



IP Strategies for Life Sciences Companies

Life Sciences & The Law

Jorge Contreras
Justin Crotty
Gillian Fenton
Jay Reilly
Erin Foley



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Meet the Faculty

Panelists

Jorge Contreras - University of Utah

Justin Crotty - Saul Ewing

Gillian Fenton - LST Strategies

Erin Foley - Foley Hoag LLP

Moderator

Jay Reilly - Foley Hoag

About This Webinar

IP Strategies for Life Sciences Companies

IP is absolutely critical for Life Sciences companies. It is the first thing investors will ask about, and it's the first thing that potential M&A and strategic partners will investigate. The strength of your IP will determine whether your innovation, great as it may be, will ever be able to help humanity. However, the IP strategy that works for your company won't necessarily work for another company.

In this episode, we'll help you understand the various strategies for optimizing protection for your product. Unlike other industries, an extremely successful Life Sciences company can be built on the basis of one claim in a single patent. There are many Life Sciences companies that don't need any patent protection at all, and in fact, patent protection might be detrimental to the long-term valuation of their company. Many Life Sciences companies rely heavily on trade secrets to protect their business, but almost all of them do it wrong. We'll give you the tools you need to develop an IP strategy that will be attractive to investors and acquirers and deter potential competitors.

About This Series

LIFE SCIENCES & THE LAW 2025

This webinar is part of a series titled “Life Sciences & The Law 2025.”

"We Bring Good Things to Life" was an advertising slogan used by General Electric between 1979 and 2003, focused mainly on General Electric's appliances and lighting fixtures. We'd argue that it would be an even better slogan for the Life Sciences industry.

The Life Sciences Industry encompasses companies and organizations that are dedicated to researching, developing, manufacturing, and distributing products and technologies to improve human and animal health. Key sectors within life sciences include biotechnology, pharmaceuticals, medical devices, and diagnostics. The industry's work ranges from bench research and small-scale manufacturing to performing small and large-scale clinical trials, developing manufacturing processes on a commercial scale, working closely with regulatory agencies, to developing pricing, marketing, and distribution strategies. The life cycle of a drug or medical device often involves many parties controlling the product at various times, involving the bench of university researchers, development by small startup companies, commercialization by larger industry players, diversification by sublicensees, and distribution by resellers.

Life sciences is a highly regulated field due to its direct impact on health and safety, with strict compliance standards overseen by regulatory bodies like the FDA in the United States and EMA in Europe. The industry is characterized by high research and development (R&D) costs, long development timelines, and significant investment in innovation and technology. The life sciences industry is also increasingly interdisciplinary, intersecting with data science, artificial intelligence, and bioinformatics to drive advancements in personalized medicine, gene therapy, and diagnostics.

Episodes In This Series

1. Life Sciences Industry Basics
Premiere date: 4/29/25
2. Life Sciences Regulatory Overview
Premiere date: 6/10/25
3. Life Sciences Startups – How to Begin
Premiere date: 7/29/25
4. Funding a Life Sciences Company
Premiere date: 10/7/25
5. IP Strategies for Life Sciences Companies
Premiere date: 11/18/25

Episode #5

IP Strategies for Life Sciences Companies

Each Financial Poise Webinar is delivered in Plain English, understandable to investors, business owners, & executives without much background in these areas, yet is of primary value to attorneys, accountants, & other seasoned professionals. Each episode brings you into engaging, sometimes humorous, conversations designed to entertain as it teaches. Each episode in the series is designed to be viewed independently of the other episodes so that participants will enhance their knowledge of this area whether they attend one, some, or all episodes.

