

**2nd BCLT
Advanced Life Sciences Institute**

**Interplay of Patent and
Regulatory Exclusivity – National
and Global Considerations**

May 2024


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Kurt R. Karst

Kurt R. Karst is a Director at Hyman, Phelps & McNamara PC. He provides regulatory counsel to pharmaceutical manufacturers on Hatch-Waxman patent and exclusivity, drug development, pediatric testing, and orphan drugs. He helps clients develop strategies for product lifecycle management, obtaining approval, managing post-marketing issues, and defining periods of exclusivity. As the co-founder and primary author of Hyman, Phelps & McNamara's [FDA Law Blog](#), Mr. Karst often leads the response to new rules and regulations, sharing his interpretation with the broader legal community.



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Joel Silver

Joel Silver is Vice President, Legal at Gilead Sciences, Inc., where he is lead counsel for the Development and Manufacturing organizations. Joel also serves as the Chair of Gilead's Pro Bono program and represents survivors of domestic violence in their restraining order hearings through the Legal Aid Society of San Mateo County. Prior to joining Gilead, Joel worked as a Patent Agent in the human and animal health divisions at Pfizer Inc. Joel also worked as a Medicinal Chemist at Chiron Corp.

Joel earned his J.D. from Seton Hall University School of Law and is admitted to the California Bar, Court of Appeals for the Federal Circuit and the United States Patent and Trademark Office.



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Michael K. Stern

Michael K. Stern is Of Counsel at Covington & Burling LLP. Drawing on his experience at the U.S. Food and Drug Administration, Michael Stern advises pharmaceutical and biotech companies on life-cycle management, FDA's regulation of the development of drugs and biologics, and the drug pricing provisions of the Inflation Reduction Act (IRA).

Michael is a leading expert on regulatory issues relating to Hatch-Waxman and the Biologics Price Competition and Innovation Act, including exclusivity and FDA-related patent issues, as well as R&D and exclusivity issues relating to orphan drugs and pediatric studies. Michael regularly counsels clients on regulatory policy and legislative issues affecting the life sciences industry.

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Allison A. Schmitt

Allison is the inaugural director of the BCLT Life Sciences Law & Policy Center. She is a research fellow at Berkeley Law, and a research fellow affiliated with the Berkeley Law – Haas Fellowship Program. She has lectured at Berkeley Law for many IP, law and technology, and life sciences classes.

Prior to her current position at Berkeley, Allison practiced law for several years (ANDA and BPCIA litigation, strategy, licensing & tech transactions). She served as a law clerk to the Honorable Stanley R. Chesler (DNJ) and the Honorable Kathleen M. O'Malley (Federal Circuit). She holds a PhD in Chemistry from Duke University, and a JD from UC Berkeley School of Law.

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Agenda

- **Overview of Regulatory Exclusivity and Relationship to Patents**
- **Innovator Regulatory Exclusivities and Strategies**
- **Generic Regulatory Exclusivities and Strategies**
- **Strategies Considerations for the Interplay of Patent and Regulatory Exclusivities**

Thank you for joining us.

2024 Advanced Life Sciences Institute Agenda: [LINK](#)

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