

C5's 18th Annual Forum on

PHARMA & BIOTECH PATENT LITIGATION

IN EUROPE

21 – 22 May 2025

Radisson BLU Hotel, Amsterdam City Center
Amsterdam

2025 Conference Co-Chairs:



Liz Cohen
Partner
Bristows LLP



Dr. Kai Rüting
Partner
Vossius & Partner



Ruud van der Velden
Partner
Hogan Lovells

UPC Judges:



Hon. Peter Blok
Presiding Judge
Unified Patent Court,
Court of Appeal,
Luxembourg




Mr. Edger F. Brinkman
Judge
Unified Patent Court,
the Hague

Attend to Gain Insights, Global Perspectives and Develop Winning Strategies. Our Stellar Faculty will Help You:

- » **ANALYZE** the emerging litigation trends in the UPC and national courts
- » **ENGAGE** with Judges from the UPC
- » **DEMYSTIFY** forum selection and parallel proceedings
- » **NAVIGATE** the evolving EU regulatory landscape and its impact on IP
- » **ADAPT** to EU competition law enforcement trends and cadence
- » **FINE-TUNE** your SPC strategies

Association and In-House Insights From:

- Adalvo
- AstraZeneca
- EFPIA
- Farmaprojects S.A.U.
- Fresenius Kabi
- Medicines for Europe
- Merck Sharp & Dohme
- Sanofi
- VIZGEN



After a transformative first year, the body of case law from the UPC continues to expand—bringing clarity in some areas while introducing uncertainty in others, particularly where national and international laws conflict or diverge. Coupled with ongoing regulatory reforms, these developments place life sciences IP lawyers at a critical juncture, requiring a keen understanding of the far-reaching implications and emerging challenge.

C5's 18th Annual Forum on Pharma & Biotech Patent Litigation in Europe stands as a pivotal assembly for legal professionals and life sciences executives navigating the ever-evolving terrain of pharmaceutical and biotechnological patent law. In a year marked by significant legal shifts and regulatory transformations, this forum is designed to dissect, understand, and forecast the implications of these changes on the industry. From the developing case law and operational nuances of the Unified Patent Court (UPC) to the intricacies of international patent litigation and the latest in EU regulatory reforms, the forum promises a comprehensive exploration of the current patent litigation landscape.

The forum also serves as a prime networking opportunity, bringing together the elite of the European life sciences patent bar to exchange ideas, share experiences, and forge connections that will drive the future of the field. **Whether you're a litigator defending the interests of a pharma/biotech company, or in-house counsel navigating the patent challenges of a global pharma corporation, this event is poised to offer valuable perspectives and actionable insights.**

Join us at C5's 18th Annual Forum to engage with the forefront of legal and regulatory developments in pharma and biotech patent litigation. **Together, we will explore the latest challenges and opportunities, shaping the strategies that will define the future of the industry.**



Liz Cohen, Partner, Bristows LLP

I'm very much looking forward to Co-chairing and Speaking at this year's C5 Pharma & Biotech Patent Litigation Forum in Amsterdam. With an interesting agenda covering a number of thought provoking topics, together with a wide variety of expert speakers, it promises to be another engaging and excellent event.

Dr. Kai Rüting, Partner, Vossius & Partner

The C5 Pharma & Biotech Patent Litigation conference is always a great forum to get the most recent updates and trends on cross-border life sciences litigation. I think this year's event will be exceptional because we will discuss and analyze the first pharma and biotech decisions of the Unified Patent Court with in-house counsel, litigators and judges. I look forward exchanging experiences and ideas in these dynamic times as well as engaging in discussions on key developments and strategies.

Ruud van der Velden, Partner, Hogan Lovells

The upcoming C5 Pharma & Biotech Patent Litigation conference in Amsterdam promises to be a great event, with insights from in-house counsel, litigators and judges on various hot topics, including developments in the national courts, the EPO and the UPC, as well as regulation reforms and public policy. I'm very much looking forward to co-chairing the event, seeing many familiar and new faces and having some interesting debates!

