, non-infringement and invalidity analysis. Dr. Chen also has a wealth of experience in post-grant challenges, technology transactions and licensing, and as investment or acquisition counsel.

Larry Coury

Larry is Senior Director of Dispute Resolution and a registered patent attorney at Regeneron Pharmaceuticals, Inc. in Tarrytown, NY. His responsibilities include overseeing all litigation matters, including patent matters, as well as assisting with post-grant review proceedings in the United States and foreign patent offices. Prior to joining Regeneron, Larry worked for a total of about 16 years at several law firms: Fish & Neave, Paul Weiss, and Cravath. Larry is admitted to practice in the NY and CT state courts, various federal district courts, and the Court of Appeals for Federal Circuit. Larry received his B.S. in Chemistry from the Massachusetts Institute of Technology, his Ph.D. in Biophysics from Harvard University, and his J.D. from Fordham Law School, where he was editor of the Intellectual Property Law Journal. Larry also worked as a laboratory scientist in the Division of Tumor Immunology at Harvard Medical School and in the Laboratory for the Epithelial Cell Biology at the University of Pittsburgh Medical Center.

Henry Gu

Henry Gu is Assistant General Counsel, Head of Intellectual Property at ARIAD Pharmaceuticals located in Cambridge, MA. Henry has extensive experience in the areas of IP litigation, IPR, patent prosecution, due diligence, IP counseling and opinion.

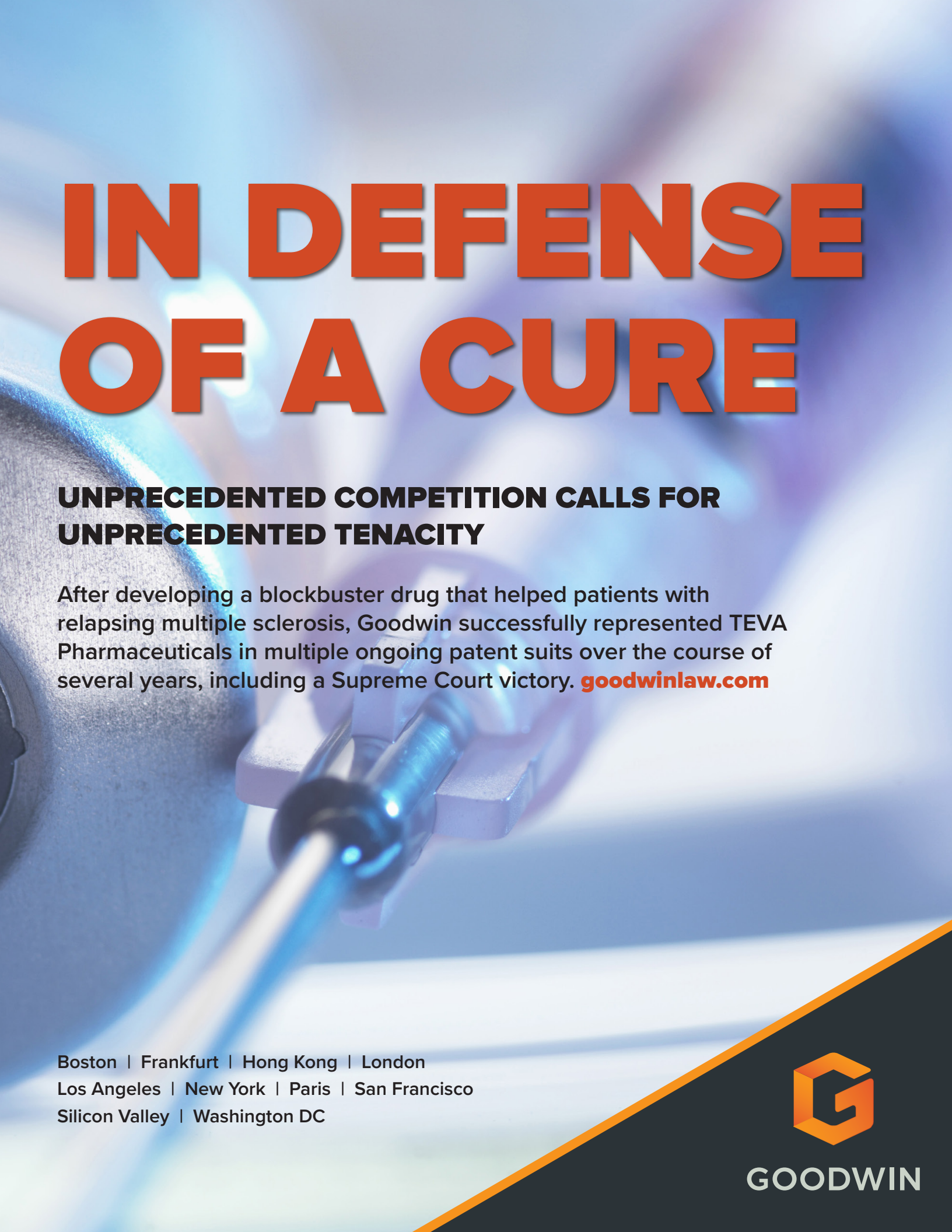
Prior to joining ARIAD, Henry was Intellectual Property Counsel at Agios Pharmaceuticals, where he was responsible for all IP matters and transactional work. Before joining Agios, Henry was Senior IP Counsel at Cubist Pharmaceuticals (acquired by Merck), where he was responsible for IP procurement and enforcement concerning several commercial products, clinical candidates and discovery programs. Prior to joining Cubist, Henry was Counsel at WilmerHale, where his practice focused on patent procurement, IP due diligence, and Hatch-Waxman litigation. Before that, Henry held an in-house position at Bristol-Myers Squibb in Princeton, NJ, where he worked on patent prosecution, lifecycle management and IP strategy. Henry also worked as a research scientist at BMS. He is an experienced inventor and has ten issued US patents.

