



Dechert Life Sciences IP Counseling Practice

Dechert
LLP



Counseling Team



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A.B., Biology, Harvard College, *Magna cum laude*, *Phi Beta Kappa*
M.D., Stanford Medical School, with research honors
Postdoctoral fellowships, Wistar Institute & MIT Dept of Biology
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B.S., Chemistry, University of Wisconsin-Madison, with honors
Ph.D., Chemistry (biophysical), University of California, Berkeley
NIH Postdoctoral Fellowship, Affymax Research Institute
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B.S., Chemistry, Georgetown University
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B.S., Macromolecular Engineering, Case Western Reserve University
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B.A., Natural Sciences, Cambridge University, England, with honors
Ph.D., Cell., Molec. & Biophys., Columbia University, with distinction
J.D., Fordham University, Law Review, Order of the Coif, *Cum laude*



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B.A., Chemistry, Princeton University, *Magna cum laude*
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B.S., Biochemistry, University of California, Los Angeles
Ph.D., Biochemistry, The Johns Hopkins University
Postdoctoral fellowships, UC Berkeley, CalTech, UCSF
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Alexander H. Swirnoff, Ph.D.
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B.A., Biology, The Johns Hopkins University

Ph.D., Neuroscience, Washington University

Postdoctoral research, Genentech

J.D., Santa Clara University School of Law, *Magna cum laude*, Order
of the Coif

Representative Counseling Matters

- For mid-cap U.S. pharmaceutical company, risk assessment and strategic advice with respect to a competing patent portfolio, including: review of offensive interference opportunities, *ex parte* and *inter partes* reexamination options, potential U.S. opposition under pending legislation, European opposition, DJ litigation, sublicense through existing licensee
- As part of acquisition diligence on behalf of a Canadian pharmaceutical company, developed strategies for accelerating certainty as to competing IP, including identification of third party patents suitable for provoking patent-patent interference in Federal district court

Representative Counseling Matters

- On behalf of a “virtual” European pharmaceutical company, IP and exclusivity strategy, and patent prosecution, for a combination product comprising two approved actives, with consideration of patent, regulatory, and off-label challenges
- Prosecution of a patent owner *ex parte* reexamination of a bacterial antigen patent in advance of vaccine interference
- For a venture-backed, pre-public, company, patent strategy for repurposing of a generic active for new clinical indication, including strategic advice re possible combination products and indication-specific reformulations

Representative Counseling Matters

- Term-extending patent strategy for biologically-derived heterogeneous composition, for which approval will be sought as a new drug under §505 of the FDCA
- For a European biotech platform company, advice regarding patent strategy and segregation of rights in concurrent collaborations with direct market competitors
- On behalf of a solo inventor, patent strategy and prosecution for an adjunctive therapy that presents significant exclusivity extension for related chemotherapeutic; successfully outlicensed by Dechert's life science transactional attorneys

Representative Counseling Matters

- For a publicly held biotechnology company, noninfringement opinion for a marketed product as to a patent formally noticed by patentee
- On behalf of a pre-public biotechnology company, invalidity opinions as to various identified patents
- For a Canadian pharmaceutical company, counseling on pharmaceutical product life cycle management, including advice regarding strategies for extending exclusivity for approved drug for new product indications

Representative Counseling Matters

- Strategic counseling for a pharmaceutical manufacturer, including antitrust, patent, and litigation counseling in advance of expected expiration of non-patent regulatory exclusivity, including preparation for possible patent infringement litigation under Hatch-Waxman Act (ANDA litigation) relating to anti-AIDS drug
- Patent strategy and prosecution services for a pre-public biotech company engaged in biodefense, including assessment of government ownership rights
- For a university faculty member, assistance in securing assignment of university rights under Bayh-Dole provisions

Representative Counseling Matters

- Patent strategy for a pre-public company, including freedom to operate, patent prosecution, and advice regarding intangible assets acquired out of bankruptcy
- Strategic IP counseling, including developing patent strategy and inter-entity agreements, for pre-public biotechnology company in connection with restructuring of business for tax purposes
- Third-party patent landscape assessments for a large public life sciences company in the areas of DNA sequencing, PCR, and other nucleic acid assays