Types of Intellectual Property

IP Basics

Types of Patents

- Utility patents: processes, machines, manufactures and compositions of matter
- Design patents: ornamental features for useful articles
- Plants: a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state

Utility Patents

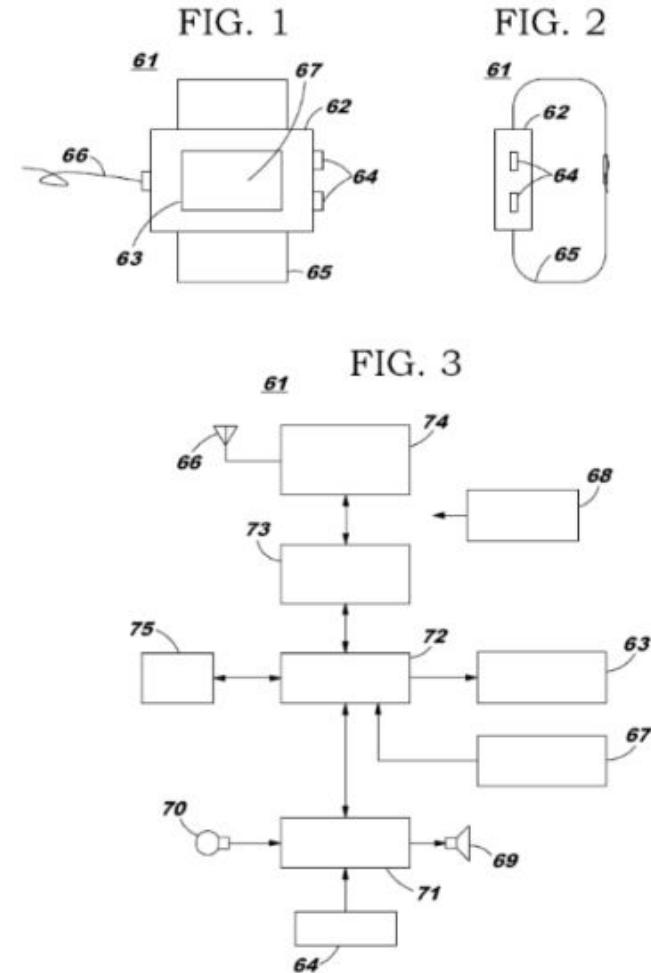
- Processes, machines, manufacturers and compositions of matter
- Term: 20 years from the earliest filing date, plus possible term extension
- A patent gives the owner the right to exclude others during the term of the patent from practicing (making, using, selling, offering for sale, and importing) the *claimed invention*

Utility Patents

Patent drawings:

- These are exemplary, and help explain the invention
- They do not, however, define the scope of the invention

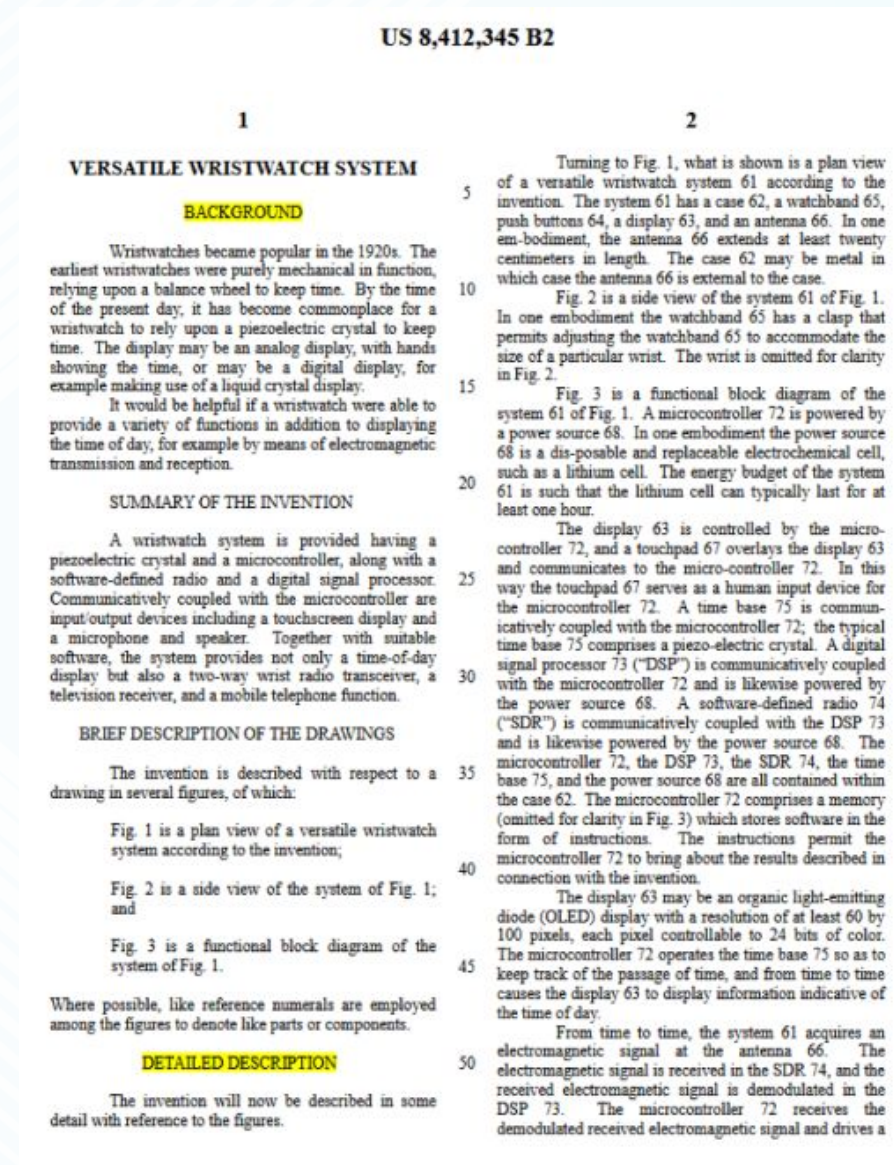
U.S. Patent April 2, 2013 Sheet 1 of 1 US 8,412,345 B2