Siegmund Y. Gutman

Siegmund ("Sige") Gutman is a partner in Proskauer's Litigation Department, and chair of its Life Sciences Patent practice. He is an accomplished patent litigator, frequently representing clients before trial and appellate courts, as well as arbitration panels. In the life sciences area, his practice focuses on developing and executing market exclusivity and freedom-to-operate strategies, including patent office and FDA regulatory strategies, for leading biologics, pharmaceutical, biotechnology, and medical device clients. He has extensive experience successfully litigating biologic drug patent and Hatch-Waxman cases, and has frequently spoken and written about issues relating to biosimilars and generic drugs. Sige also has extensive experience with inter-partes patent office actions, including inter partes reviews (IPRs) and oppositions, and providing strategic patent counseling, including addressing product life cycle management and patent portfolio development issues, as well as preparing third-party patent landscape analyses. Sige's background combines a graduate degree in molecular and cell biology and biophysical chemistry with more than 20 years of industry experience, including serving as senior patent litigation counsel for Amgen.

William Haulbrook

William Haulbrook, Ph.D., partner in the IP Group at Choate Hall & Stewart, has more than fifteen years specializing in patent portfolio development in the US, Europe and Asia, as well as post grant proceedings, litigation support and IP due diligence in a variety of fields. Dr. Haulbrook was named an "IP Star" by Managing Intellectual Property in 2016.



