

Chemistry and the Law

NEWSLETTER

CHAIR'S MESSAGE

JONATHAN L. KENNEDY



As Chair of the Division of Chemistry and the Law (CHAL), I thank you for your interest in our Division and for reading our Fall newsletter. We are excited to inform you of some new things going on with CHAL.

CHAL has been actively seeking to expand our digital presence and contact with our members. This has included development of CHAL LinkedIn page (www.linkedin.com/company/acs-chemistry-and-the-law/) as well as a redesigned website (www.chemistryandthelaw.org). We are hoping that these updated platforms will help us more actively engage with our members. We encourage you to follow our LinkedIn page for updates with CHAL and check out our website for information on getting involved with CHAL or simply to view our newsletters or webinar series.

The August meeting in Boston will feature CHAL's traditional schedule of events, including, the not-to-be-missed **CHAL reception on Monday, August 20th from 6 - 8 PM** in Room 258C of the Boston Convention & Exhibition Center. This of course is open to all and will feature complimentary appetizers and drinks. We look forward to seeing you there.

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CHAIR'S MESSAGE

Other places we hope to see you at the Boston meeting include our public Executive Committee meeting, networking lunch, Division Row at Sci-Mix, and during our programming.

We want to thank the Finnegan, Henderson, Farabow, Garrett & Dunner, LLP law firm for hosting our Executive Committee meeting at their office located at 2 Seaport Lane, Boston, MA 02210 on **Sunday, August 19th from 5 - 7 PM**. As always, our Executive Committee meeting is open to the public and you are more than welcome to join us. Even if you cannot attend the Executive Committee meeting in Boston, you are always welcome to join our monthly teleconferences and get more involved with CHAL.

CHAL also invites you to join its networking lunch on **Monday, August 20th from 12 - 1:30 PM** in the Webster Room at the Westin. Tickets for the lunch are still available.

CHAL is also excited to be participating in Division Row during Sci-Mix on **Monday, August 20th from 8 - 10 PM** in the exhibitor hall. Please stop by our poster among the other divisions. We would love to see you there!

Our Boston programming includes a great lineup of speakers on a variety of topics related to chemistry and the law. We have talks addressing recent court decisions affecting chemical patents, developments in pharmaceutical patent law, extensions to patent term in the U.S. and abroad, developments in protecting nanotechnology, protecting your ideas in the chemical arts, non-traditional careers in chemistry, and a variety of other topics including drug compounding

legislation, patent strategy supporting business objectives in renewable energy, blockchain technology and the chemical industry, patents as a research tool, and deriving insights from IP search reports.

In addition to the programming at National Meetings covering a variety of topics intersecting law and chemistry, CHAL is offering a webinar series through ACS webinars again. We hope that you keep an eye out for our webinars through our new LinkedIn page as well as our website where we are arranging for old webinars to be archived and viewable. Additionally, if there are topics that you wish to see presented on, either in our programming at the National Meetings or in our webinar series, please reach out to let us know. CHAL seeks to be a resource to the ACS members so that you can stay on top of the legal developments that impact chemical industry and business.

We are looking forward to the Spring meeting in Orlando focused on Chemistry and New Frontiers. It is not too late to submit an abstract for programming with CHAL. Please feel free to submit an abstract or plan a symposium dealing with law and chemistry. Our abstract submission deadline for the Spring meeting can be viewed on our LinkedIn page and our new website.

For those attending the National Meeting in Boston, we hope you enjoy the conference and have an opportunity to attend some of our programming.

Jonathan L. Kennedy

COUNCILORS' REPORT

COUNCILORS' REPORT

ALAN EHRLICH & JIM CARVER

Items for 256th Meeting - Boston.

The Council meets at 8:00 AM, Wednesday, August 22 in Ballrooms A-C at the Hynes Convention Center. Non-Councilors may attend, but must sit in a separate section.

The Council will elect committee members to three committees for 2019-2021. These are the Council Policy Committee, the Committee on Nominations and Elections, and the Committee on Committees.