Representative Counseling Matters

- For a large public life sciences company, investigation and assessment of priority evidence and possible interference strategy relating to a third-party patent; advice regarding acquisition of the patent for purposes of provoking an interference with a competitor and litigation adversary
- Patent prosecution, portfolio development, and strategic counseling for a nanotechnology company in discussions regarding licensing/acquisition of patent portfolio regarding oral care technology
- For pre-public European biotech startup, assessment of target-specific patent estate owned by global pharma company

Representative Due Diligence Matters

- For a pharmaceutical company, due diligence on IP portfolio directed to opioid receptor antagonist compounds for purposes of a potential license
- For a pharmaceutical company, we recently completed a clearance analysis relating to their lead small molecule drug candidate
- For a pharmaceutical company, we recently did an orange book opinion demonstrating that their patent covers a new form of the product and therefore can be listed in the orange book
- For a pharmaceutical company, we recently did a complex inventorship analysis relating to the company's lead small molecule drug candidate wherein the molecule was developed through a collaboration with a third party

Representative Due Diligence Matters

- On behalf of a Canadian pharmaceutical company, IP diligence for potential acquisition of pre-public U.S. company, including strategic advice regarding possible threatened patent litigation
- On behalf of a European specialty pharma company, IP diligence on acquisition of a public U.S. company
- On behalf of a European company, IP diligence and prospective strategy for proposed acquisition of a pre-public UK company
- On behalf of U.S. mid-cap pharmaceutical company, worldwide IP diligence for potential product acquisition from a global pharmaceutical company

Representative Due Diligence Matters

- License, multi-jurisdictional IP, and EU competition law due diligence with Dechert EU competition attorneys on behalf of a monoline insurer of commercial paper backed by the securitized ex-U.S. royalty stream of two biopharmaceutical products
- In support of a potential IP asset purchase by a European pharmaceutical company, due diligence on a potentially interfering patent portfolio owned by a U.S. pharmaceutical company
- For a global pharmaceutical company, diligence on two parties' competing patent portfolios, with related advice regarding interference and IP asset purchase strategies

Representative Due Diligence Matters

- For potential acquisition by a private equity firm, detailed IP diligence on marketed and developmental drugs of a publicly-held pharmaceutical company, including assessment of likely outcomes of ongoing patent infringement litigation
- On behalf of a private equity firm, IP diligence for the purchase of participation rights in sales of a marketed pharmaceutical product and pharmaceutical product in development
- Due diligence reviews of IP portfolios surrounding three pharmaceutical clinical products and a platform discovery technology in connection with a potential corporate acquisition by a mid-sized pharmaceutical company

Representative Due Diligence Matters

- IP due diligence reviews related to research tool technologies in connection with licenses and/or corporate acquisitions on behalf of a large maker of research tools
- Due diligence review of IP portfolios for regulated cosmetic products in connection with a potential corporate acquisition by a large international pharmaceutical company
- Due diligence review of IP portfolios surrounding three pharmaceutical clinical products in connection with a potential investment by a private investment firm

Representative Due Diligence Matters

- Due diligence reviews of IP portfolios surrounding various gene therapy technologies in connection with a potential license by a small, start-up biotechnology company
- Due diligence review of an IP portfolio surrounding certain pharmaceutical products and drug delivery devices and technologies in connection with a potential corporate acquisition by a mid-sized pharmaceutical company

Representative Interference Matters

- ***Pevarello v. Lan***

- Represented Newron Pharmaceuticals S.p.A. (Milan, Italy) in an interference with Purdue Neuroscience. Favorable judgment on substantive motions preserved Newron's company-critical U.S. patent and ensured Newron's freedom to operate.
- During the interference, Dechert attorneys assisted Newron in partnering out another compound to an international pharmaceutical company.
- Subsequently prosecuted to allowance a reissue of Newron's involved patent (issuance pending)

- ***Gissman v. Lowy et al.***

- Represented the German Cancer Research Institute (GCRI) in an interference against the National Institutes of Health relating to a vaccine to prevent cervical cancer. The vaccine is currently being marketed by Merck under the trade name Gardasil. The interference settled favorably for the GCRI.