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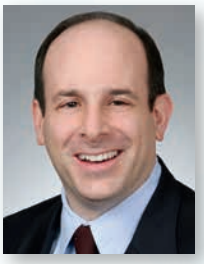
David Hoffman

David Hoffman studied biology as an undergraduate, completed a Ph.D. in Molecular, Cellular, and Developmental Biology at the University of Colorado, Boulder, and did postdoctoral research with Larry Gold (CU-Boulder), Jean-Jacques Toulme (INSERM, U. 386, Bordeaux), Alan Zahler (UC-Santa Cruz), and Cassie Conley (NASA-Ames Research Center) before attending Cornell Law School. He spent six years in private practice with Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, and Morrison & Foerster, LLP, working on patent infringement litigation matters before the U.S. District Court for the Northern District of California and the Court of Appeals for the Federal Circuit, patent application drafting and prosecution in the US and abroad, due diligence (company- and investor-side), and client counseling and strategic patent portfolio management. Subsequently, he left private practice to become in-house corporate patent counsel, first with Bavarian Nordic and most recently with Genomic Health. At Bavarian Nordic, he managed all U.S. patent prosecution, as well as a complex in-license from and a cooperative research and development agreement with the National Cancer Institute covering research and clinical development of various immunotherapies for the treatment of cancer, including lead product PROSTVAC (currently in a pivotal Phase III trial). At Genomic Health, he was the lead patent attorney, but also worked with the compliance team to review marketing materials and with the contracts team to negotiate and manage a range of collaboration agreements governing ongoing work on the clinical validation of prognostic products aimed at healping breast, colon, and prostate cancer patients make more informed treatment decisions.

Howard W. Levine



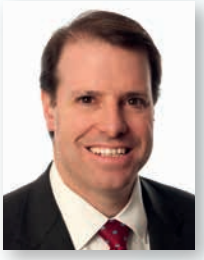
Howard Levine is an attorney in Finnegan, Henderson, Farabow, Garrett & Dunner, LLP's Washington, D.C. office. His practice concentrates on patent litigation before the federal district courts and the U.S. Court of Appeals for the Federal Circuit, primarily in the areas of biotechnology and pharmaceuticals. Mr. Levine has extensive experience in cases arising from the filing of Abbreviated New Drug Applications (ANDA).

Over the last 20 years, Mr. Levine has represented both pharmaceutical and biotechnology companies in technologies ranging from the inhibition of NF-κB to genetically engineered corn. He was involved in litigations between Eli Lilly, Genentech, and the Regents of the University of California regarding human insulin, the first biotechnology product to be marketed. Mr. Levine has conducted all aspects of pre-trial, trial, and post-trial proceedings, including appeals to the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court. Mr. Levine holds a JD from George Mason University.

Charles Lyon

Charles Lyon, DPhil, Co-chair of the Intellectual Property Group at Choate Hall & Stewart, has led or been involved with hundreds of IP due diligences on behalf of investors, investment banks and potential acquirers or partners Dr. Lyon also routinely provides opinions regarding validity and infringement in the context of product clearances. Dr. Lyon is particularly sought after for his efficiency and ability to clearly communicate those issues that are most likely to affect the risks and overall valuation of the underlying transaction or product. While he practices mostly in the life sciences sector, Dr. Lyon's research experience as a chemist means that he is also routinely called upon by clients in the chemical industry. He has been named "Intellectual Property Trailblazer" by *The National Law Journal,* "Up & Coming Lawyer" by *Massachusetts Lawyers Weekly*, a *Massachusetts Super Lawyers Rising Star*, a "World's Leading Patent Practitioner" by *IAM Patent 1000*, and an "IP Star" by *Managing Intellectual Property.*

Eric Marandett



Eric Marandett, co-chair of the Intellectual Property Litigation Group at Choate Hall & Stewart, has more than 20 years of experience representing major pharmaceutical and biotech companies in patent infringement, licensing disputes and other intellectual property litigation. Mr. Marandett also assists clients in assessing collaborations, acquisitions and joint ventures, particularly in the life sciences industry. Mr. Marandett was named the 2017 Boston "Lawyer of the Year" for Patent Litigation by Best Lawyers. He is listed in the *Massachusetts Super Lawyers Top 100, The Legal 500* and *Chambers USA*. He has also been named a World's Leading Patent Litigator by *IAM 250* and an "IP Star" by *Managing Intellectual Property*.