The Council will also vote on two petitions for Bylaw amendments. The Bylaw on Affiliation with Other Technical Organizations currently requires approval by the respective Local Section or Division governing body as well as the Committee on Constitution and Bylaws. The petition will add an additional approval step by the respective Council Committee on Local Sections or Divisions.

The second petition will remove prohibitions on International Chemical Sciences Chapters receiving funds from the Society and on Council representation. The petition is similar to one defeated in the Washington, DC meeting by 8 votes. The revised language is designed to address objections raised in Washington.

A third petition is on the agenda for

consideration, meaning it is not discussed at this meeting but is up for action in the next (Orlando) meeting. The petition is directed to Streamlining ACS documents. This petition comes out of the Joint Board-Council Policy Committee Task Force on Government Design. The intent is to rearrange the Constitution and Bylaws and add Standing Rules so that the hierarchy for each document is internally consistent - the Constitution defining, the Bylaws authorizing, and the Standing Rules operationalizing (to coin a word). That is, moving from Constitution to Bylaws to Standing Rules will provide progressively more detail and become progressively easy to amend. In this petition, there will be no substantive changes to current provisions, only restructuring.

A Special Discussion Item is also on the Council Agenda. The topic is "What role(s) should ACS play in preventing sexual harassment in the sciences?"

Finally, there is a petition to Charter an International Sciences Chapter in Colombia.

Directors-at-Large are elected only by Councilors in the Fall election cycle. However, there is a Town Hall meeting for candidates for 2019-2021 that is open to all, Sunday, August 19, 4:30 - 5:30, Constitution A/B, Sheraton Boston Hotel. There is also an opportunity to meet the Candidates for President-Elect for 2019, Luis Echegoyen and Thomas Gilbert, Monday, August 20, 1 - 4 PM, near the Poster Session Area of the ACS Exposition, Exhibit Hall A, Boston Convention & Exhibition Center.

COUNCILORS' REPORT

Items from 255th Meeting - New Orleans.

The Council heard presentations by four nominees for President-Elect for 2019 - Harmon B. Abrahamson, Luis A. Echegoyen, Thomas R. Gilbert, and Mary Virginia Orna. The Council selected Luis A. Echegoyen and Thomas R. Gilbert as candidates. There were no subsequent petition candidates.

Two District Directors are elected each year by ACS members in the respective districts. This year, Directors from Districts I (northeast) and District V (midwest) will be elected for 2019-2021. Candidates are selected by Councilors from those districts from nominees selected by the Committee on Nomination and Elections (N&E). For District I, the candidates are Katherine Lee and Laura Pence. For District V, the candidates are John Adams and Joseph Heppert.

Two Directors-at-Large are elected by Councilors each year from candidates selected by N&E. For 2019-2021 terms the candidates are Frank Blum, Lee Latimer, Ingrid Montes and Angela Peters. There were no petition candidates.

The Council approved a Petition on the Composition of Society Committees, which will change the requirement for Councilors on Society Committees from at least two thirds (2/3) to a majority, and remove the requirement that the Chair and Vice-Chair of a Society Committee must be Councilors.

However, a Petition for Election of Committee Chairs, which would have allowed

the voting members of all ACS committees to select their own Chairs, failed to gain the approval of Council.

The Council voted to set the member dues for 2019 at \$175. This rate is established pursuant to an inflation-adjustment formula in the ACS Constitution and Bylaws.

A proposed formula for allocating dues funds to divisions, recommended by the Committee on Divisional Activities, was recommitted to the committee.

The Council approved the recommendation of the Committee on Committees that the Committee on Ethics be continued; and that the committees on Publications and on Younger Chemists be continued contingent on approval by the Board of Directors.

In 2017, ACS generated a Net from Operations of \$28.6 million, which was \$4.8 million higher than 2016. Total revenues were \$553.1 million, increasing 5.0% or \$26.4 million over 2016. Expenses ended the year at \$524.5 million, which was \$21.6 million or 4.3% higher than prior year. This was attributable to strong performance from the Society's Information Service units (CAS and ACS Publications) and a continued emphasis on expense management across the ACS.