Utility Patents

Patent specification:

- Background: gives state of the art, and what problems the invention is supposed to solve
- Summary: gives high level description of the invention, and may explain why it is an improvement over the prior art
- Detailed Description: provides exemplary embodiment(s) of the invention, and typically is read in conjunction with drawings



Utility Patents

Patent claims:

- Patent claims are word descriptions of the required features of a process, device, or composition of matter
- Patent claims define the scope of the invention and what the patent owner can exclude others from doing
- Typically, patent claims say: a device or method “comprising”
- “Comprising” is a term of art that means: at least what is listed, but can include more

US 8,412,345 B2	
3	4
human interface device accordingly. In one embodiment the electromagnetic signal is a television signal and the human interface device is the display 63. In another embodiment the electromagnetic signal is a mobile telephone signal and the human interface device is a speaker 69.	5. The system of claim 1 further comprising an antenna external to the case and extending at least twenty centimeters in length.
The alert reader will have no difficulty devising myriad obvious variations and improvements of the disclosed embodiments, all of which are intended to be encompassed within the claims which follow.	6. A method for use with a wristwatch having a case with respect to a time of day and with respect to passage of time, the method comprising:
We claim:	operating a time base within the case by a microcontroller within the case so as to keep track of the passage of time;
1. A versatile wristwatch system comprising:	15 displaying upon a display within the case information indicative of the time of day;
a microcontroller powered by a power source;	acquiring an electromagnetic signal at an antenna external to the case;
a display controlled by the microcontroller;	20 receiving the electromagnetic signal in a software-defined radio located within the case and connected with the antenna;
a touchpad overlaying the display and communicating to the microcontroller;	25 demodulating the received electromagnetic signal in a digital signal processor located within the case and communicatively coupled with the software-defined radio;
a time base communicatively coupled with the microcontroller;	30 driving a human interface device by a microcontroller located within the case as a function of the demodulated received electromagnetic signal.
a digital signal processor communicatively coupled with the microcontroller; and	35 7. The method of claim 6 wherein the electromagnetic signal is a television signal and the human interface device is a display within the case.
a software-defined radio communicatively coupled with the digital signal processor;	40 8. The method of claim 6 wherein the electromagnetic signal is a mobile telephone signal and the human interface device is a speaker within the case.
a power source powering the microcontroller, the digital signal processor, and the software-defined radio;	*****
the microcontroller, the digital signal processor, the software-defined radio, and the power source all contained within a case,	
the system further comprising a watchband connected with the case and adjustably sized for encirclement of a human wrist.	
2. The system of claim 1 wherein the power source is a lithium cell.	
3. The system of claim 1 wherein the display has a resolution of at least 60 by 100 pixels, each pixel controllable to 24 bits of color.	
4. The system of claim 1 wherein the time base comprises a piezoelectric crystal.	