Karen Martin

Karen Martin is Director of Intellectual Property at Shire, where she manages worldwide patent and trademark portfolios in the pharmaceutical and biotech space, as well as post-grant, diligence, and transactional activities. Prior to joining Shire, Karen practiced intellectual property law at Wolf, Greenfield & Sacks in Boston, MA, where she counseled clients in various technical areas including pharmaceuticals, polymers, sensors, imaging technologies, and optoelectronic devices. Karen obtained her law degree from Suffolk University Law School and holds a Ph.D. in Organic Chemistry from MIT and a B.S. in Chemistry from Boston College.

Nicholas Mitrokostas

Nicholas Mitrokostas, a partner in Goodwin's IP Litigation Group, focuses his practice on intellectual property, with an emphasis on patent litigation and inter partes review proceedings in the Patent Trial and Appeal Board (PTAB). Mr. Mitrokostas has extensive trial and PTAB experience representing clients in the pharmaceutical and biotechnology industries in patent and antitrust litigation. He also has experience counseling and representing higher educational institutions in these matters. Mr. Mitrokostas is a frequent speaker and author on intellectual property law and its impact on the life sciences industry. Most recently, Mr. Mitrokostas authored "Pharmaceuticals at the Patent Trial and Appeal Board", published by Goodwin. He has also presented on "Patent Reform in the U.S. Congress" at the Annual Conference of the International Generic Pharmaceutical Alliance. Mr. Mitrokostas is a member of the board of editors of BigMoleculeWatch.com, a blog on developments in the biosimilars industry.

Julia Pike

Julia Pike is Vice President of IP, North America at Sandoz Inc. In this position, she has had a leading role in the first wave of US biosimilars litigation, including the first litigations on critical aspects of the BPCIA. Since leaving private practice, Julia has been in-house counsel for many years including at Mayne Pharma and Hospira Inc. In those roles, she led IP strategy worldwide, including the Hatch-Waxman and BPCIA legislation in the US, PM(NOC) regulations and litigation arising from patent linkage around the world. She joined Sandoz in 2008. At that time she had responsibility for Sandoz's European public affairs, including development of the Unified Patent Court and the European environment for biosimilars. She spent five years leading Sandoz's global IP litigation function. She was an author of the European Generic Medicines Association report, "Patent-Related Barriers To Market Entry For Generic Medicines In The European Union". Julia earned her Master of Laws (Intellectual Property) from the University of Melbourne, and also holds a Bachelor of Laws/Bachelor of Science degree.

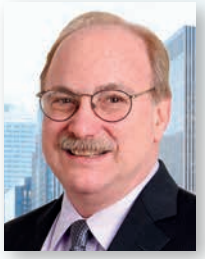
Filko Prugo

Filko Prugo is a USPTO registered patent attorney and first chair trial lawyer who focuses his practice exclusively on contested patent matters in the pharmaceutical and biologics space. For nearly 20 years Filko has represented biopharmaceutical industry leaders and is one of only a handful of attorneys who has argued before the USPTO, Federal District Courts in Hatch-Waxman trials and the Federal Circuit. Filko has been repeatedly recognized as an expert in patent litigation by the *Legal 500* and as a leading life sciences lawyer by *LMG Life Sciences*. Filko was most recently named as a leading practitioner by Law Business Research in its "*Who's Who Legal: Patents 2016*" publication.