Additional information can be found at www.acs.org. At bottom, click 'About ACS', then 'ACS Financial Information'. There you will find several years of the Society's audited financial statements and IRS 990 filings.

COUNCILORS' REPORT

ACS ended 2017 with over 150,000 members. While this means that ACS remains the world's largest scientific society, this number represents a continuing decline in overall membership for the sixth year in a row. The Committee on Membership Affairs is committed to working with Council, the Board of Directors, the Committee on Budget and Finance, ACS staff, and other stakeholders to halt this trend and return ACS to a growing and engaged membership.

As of Monday, March 19, total attendance at the New Orleans meeting was 16,585 (final count 16,752). This is higher than either the Spring, 2013

and Spring, 2008 meetings in New Orleans and well above the median of all meetings over the past 10 years (14,000).

The ACS Board of Directors met in Open Session on March 18, which featured a presentation from Dr. Lisa M. Balbes (Balbes Consultants, LLC) on *Nontraditional Careers in Chemistry: Thinking Outside the Beaker*. She also introduced two alumni from the ACS Scholars Program, Brandon Presley and Isa Watson, who briefly shared their career paths to date with the assembled audience.

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References, including internet sites, cited as bibliography or for general interest, are intended for readers' convenience only, and are not endorsed as to opinions or for detailed accuracy or timeliness, which are the responsibilities of the authors and publishers of those references. Internet site citations were thought to be timely within a few weeks before this newsletter would be fixed for publication; however, some may have become stale. Mention of publications, products, or services is intended for readers' convenience only and not as commercial endorsement. Discussion of legal issues is for information and educational purposes and is not legal advice; legal advice should be sought from licensed lawyers formally consulted for that purpose. Readers' comments are welcome and future articles from them are invited -- especially to broaden the range of topics and viewpoints -- address all inquiries to chal@chemistryandthelaw.org.

SCHEDULE OF EVENTS

Sunday
August
19

2:00 PM - 3:30 PM
Strengthening Your Patent Rights in Light of Recent Federal Circuit Court Decisions

Organizers and Presiding: X. Pillai and A. Berks
Room 154, Boston Convention & Exhibition Center

5:00 PM - 7:00 PM
CHAL Executive Committee Meeting,
Finnegan LLP, 2 Seaport Lane, Boston, MA

Monday
August
20

9:00 AM - 11:30 AM
Developments in Pharmaceutical Patent Law

Organizer and Presiding: Brian Trinque
Room 154, Boston Convention & Exhibition Center

12:00 PM - 1:30 PM
CHAL Networking Lunch
Webster Room, Westin

2:15 PM - 4:30 PM
Extensions to Patent Term in the U.S. and Worldwide
Organizer and Presiding: Richard Bone
Room 154, Boston Convention & Exhibition Center

6:00 PM - 8:00 PM
CHAL Networking Reception
Room 258C of the Boston Convention & Exhibition Center

8:00 PM - 10:00 PM
SCI-MIX
Exhibit Halls B2/C Convention Center

Tuesday
August
21

9:30 AM - 12:00 PM
Recent Developments in Protection of Nanotechnology-Related Intellectual Property

Organizer and Presiding: Krista Bianco and Kristi McIntyre
Room 154, Boston Convention & Exhibition Center; Co-sponsored by MPPG

1:00 PM - 5:00 PM
Protecting Your Ideas in the Chemical Arts
Organizer and Presiding: Alina Khankin
Room 154, Boston Convention & Exhibition Center
Co-sponsored by SCHB

Wednesday
August
22

9:30 AM - 12:00 PM
Non-Traditional Careers in Chemistry

Organizers and Presiding: Krista Bianco and Kristi McIntyre
Room 154, Boston Convention & Exhibition Center
Co-sponsored by PROF, SCHB, WCC, and YCC

1:30 PM - 4:00 PM
The Many Faces of CHAL: Where Chemistry Meets the Law
Organizer and Presiding: Krista Bianco
Room 154, Boston Convention & Exhibition Center