Complimentary Webinar

Preliminary Forum Selection Insights & Strategies

16 APRIL 2025 • 13H00–14H00 CET

Hosted by



Liz Cohen
Partner, **Bristows LLP**



Dr. Kai Rüting
Partner, **Vossius & Partner**



Gertjan Kuipers
Partner, **Hogan Lovells**

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C5's Global Life Sciences IP Advisory board was created as a part of C5's ongoing effort to provide industry leading content and a world renowned speaker faculty. The board is composed of a selection of advisers from around the globe, including leading pharmaceutical and biotech companies. This 'inner circle' counsels C5 on the impact of litigation trends and emerging topics.

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Mr. Edger F. Brinkman
Legally Qualified Judge,
Local Division, The Hague
Unified Patent Court



Hon. Peter Blok
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Member
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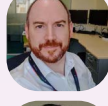
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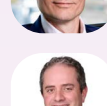
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Oscar Lamme
Partner | UPC Representative
Simmons & Simmons
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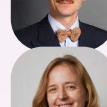
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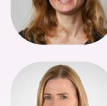
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Bird & Bird



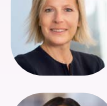
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UK Patent Attorney
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Ingrid Vandenborre
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Goodwin Procter LLP



Dr. Tobias Wuttke
Equity Partner
BARDEHLE PAGENBERG



Dr. Jörk Zwicker
Partner
Zwicker Schnappauf & Partner

21 May | Day One

Good networking opportunities with in-house Counsel and leading IP law firms. Hot topics, great speakers and convenient number of attendants.

Anna Lopez Lozano, ESTEVE QUÍMICA

7h45 Registration and Breakfast

8h45 Opening Remarks and Year in Review from the Conference Co-Chairs



Liz Cohen
Partner
Bristows LLP



Dr. Kai Rütting
Partner
Vossius & Partner



Ruud van der Velden
Partner
Hogan Lovells

C5'S UPC INSTITUTE

9h15 **Plausibility and Post-Publication Evidence in Inventive Step: Emerging Trends Since G2/21**

- Analyzing the guiding principles set by the Enlarged Board for using post-published evidence in inventive step assessment in the G2/21 decision and subsequent written decision of T0116/18 (the referring case which led to the G2/21 decision)
- Differentiating between the EPO approach and that used by the UPC
- Reconciling the EPO's application with national courts and navigating inconsistent applications
 - E.g., Dutch court of appeal issued two recent decisions on plausibility, but these are not applied at the EPO
- Detailing the impact of these decisions on determining inventive step and devising strategies for effectively incorporating post-published evidence in light of national, UPC and EPO decisions

Dr. Sönke Holtorf
Director, Biotechnology
European Patent Office



Dr. Eva Ehlich
Partner
Maiwald Intellectual Property

MODERATED BY:

Dr. Ian Jones
European & UK Patent Attorney /
UPC Representative
Gill Jennings & Every LLP



10h15 **Navigating Preliminary Injunctions at the UPC: Key Developments and National Comparisons**

- Analyzing the developing caselaw for preliminary injunctions at the UPC
- Establishing "sufficient certainty" that the patent in suit is valid and infringed
- Interpreting the standard of "urgency" throughout the Local Divisions
 - E.g., "imminent infringement" (in the biosimilar preliminary injunction case between Novartis and Celltrion)
 - E.g., "unreasonable delay" (UPC Court of Appeal in Ortovox v Mammut)
- Navigating the presumptions with respect to irreparable harm
- Identifying the prerequisites for re-opening a UPC preliminary injunction case
 - E.g., in the diagnostic device case between NanoString and 10x Genomics



Simona Levi, Ph.D.
Chief Legal Officer
VIZGEN



Dr. Tobias Wuttke
Equity Partner
BARDEHLE
PAGENBERG



Dr. Moritz Schroeder
Partner
Bird & Bird



MODERATED BY:
Anita Varma
Partner
White & Case LLP

11h00 Networking Break



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11h15 **UPC Judge's Panel: Insights from the Bench**