Gerald Quirk

Gerald Quirk is Chief Legal Officer at Syros Pharmaceuticals, Inc. (Nasdaq: SYRS), a Cambridge, Massachusetts-based company that is pioneering the understanding of the non-coding region of the genome to advance a new wave of medicines that control expression of disease-driving genes. Syros has built a proprietary platform to systematically and efficiently analyze this unexploited region of DNA in human disease tissue to identify and drug novel targets linked to genomically-defined patient populations. Mr. Quirk has more than 20 years of senior leadership and legal experience in the biotechnology industry, including as Executive Vice President of Business Operations and General Counsel at Tokai Pharmaceuticals, where he was responsible for legal and business operations, including human resources, corporate communications and information technology, as Vice President of Corporate Affairs and General Counsel at Infinity Pharmaceuticals with responsibility for the company's legal, intellectual property, finance and corporate communications activities, and in a number of progressively responsible legal and business development positions at Genzyme Corporation. Mr. Quirk also served as partner and co-chair of the life sciences practice at Choate, Hall & Stewart LLP, where he represented leading biopharmaceutical companies in corporate and securities law matters, and in licensing and product development transactions. Mr. Quirk holds a B.A. in political science from Swarthmore College, an Ed.M. in educational administration from Harvard University, and a J.D. from Northeastern University.

Robert S. Schwartz, Ph.D.



Robert S. Schwartz, Ph.D. focuses his practice on biotechnology and pharmaceutical patent litigation in both district court and patent office proceedings. Dr. Schwartz's primary focus is in the areas of biotechnology, particularly protein biochemistry, cell biology, molecular biology, genomics, proteomics and the chemical arts. Prior to his legal career Dr. Schwartz was a Professor of Medicine at the Albert Einstein College of Medicine where he engaged in grant-funded medical research relating to blood diseases.

Christina Schwarz

Christina Schwartz's practice focuses on complex patent litigation under the Hatch-Waxman Act and contested proceedings before the United States Patent Office, including *inter partes* review proceedings and patent interference proceedings. She has experience counseling clients, providing opinions, and working on cases involving a range of pharmaceutical and biotechnology products, including drugs or treatments for immunosuppression, renal disease, HCV, Pompe disease, schizophrenia, modified dosage forms, drug delivery devices and polymers.

In 2007, Christina served as a law clerk to the Honorable Justice Roger T. Hughes of the Federal Court Canada.

Robert F. Shaffer

Rob Shaffer is an attorney in Finnegan, Henderson, Farabow, Garrett & Dunner, LLP's Washington, D.C. office. He tries cases in a wide spectrum of technologies, including pharmaceutical, medical device, biologics, e-commerce, and mechanical fields. He has served as lead counsel before district courts (judge and jury), arbitrations, and the U.S. International Trade Commission (ITC). Mr. Shaffer regularly leads litigation teams on significant Hatch-Waxman Paragraph IV disputes, representing leading innovative pharmaceutical companies across the country in dozens of major cases.

In addition to his litigation practice, Mr. Shaffer advises clients on a variety of patent matters, including licensing, patent procurement, and pre- and post-litigation strategies. He has written opinions of counsel and has successfully navigated clients through settling complex disputes in private mediation and other alternative dispute resolution proceedings without litigation. Mr. Shaffer holds a JD from George Mason University.

Mark Shtilerman

Mark Shtilerman is a Senior Counsel at Deerfield Management Company L.P. He joined Deerfield in 2014 with more than 14 years' experience of counseling companies in all aspects of intellectual property procurement, enforcement and licensing. Mark is a technically trained patent attorney registered to practice before the US PTO. Prior to Deerfield, Mark was an attorney in nationally recognized law firms, and he was a patent agent at a biotechnology company before then. Mark received a Ph.D. in Biochemistry and Molecular Biophysics from University of Pennsylvania, post-doctoral training at Harvard Medical School and Brigham & Women's Hospital, and a J.D. from Fordham University School of Law.

Professor Saurabh Vishnubhakat

Saurabh Vishnubhakat is an associate professor of law and an associate professor of engineering at the Texas A&M University. He is also a fellow at the Duke Law Center for Innovation Policy. He writes and teaches on intellectual property law, civil procedure, and administrative law, particularly from an empirical perspective. He was previously a faculty fellow at Duke Law School, where he co-taught patent law, and began his career as a legal advisor at the United States Patent and Trademark Office, where he counseled the agency's first two chief economists on IP law and policy. He holds a J.D. and LL.M. in intellectual property law from the University of New Hampshire School of Law (formerly the Franklin Pierce Law Center) and a B.S. in biochemistry from the Georgia Institute of Technology.