CHAL NETWORKING & MEETING HIGHLIGHTS

Monday
August
20

CHAL Networking Luncheon

12:00 PM - 1:30 PM

Webster Room, Westin (next to convention center)
(Note: a ticket is required for this event)

Sponsors:  REED TECH
A LexisNexis® Company  LexisNexis®

Presentation: “Leveraging Big Data and Business Intelligence throughout the Patent Lifecycle,”
Jesse Sands

Monday
August
20

CHAL Reception

6:00 PM - 8:00 PM

Room 258C, Boston Convention & Exhibition Center
Open Bar and Hors D’oeuvres

Sponsors:  LATHROP GAGE  McDermott Will & Emery

All Attendees welcome – No ticket required!

Meeting Highlights

Monday morning, August 20

Developments in Pharmaceutical Patent Law

Pharmaceutical Patent Prosecution Primer

Dr. Brian Trinqué, Lathrop Gage LLP, Boston MA

Abstract: The pharmaceutical patenting process includes identifying an invention, writing a patent application that protects that invention, and prosecuting the application before the U.S. Patent Office (and patent offices throughout the world). A basic understanding of this process is a must for any scientist (academic, industrial, or otherwise). This talk will provide an overview

of our current patent laws, and demonstrate how those laws are applied to a variety of pharmaceutical innovations, such as novel chemical entities and formulations. This talk will also provide a foundation for understanding the rest of today’s discussions.

Obviousness, the CAFC, and Second Generation Filing Strategies

Dr. Benjamin A. Vaughan and Dr. Nicole Sassu, Lathrop Gage LLP, Boston MA

Abstract: This lecture provides an overview of obviousness as it relates to pharmaceuticals and commercial drug formulations. Additionally, patent strategies and the most recent federal circuit cases relating to “second generation” filings, which are directed toward discoveries involving previously-



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known pharmaceuticals, such as pharmaceutical formulations, dosing strategies, and combination therapies will be discussed. Relevant case law related to second generation filings will be reviewed to provide important insight into effective patent specification and claim drafting strategies for such discoveries. This presentation will be useful to those with all levels of experience in pharmaceutical patent law.

What Constitutes an Inventor? A Review of Federal Circuit Case Law

*Dr. Andrew Ehle, Lathrop Gage LLP,
Boston MA*

Abstract: Determining inventorship is a crucial part of intellectual property law. Often, disputes about who should be listed as an inventor on a given patent application can only be resolved by examining the specific contributions of each person involved in the research that led to the patentable material. To examine the legal context for what constitutes “significant contribution to the invention,” and thereby inventorship, several key Federal Circuit Cases will be discussed. This presentation will be useful to those with all levels of experience in pharmaceutical patent law.

Definiteness and the Medicines Co. and Forest Labs. Decisions

*Dr. Brian Trinque, Lathrop Gage LLP,
Boston MA*

Abstract: Pharmaceutical patent practitioners implement IP strategies for medicines well beyond the granting of a basic composition-of-matter patent. Novel formulations,

combination therapies, dosing strategies, and patient stratifications are just a few examples of the discoveries arising from clinical development that can inspire new patent applications, which will protect these inventions, and, importantly, extend patent protection for a product. Practitioners must often strike a balance between the trifecta of the examples, which illustrate the discovery and serve as a building block for the filing; the specification, which provides an invention narrative that advocates for successful patenting; and, finally, claim breadth, which one hopes to maximize, but is grounded by the realities of novelty, obviousness, written description, and enablement. The *Forest Labs., Inc. v. Teva Pharms. USA, Inc.*, decision, which was released at the end of 2017, and the *The Medicines Co. v. Mylan* decision before it, are important reminders that claim definiteness must be given equal weight when preparing applications directed toward such “second generation” pharmaceutical discoveries. In particular, these decisions show that our definiteness requirements can impact patent prosecution, as well as claim interpretation and validity during an infringement action.