Hon. Peter Blok
Presiding Judge
**Unified Patent Court,
Court of Appeal, the Hague**



Mr. Edger F. Brinkman
Legally Qualified Judge,
Local Division, The Hague
Unified Patent Court



INTERVIEWED BY:
Professor Willem Hoyng
Partner, **Hoyng Rokh Monegier**
Chairman, **Advisory Committee
of the UPC**
Member, **Drafting Committee of the
Rules of Proceedings of the UPC**

In this special fireside chat, attendees will benefit from a firsthand judicial accounting of how the UPC has influenced patent litigation in Europe, including changes in procedural dynamics, case management, and decision-making trends.

12h00 **G1/24 Referral on Claim Interpretation When Assessing Patentability: Resolving Disharmony in EPO and UPC Case Law?**

The EPO Enlarged Board of Appeal has heard oral arguments on a critical question: whether or not, and to what extent, the claims of a European patent can be interpreted using the description and figures. Settling the disharmony of EPO case law, and harmonizing the EPO and UPC's approach, will provide important guidance on how to interpret the validity of the patent and the scope of protection provided by the patent. Topics of discussion include:

- Identifying the key cases that led to the divergence in EPO case law with reference to Articles 69 and 84 EPC
 - E.g., the approach used in T 0169/20, T 0223/05, T 1924/20 versus the approach used in T 556/02, T 1473/19, and the ongoing proceedings in T 439/22 (where the Board referred the claim interpretation questions to the Enlarged Board of Appeal)
- Identifying the UPC's approach to claim interpretation at first instance and at the Court of Appeal
 - E.g., the first instance infringement action filed by 10x Genomics against NanoString; NanoString's subsequent appeal (CoA decision UPC_CoA_335/2023); and NanoString's parallel EPO opposition proceedings
- Analyzing the submissions of the amicus curiae briefs and the letter from the president of the EPO for the referral
- Summarizing the oral arguments in the referral (scheduled to be heard March 2025)
- Forecasting the Enlarged Board's decision and adjusting patentability strategies accordingly



Sabrina Duschner
Vice-President, Patent Litigation
Fresenius Kabi



Dr. Rose Hughes
Patent Attorney & IP Strategist
Evolve



Emma Demetriades
Partner
Carpmaels & Ransford LLP



MODERATED BY:
Markus Rieck
Partner
**Fuchs Patentanwälte
Partnerschaft mbB**

12h45 **Networking Luncheon**

13h45 **Advancements in Antibody Patent Prosecution: Distilling Strategies for Future Success from the UPC, EU and US Case Law**

Session leaders will dissect recent influential decisions and explore their implications for prosecution and litigating antibody patents in different jurisdictions. Topics of discussion will include:

- Adopting effective strategies for claiming antibodies, considering different patent office interpretations and how to draft claims that secure protection across jurisdictions
- Examining how recent EPO decisions, like T 0499/18, and the UPC Central Division's revocation of Amgen's patent, influence the acceptability of claims where a combination of antigen plus function is used to define an antibody
- Contrasting the U.S. Supreme Court's decision, which deemed claims of two Amgen patents invalid due to insufficient enablement for a genus of antibodies, with UPC caselaw
- Understanding the nuances of epitope-based claims, functional antibody claims, combination therapies, companion diagnostics



Pamela Tuxworth
Partner | European &
UK Patent Attorney
J A Kemp



Dr. Jörk Zwicker
Partner
Zwicker Schnappauf & Partner



MODERATED BY:
Ruud van der Velden
Partner
Hogan Lovells
2025 Co-Chair

14h30 Demystifying Forum Selection and Parallel Proceedings: Developing Strategic Litigation Pathways at the UPC and Beyond

- Deciphering which substantive law applies at the UPC
 - » E.g., what are the tendencies of the UPC's Local Divisions in applying EPO and national law?
- Distilling the factors for selecting the Local Division versus other venue
- Analyzing the role and use of experts in infringement and invalidity proceedings at the UPC
- Analyzing the evolving relationship between EPO opposition proceedings and validity challenges within the UPC
- Assessing how decisions in one forum influence strategies and outcomes in the other and navigating parallel proceedings
- Assessing if the UPC is a pharma-friendly venue through an analysis of the first decisions
- Contrasting the UPC with the U.S., the UK, the Netherlands and Germany