Representative Interference Matters

- ***Kishore v. Burrell***
 - Represented British American Tobacco in an interference against Monsanto relating to genetically-modified potatoes; the interference was settled after the preliminary motions were filed
- ***University of New Mexico v. Fordham University***
 - Represented Fordham in an interference against the University of New Mexico relating to heat shock proteins; Fordham prevailed on priority

Representative Interference Matters

- ***Lomedico v. Yamada***
 - Represented Roche in a three-party interference against Immunex Corporation and Dainippon Pharmaceutical Co., Ltd. involving recombinant DNA technologies for producing interleukin-1 alpha (IL-1 alpha) and an additional interference against Dainippon for methods of treating diseases using IL-1 alpha; the interferences were settled after a decision on motions and exchange of priority evidence
- ***Bloembergen et al. v. Rimsa et al.***
 - Represented Japan Corn Starch against National Starch in the appeal from the adverse decision in the interference under 35 U.S.C. § 146; the case was favorably settled

Representative Interference Matters

- ***Incyte Pharmaceuticals, Inc. v. Falb and Gimbrone***
 - Represented Millennium Pharmaceuticals in an interference against Incyte relating to a novel gene; Millennium prevailed on priority
- ***Dodds v. Hulshoff***
 - Represented Sepracor, Inc. in an interference against Andeno (and Tanabe) involving the synthesis of a compound that is useful for making Dilitiazem; Sepracor prevailed on priority and in the subsequent appeal under 35 U.S.C. § 146
- ***Tempesta v. Cariel and Jean***
 - Represented Shaman Pharmaceuticals in an interference against Cariel; Cariel conceded priority after Shaman demonstrated that Cariel engaged in inequitable conduct

Representative Interference Matters

- ***Bolognesi v. Shafferman***

- Represented Trimeris Corp in an interference against the NIH relating to the peptide T20, currently marketed as FUZEON to treat HIV. Trimeris successfully dissolved the interference by demonstrating that there was no interference-in-fact

- ***Wertz et al. v. Rose***

- Represented Yale University in an interference against University of Alabama relating to a recombinant VSV virus that can be utilized in a vaccine against HIV; Yale prevailed on priority

- ***Furman v. Cheng***

- Represented Yale University in an interference against Glaxo relating to a compound to treat HIV; Yale prevailed on priority

Representative Litigations and Oppositions

- ***Martek v. Lonza***

- Represented Martek in a litigation against Lonza in the Federal District Court of Delaware relating to the production of omega-3 fatty acids by the fermentation of certain algae; the jury found all three asserted patents infringed and not invalid
- Represented Martek in companion German infringement action in which the Court held that Lonza infringed Martek's patent
- Spearheaded the defense of numerous European oppositions resulting in the maintenance of Martek's patents relating to omega-3 fatty acids

Representative Litigations and Oppositions

- ***Endo v. Impax***
 - Currently representing Endo Pharmaceuticals in its ongoing ANDA litigation against Impax involving Endo's Opana® ER drug product
- ***Endo v. Actavis***
 - Currently representing Endo Pharmaceuticals in its ongoing ANDA litigation against Actavis involving Endo's Opana® ER drug product

Representative Litigations and Oppositions

- ***Applera v. BioRad et al.***
 - Developed and advised Applera on patent enforcement strategies in U.S., Japan, and Germany on patent directed to real time PCR instruments
 - Represented Applera in two Japanese invalidity actions and a European opposition involving counterpart Japanese and European real time PCR instrument patents

Representative Litigations and Oppositions

- ***Cell Genesys***
 - Represented Cell Genesys in the defense of numerous European Patent Office oppositions relating to gene activation technology, resulting in licensing fees in excess of \$30 million from a major pharmaceutical company
- ***Pharmacopeia v. Affymax***
 - Represented Pharmacopeia in the defense of a European Patent Office opposition involving Affymax's basic patent on encoded combinatorial molecule libraries; Affymax's patent was declared invalid and revoked in its entirety
- ***Confidential matter***
 - Ongoing representation of U.S. pre-public biotech company in European opposition to third party patent

Representative Litigations and Oppositions

- **Confidential Matter**
 - Conducting third-party peer review of patent portfolio covering drug product and advising client with respect to litigation strategy

- **Confidential Matter**
 - Representing client with respect to worldwide patent enforcement, defense, opposition and interference strategies on patents and applications directed to technologies for performing proteomics assays