Meeting Highlights **Monday afternoon, August 20** *Extensions to Patent Term in the U.S. & Worldwide*

Extensions to patent term in the U.S. and worldwide

*Richard Bone, McDermott Will & Emery LLP,
Menlo Park, CA*

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Abstract: This symposium will address methods of obtaining patent terms that extend beyond the normal 20-year terms afforded by most countries. The Hatch-Waxman regime in the U.S. provides a system for awarding extensions to patent term for drug products that have been subjected to a regulatory approval process. Patent Term Adjustment is now also a key component of a strategy to extend U.S. patent term. Other countries worldwide offer Supplementary Protection Certificates to provide patentees with extended coverage for products that have received marketing authorization. These provisions, when coupled with data exclusivity possibilities, provide a valuable extension of rights for approved drug products.

Patent term extension in the U.S.

Kristin Connarn, McDermott Will & Emery LLP, Boston, MA

Abstract: Patent term extension (PTE) is a valuable benefit to developers of patented small molecule pharmaceutical products that exists within the Hatch Waxman framework. Nevertheless, the PTE statute, 35 U.S.C. § 156, embodies limitations that are quite stringent and mean that most patent holders need to strategize carefully in order to maximize the potential extension to term that can be afforded. Although there has been only a small amount of litigation to test the language of 35 U.S.C. § 156, the cases that have been decided have had an important impact on defining the scope of the extension.

Supplementary protection certificates in the European Union

Isobel Finnie, Haseltine Lake LLP, Bristol, UK

Abstract: Holders of patents to medicinal products in Europe must use Supplementary Protection Certificates (SPCs) to secure extensions of protection as compensation for delays to marketability arising from the regulatory approval process. SPCs, though creatures of national patent offices, have given rise to a unique body of case law, at the national level as well as at the Court of Justice of the European Union. We will review the statutory framework that governs SPC practice, as well as strategies for obtaining SPCs in as many European jurisdictions as is practicable.

Patent term extensions and data exclusivity in Australia, New Zealand and South East Asia

Jess Gledhill¹, John Landells², jlandells@fbrice.com.au. (1) FB Rice, Sydney, New South Wales, Australia (2) FB Rice, Melbourne, Victoria, Australia

Abstract: Getting the most value out of aging key patents means exploring options to extend patents past their standard 20 year term. Only some countries allow for such patent term extensions and there are varying differences between those countries. This presentation will address the legal requirements for patent term extensions relating to pharmaceutical patents in Australia and Singapore, the two countries in the region that permit patent term extensions. In particular, the presentation will explore the value and difficulties in obtaining patent term extensions including conditions that must be satisfied for the grant of an extension of term (including claim type), calculation of extension term, rights during the extension period, and relevant recent case law. The presentation will also address the more broadly available form of supplemental protection,

CHAL MEETING HIGHLIGHTS

that being data exclusivity (the protection of clinical test data), in Australia, New Zealand and South East Asia (including Singapore, Malaysia and Vietnam).

Patent term adjustment in the U.S.

*Richard Bone, McDermott Will & Emery LLP,
Menlo Park, CA*

Abstract: The U.S. has also for almost two decades operated a scheme for compensating all patentees for certain types of delay that occur

during examination of a patent application. This system has been tested in litigation many times now, invariably by pharmaceutical companies. I will explain the basic structure of patent term adjustment calculation, illustrated by several of the key cases that have probed potential ambiguities in the statutory framework. I will also explain the potential perils of obviousness type double patenting in complex patent families. The combination of patent term adjustment and patent term extension offers a unique framework for maximizing patent term in the U.S.

Other Symposia Co-Sponsored by CHAL

Sunday, August 19 (Day): Chemical Structure Searching for Patent Information

Sponsored by CINF, Cosponsored by CHAL and CPRM

Tuesday, August 21 (Afternoon): NASA Space Symposium

Sponsored by PMSE, Cosponsored by CHAL and 22 other divisions

Sunday, August 19 (Afternoon): Intellectual Property Basics for Chemical Businesses

Sponsored by SCHB, Cosponsored by CHAL and PROF

Wednesday, August 22 (Day): Pesticides & Chemophobia in the News: What You Need to Know as a Scientist & Consumer

Sponsored by AGRO, Cosponsored by AGFD, CHAL, CHAS and ENVR

CHAL PROGRAMMING

Call for Abstracts

The Division of Chemistry and the Law is currently accepting papers and symposia for the 257th National Meeting of the American Chemical Society, to be held March 31 - April 4, 2019, in Orlando, FL.