Liz Cohen
Partner
Bristows LLP
2025 Co-Chair



Oscar Lamme
Partner | UPC Representative
Simmons & Simmons
Netherlands



MODERATED BY:
Dr. Kai Rütting
Partner
Vossius & Partner
2025 Co-Chair

15h30 Networking Break

15h45 Updated Strategies for Defending and Enforcing Patent Rights in Non-UPC Jurisdictions: Spotlight on Brazil and China

- Analyzing the impact of UPC developments on non-member states and how these jurisdictions are responding to the changing European patent landscape
- Exploring the specific challenges and opportunities in Brazil and China, highlighting their unique patent environment and implications for global patent strategies
- Identifying the key considerations for enforcing patents in non-UPC jurisdictions
- Developing defense strategies and tactics for patent litigation in these jurisdictions



Eduardo Hallak
Founding Partner
Licks Attorneys



Huiya Wu
Partner
Goodwin Procter LLP

16h45 Developments in EU Competition Law Affecting Pharmaceutical Patents: Preparing for New Enforcement Trends and Economic Impacts

In January 2024, the EC published a report providing an overview of the enforcement of EU antitrust and merger rules between 2018 and 2022. Then in October 2024, the EC fined Teva 462.6 million euros for allegedly abusing its dominant position to delay competition to its blockbuster multiple sclerosis pharmaceutical, Copaxone. The radical ruling, which Teva is appealing, and the EC's enforcement report, provide valuable insights into the enforcement cadence of Europe's antitrust authorities and raises important questions as to the boundary between legitimate and illegal means of competition in the pharmaceutical sector.

- Reviewing the core principles and past cases that have interpreted "abuse of dominant position" under Article 102 of the Treaty on the Functioning of European Union and "misuse" of the patent system
 - » E.g., the January 2024 report published by the EC
- Analyzing the facts of the Teva case and identifying the two practices the EC considered as delaying competition
- Unpacking the EC's finding that Teva "artificially" extended its patent protection for Copaxone through playing "the divisionals game"
- Dissecting the EC's finding that Teva engaged in exclusionary disparagement of a competing glatiramer acetate
- Creating a roadmap for the future of divisional applications that incorporates this unprecedented enforcement cadence
- Developing defensive strategies against large patent portfolios
- Contacting the EC to potentially launch an investigation



Boris Andrejaš
Case Handler Officer
European Commission,
DG Competition



Ingrid Vandenborre
Co-head European Antitrust/
Competition Practice
**Skadden, Arps, Slate, Meagher
& Flom LLP**



MODERATED BY:
Brigitte Taravella-Carion, Ph.D.
European Patent Attorney
Sanofi

17h30 Networking Cocktail

18h30 Conference Adjourns to Day Two

8h00 Registration and Breakfast

Manuel Duraes Rocha, ABREU ADVOGADOS

8h50 Co-Chairs' Welcome Back and Recap of Day One



Liz Cohen
Partner
Bristows LLP



Dr. Kai Rütting
Partner
Vossius & Partner



Ruud van der Velden
Partner
Hogan Lovells

9h00 **Changes to IP Regulatory Rights Flowing from the EU Pharmaceutical Law and Regulation Reforms: Key Takeaways for Industry**

The proposed legislation includes several regulatory updates that are critical to the work of litigators and patent attorneys as they directly impact life cycle management of valuable biopharma patents. The following changes from the proposed legislation and regulation will be highlighted, and their impact on life cycle management explored:

Orphan Market Exclusivity (OME)

- Unpacking the Commission's new concept of modulated OME with varying exclusivity periods depending on the type of orphan product
- Appreciating the impact of the Commission's proposed global orphan marketing authorization

Regulatory Data Protection (RDP)