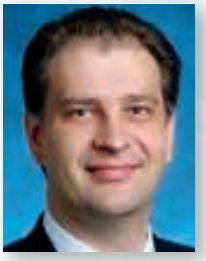
Claire Vasios

Claire Vasios is Vice President of Intellectual Property for Alkermes, a global biopharmaceutical company with its headquarters in Dublin, Ireland. She has been in the lead IP role at Alkermes for over 20 years, managing all aspects of intellectual property relating to the company's discovery, development and commercial programs. Dr. Vasios' responsibilities include patent portfolio development, management of third-party patent disputes in US and international patent offices, providing IP support in the context of business development activities, and strategic input on IP/FDA issues. She leads a team of four patent attorneys, two in Alkermes' Massachusetts office and two European Patent Attorneys located in Ireland. Dr. Vasios is a registered US Patent Agent and holds a Ph.D. degree in Microbiology from the University of Medicine and Dentistry of New Jersey/Rutgers Medical School.

Peter Waibel

Peter Waibel is Vice President, Head of Patent Litigation, for Novartis Pharmaceuticals Corporation. Mr. Waibel is responsible for management of all aspects of patent litigation for Novartis' innovator pharmaceutical and biopharmaceutical products in the US and Canada, including the support of all Hatch-Waxman related activities, such as Orange Book listings, Paragraph IV certifications and other regulatory issues associated with patents and exclusivities. Prior to joining Novartis, Mr. Waibel was a Senior Patent Attorney for NovoNordisk after practicing patent law at Frommer, Lawrence and Haug. Before joining Frommer, Mr. Waibel worked in the pharmaceutical industry in a number of technical and regulatory areas engaged in a variety of activities in the pharmaceutical, biotechnology and diagnostics industries prior to attending law school. Mr. Waibel holds a J.D. from Saint John's University, a M.S. in Applied Mathematics and Statistics from New York University and a M.S. in Medicinal Chemistry from the Saint John's University College of Pharmacy.

Willem F.C. de Weerd



Currently Corporate Patent Counsel at Merck Serono in Switzerland responsible for IP matters globally relating to biologics, biosimilars, and medical devices. Responsible for all aspects relating to IP, including strategic planning, licensing, pre-litigation and litigation activities, as well as supporting R&D in order to expand Merck Serono's patent portfolio. Previously in private practice at Kenyon & Kenyon LLP in New York providing clients of the firm in the life sciences field with legal opinions on IP related matters and obtaining patent rights for clients. Prior to joining Kenyon & Kenyon practiced patent law at Rothwell, Figg, Ernst & Manbeck in Washington DC focusing on Hatch Waxman litigation. Before embarking on a legal career obtained a Ph.D. in Biochemistry.

Ha Kung Wong

Ha Kung Wong practices general intellectual property law with an emphasis on complex patent and trade secret litigation in pharmaceuticals, biologics and chemistry. Cases Mr. Wong has litigated include those related to proton pump inhibitors, anti-epileptic drugs, anti-tussives and other pharmaceuticals. Mr. Wong also has extensive experience with intellectual property counseling, pre-suit investigations, licensing and due diligence.

Mr. Wong currently is the Chair of the Recruiting Committee, serves as faculty for NITA (the National Institute of Trial Advocacy) and Lawline, and has been named a "Furthered 40" by Lawline for his contributions.

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Proskauer's collaborative Life Sciences Patent practice focuses on partnering with leading biologics, pharmaceutical, biotechnology and medical device clients to meet their business objectives by developing and executing market exclusivity and freedom-to-operate strategies.

We employ comprehensive strategies that draw from our deep knowledge of and extensive experience with patent litigation, contested patent office proceedings, FDA regulations, patent prosecution and patent transactions, including licenses and assignments.