CHAL welcomes submissions on all legal topics impacting the chemical sciences, including, but not limited to, intellectual property, patents, copyrights, trademarks, trade secrets, forensic chemistry, food and drug law, regulatory law, product liability, tort law, environmental law, employment agreements, professional ethics, expert witnesses, chemical consulting, chemical health and safety, chemical information, administrative law and rule making, biotechnology, pharmaceuticals, licensing and technology transfers, and litigation.

Please submit abstracts for individual presentations or Sci-Mix posters on-line through MAPS at <https://acsmaps.abstractcentral.com/members/client/acs.jsp> under the session entitled "The Many Faces of CHAL: Where Chemistry Meets the Law." Abstracts must be submitted by November 5, 2018.

For submission of half-day or full-day symposia with multiple speakers, please contact Krista Bianco at krista.bianco@finnegan.com or Kristi L. McIntyre at kristi.mcintyre@finnegan.com.

Announcing CHAL's Website Redesign and Formation of LinkedIn Group

CHAL is pleased to announce the launch of its redesigned webpage. Check out <https://www.chemistryandthelaw.org/> for recent announcements, archives of past CHAL webinars and newsletters, and information on how to become involved in CHAL.

To further connect with CHAL and other CHAL members, you can also follow CHAL on LinkedIn at <https://www.linkedin.com/company/acs-chemistry-and-the-law/>.

CHAL FEATURED ARTICLE

Elaine Cheeseman
Science IP

The CAS Transformation Story: Scientific Information Solutions to Accelerate Innovation

For decades, CAS, a division of the ACS, has been providing the content and chemical information solutions that fuel global innovation. Now we can do more to help you tackle your biggest information challenges and opportunities. With over 100 years' experience, no one knows more about working with scientific information than CAS. We have the unique content collection, unmatched subject matter expertise, and specialized technology needed to solve big scientific information challenges.

As a strategic shift for CAS, organizations now have unrestricted access to the value possible from a relationship with CAS.

Now CAS is available to work with organizations on projects such as:

- Integration with proprietary data and workflows
- Access to CAS technology, content, and expertise
- World-class products like STN and SciFinder n
- Highly customized services

It begins with global innovation

Every single day, thousands of new scientific publications reveal novel discoveries. CAS collects and analyzes the world's disclosed science to help advance discovery.

Scientists serving science

CAS employs hundreds of scientists who read the literature every day to extract, organize, and connect the valuable details within. These scientists have amassed a wealth of knowledge that assists them in uncovering insights and trends not found by technology alone.

Developing new technology

Our developers build chemically-intelligent solutions, such as SciFinder® and STN® that leverage and integrate scientific

information to solve big data challenges.

Delivering insight

CAS products and services provide comprehensive, reliable answers to a myriad of questions that researchers, business leaders and information professionals ask every day.

Making an impact

Having the right information at the right time is the foundation of successful and efficient innovation. Partnering with CAS empowers organizations around the world to turn information into a strategic advantage.

CAS products:

CAS offers a wide range of solutions designed to meet the needs of research, patent, regulatory, and business professionals in every phase of the innovation process. Built on the foundation of the robust CAS content collection, our products will help you get there faster. Our products include SciFinder/SciFinderⁿ, STN, PatentPak, NCITM Global, MethodsNow[®], and ChemZentTM.

CAS services:

Your organization's scientific knowledge needs can change very rapidly, leaving gaps that stress teams and put the success of important projects at risk. In today's dynamic environment, it is challenging to maintain the diverse talent pool you need to adequately staff all your innovation projects while effectively managing your costs. What if you had a reliable source of experts with a wide range of skills that you could call upon anytime you needed to fill gaps? Let us know how we can help you.

Please visit our web site at www.cas.org, call us at 800-848-6538 (North America), or email us at help@cas.org.

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