- Appreciating the changes needed to account for a shortened regulatory and market exclusivity protection (the Commission's proposed two-year reduction in baseline RDP)
- Utilizing the potential extensions of RDP, currently listed as cumulative and with no cap

New Transparency Laws

- Rethinking market applications in light of new transparency laws that require much earlier disclosure of clinical trial results

Bolar Exemption

- Anticipating the impact expanded scope of the Bolar exemption on patent and litigation strategies



Sergio Napolitano
General Counsel and
External Relations Director
Medicines for Europe



Michael Swita
Director of IP Policy
European Federation of
Pharmaceutical Industries
and Associations (EFPIA)



MODERATED BY:
Mike Gruber, LL.M.
Partner | UPC Representative
HOFFMANN EITLE

C5'S SPC THINK TANK

10h00 **The Unitary SPC and the Recast of Existing SPC Regulation: Developing Strategies for the New EU SPC Landscape**

- Understanding how the proposed unitary SPC integrate with the unitary patent system
 - » Appreciating the expected benefits and challenges of a centralized SPC application procedure
- Analyzing the Impact on filing strategies and implementation
 - » How will the new unitary SPC system affect current SPC filing strategies under the Unified Patent Court?
 - » What are the key considerations for implementing a unitary SPC, and which institution might be best suited for this role?
- Debating the coexistence of unitary and national SPCs
 - » How should the industry navigate the coexistence of unitary and national SPCs?
 - » What could be the implications of a unified examination and grant procedure for both types of SPCs?
- Addressing legal uncertainties and solutions
 - » What potential legal uncertainties could arise from the new SPC reforms?
 - » What are the practical challenges in implementing the unitary SPC, especially regarding examination, granting, and appeals?
 - » How can these uncertainties be addressed to ensure a smooth transition and effective implementation?



Dr. Martijn de Lange
Patent Examiner
Netherlands Patent Office



Jiri Slavik
Director of IP
Adalvo



David Carling, PhD
Partner | UK & European Patent
Attorney | UPC Representative
Potter Clarkson



MODERATED BY:
Christopher Brückner
Partner
Denemeyer Law

11h00 Morning Networking Break

11h15 **The Key Cases to Consider for Your SPC Strategy:**
From Active Ingredient to Combination Products and Beyond

- Navigating Combination Products:
 - » Advocate General joint cases *Teva II C-119/22* and *MSD C-149/22*
- Analyzing "loose" combinations
 - » UK Court of Appeal *Newron Pharmaceuticals v The Comptroller General of Patents* ([2024] EWCA Civ 128)
- Benchmarking the status of Forsgren applications
 - » France's Supreme Court decision to uphold the rejection of the Herceptin Hylecta SPC Application (Court de Cassation appeal number 21-15.221) and the UK IPO's rejection of the Herceptin Hylecta and Mabthera SPC applications (IPO decision BL O/0257/24)
- Exploring the CJEU's interpretation of Article 3(b) and 3(d) of the SPC Regulation
 - » CJEU Genmab C-181/24
- Strategizing new medical indications and second medical use:
 - » Merck Serono's appeal to the Court of Appeal of England and Wales, attempting to overturn *Santen*
- Scrutinizing antibody SPC applications, article 3(a) post-Royalty Pharma (C-650/17)
 - » The French Supreme Court's pending decision on Dana-Farber's SPC application for avelumab and correlated applications (e.g., the Portuguese Supreme Court's decision to reject Dana-Farber's application for atezolizumab)



Dolores Cassidy
Head of SPC and
Patent Examination
**Intellectual
Property
Office of Ireland**



Christian Helbig
Founding Partner |
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IP Counselors
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Elodie Ferraty
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MODERATED BY:
Oliver Kingsbury
Partner
**Elkington & Fife
LLP**



Mark Ness
Assistant General
Counsel, IP
AstraZeneca

12h15 Networking Luncheon

13h30 **The Generic and Biosimilar Landscape:**
SPC Manufacturing Waiver, Market Trends and Emerging Litigation Strategies