We are pleased to welcome our newest partner and Vice Chair of our Life Sciences Patent practice, Boston-based Fangli Chen, Ph.D., who joined the firm on March 1, 2016.

For more information about our Life Sciences Patent practice, please contact:

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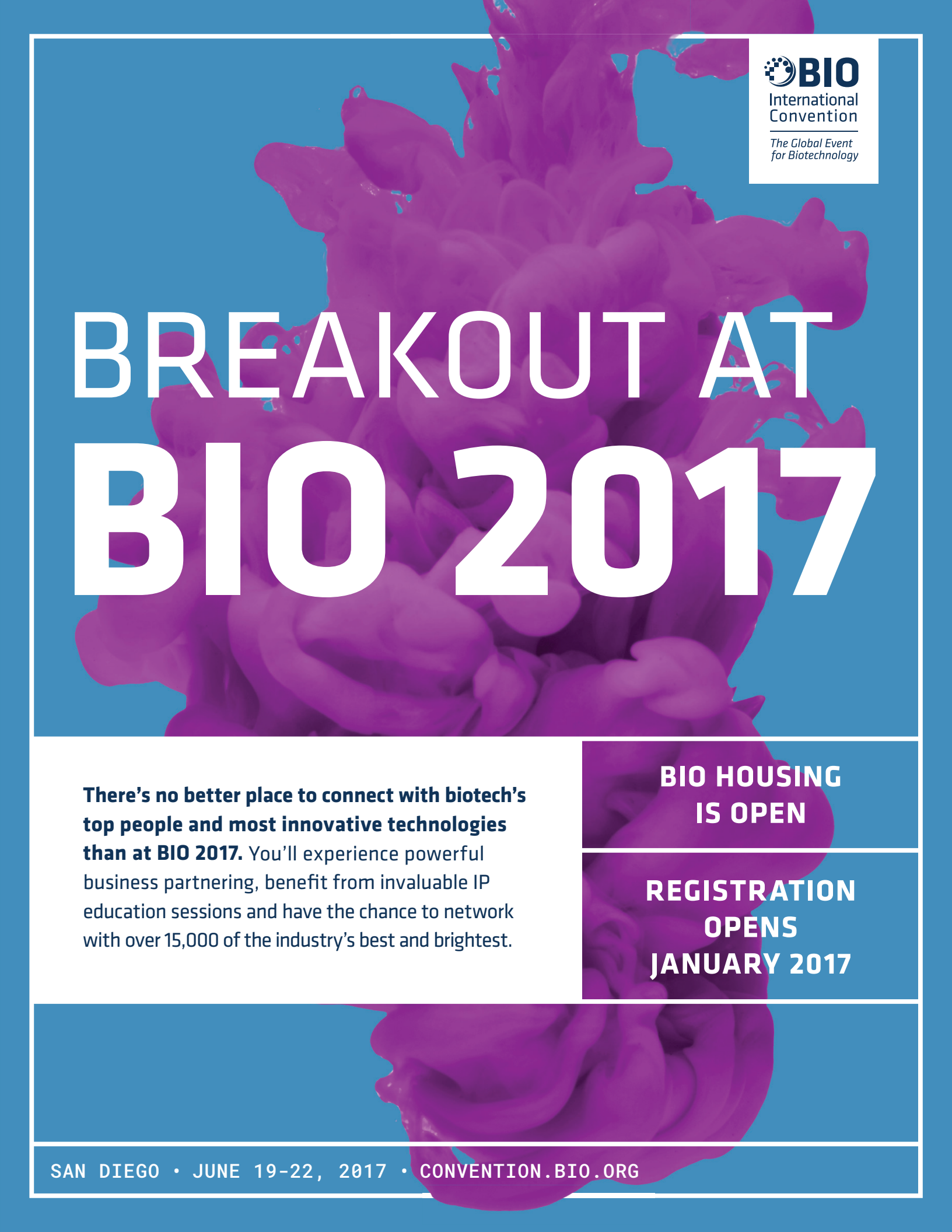
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