- Analyzing the impact of the SPC Manufacturing Waiver on the generic and biosimilar industries
 - » Identifying the emerging litigation trends arising from the waiver's use
 - » Distilling insights from the SPC manufacturing waiver review
- Comparing data requirements for the approval of a biosimilar versus the reference medicine in the EU
- Assessing the impact of different EU Member States decision regarding the automatic substitution of biosimilars at the pharmacy level on market uptake
- Comparing EU biosimilar uptake in cancer, diabetes, and rheumatoid arthritis
- Navigating the generic and biosimilar markets amid challenging US litigation trends
 - » Analyzing when and whether to engage the in the patent dance



Jiri Slavik
Director of IP
Adalvo



Catherine Drew
Partner
Pinsent Masons



Dámaso Gallardo
European Patent
Attorney
and Litigator
**Farmaprojects
S.A.U.**



MODERATED BY:
Kristof Roos
Partner
**Crowell Moring
LLP**

14h15 Networking Break

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15h00 **Patents, Public Health, and Pandemic:** Navigating Litigation and Licensing While Balancing Access and Innovation

This session will analyze the COVID-19 vaccine litigations as part of the debate on the intersection of patent law, public health policy, and global access, highlighting strategic considerations and broader implications for the life sciences IP community in the event of a future pandemic. Topics of discussion will include:

- Exploring key takeaways from the COVID-19 vaccine patent disputes to inform future IP management strategies in health emergencies and on vaccine innovation
 - » E.g., Moderna vs. Pfizer/BioNTech mRNA vaccine dispute, assessing their legal arguments, impact on the pharma industry, and implications for biotech patent law
- Scrutinizing the interplay between public health policies, emergency use authorizations, and patent rights during pandemics and debating the ethical and legal challenges of balancing access with protection of innovation through patents
- Distilling the Commission's new mechanism for granting EU-wide compulsory licenses under patent rights without the consent of the patent holder in response to EU emergencies or crises
- Assessing the impact of voluntary patent pledges, such as AstraZeneca's non-profit vaccine pledge, on IP management in health crises



James Horgan
Chief IP Counsel, International
Litigation and Policy
Merck Sharp & Dohme (UK)



Adam Mossoff
Professor of Law
**Antonin Scalia Law School,
George Mason University**



MODERATED BY
Nina Bayerl
Partner
Freshfields

16h00 **AI in Drug and Therapeutic Discovery:** Navigating Patent Challenges and New Regulatory Landscapes

The landscape for patenting AI technologies in drug discovery is being shaped by new regulations and case law, impacting how companies approach IP protection and litigation. This session will detail the evolving challenges and opportunities in patenting AI-assisted drug discovery innovations, considering recent legal and regulatory developments in Europe and the U.S. Points of discussion will include:

- Exploring the impact of the European Union's AI Act, the first comprehensive AI law, on AI in drug discovery
- Examining the increasing trend of patent filings related to AI and machine learning in drug discovery
- Developing strategies for patenting AI innovations, including the challenges of meeting patentability criteria like novelty and non-obviousness
- Analyzing the importance of data exclusivity in AI-driven drug discovery, focusing on strategies for protecting proprietary data and the implications for patent enforcement
- Addressing the challenges of managing IP for AI-assisted drug discovery in a global context, taking into account different regulatory environments and the need for harmonized strategies



Richie Paul, Ph.D.
VP & Head of IP
**Alkermes Pharma Ireland
Limited**



Daniel G. Rudoy, PhD
Shareholder | Executive
Committee Member
Wolf, Greenfield & Sacks, P.C.



MODERATED BY:
Camille Terfve
Partner
Mewburn Ellis

17h00 **Conference Concludes**

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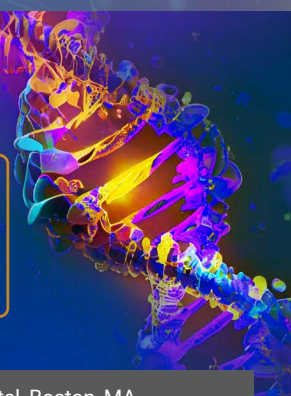
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