Utility Patents

- To infringe a patent claim, each and every claim limitation must be present in the accused device literally or equivalently
- If a product meets all the limitations, it infringes, regardless of whether it also includes other features (even separately patentable features).
- Patent infringement is a “strict liability” tort. There is no requirement that one knew of the patent to be an infringer.
- “Innocent” infringement is not a defense.

1. A versatile wristwatch system comprising;

a microcontroller powered by a power source;

a display controlled by the microcontroller;

a touchpad overlaying the display and communicating to the microcontroller;

a time base communicatively coupled with the microcontroller;

a digital signal processor communicatively coupled with the microcontroller; and

a software-defined radio communicatively coupled with the digital signal processor;

a power source powering the microcontroller, the digital signal processor, and the software-defined radio;

the microcontroller, the digital signal processor, the software-defined radio, and the power source all contained within a case,

the system further comprising a watchband connected with the case and adjustably sized for encirclement of a human wrist.

Trade Secrets

- Trade Secret: Information that derives independent economic value from not being generally known and is subject to reasonable efforts to keep it secret (e.g., formulas, methods, customer lists, source code, pricing strategies).
- No registration required
- Reasonable measures to protect: Use NDAs, access controls, data security, need-to-know restrictions, employee training, marking documents “confidential,” and exit procedures to recover devices and remind of duties.
- Duration of protection: Potentially indefinite—protection lasts as long as the information remains secret and reasonable safeguards persist.

Issues for Life Science Applicants

- 35 USC § 101 limits patent eligible subject matter
- Natural phenomenon and abstract ideas are excluded from patent eligibility

Issues for Life Science Applicants

- 35 USC § 112 requires that applicants provide a written description of their invention such that a skilled person could conclude that they had invented what they claimed
- This is a serious burden when attempting to protect antibodies

Design Patents

- What do design patents protect?
 - The design embodied in or applied to an article of manufacture. A design patent does not cover the article itself, the way it functions or any internal mechanical structure. A design patent merely protects the appearance of the tangible article.
- Design patent term:
 - 15 years from the filing date for design patent applications filed on or after May 13, 2015
 - 14 years from grant for applications filed before May 13, 2015
- Typically more important for:
 - Medical devices and instruments, Drug delivery devices, Diagnostics hardware and consumables, Digital health and device GUIs

What Happens If A Patent Is Infringed?

- Before launching a new product, better check to see what is out there.

How To Determine If There Is Possible Infringement

- Searching for patents
 - Competitors' products
 - ✓ Patent markings
 - ✓ Search their patent portfolio
 - Conduct patent search. Of the millions of issued patents, only a small percentage are commercialized.
 - Freedom to Operate search

Note: The claimed inventions in expired patents are deemed dedicated to the public. However, be aware of improvement patents that cover additions to base patents

Freedom to Operate (FTO) Search

- Once you have a fairly complete idea of the proposed product, before incurring costs of tooling, materials, etc., a FTO search may be warranted.
1. Create write up of proposed product, including features and operation
 2. Identify likely competitors
 3. Identify any relevant patents of which you are aware
 4. Specify relevant geographical areas for search
 5. Contact TOMY legal

Freedom to Operate (FTO) Search

FTO Limitations:

- Impossible to search all patents. Over 10 million in U.S.
- Difficult to account for different ways of describing something.
- Design patents difficult to search.

What To Do With Identified Patents

Regardless of how a relevant patent is identified, what do you do when a relevant patent is identified?

1. Is the patent still in force?
 - Patent can expire through the exhaustion of the patent term or failure to pay maintenance fees. Careful of patent term extensions. Patents can also be invalidated either during litigation or in subsequent patent office proceedings.
2. What does the patent actually cover?
 - Patent claims are made up of legal language that may require substantial analysis.
3. Can the patent be avoided?
 - Some patent claims are written in such a way that minor changes to product design can avoid the patent.

Injunctions – Rare after eBay v. MercExchange (2006)

- Holding (no automatic injunctions): The Supreme Court unanimously held that permanent injunctions in patent cases are not automatic after a finding of infringement. Courts must apply the traditional four-factor equitable test and consider the claim “as a whole.”
- Four-factor test reaffirmed: A patentee seeking a permanent injunction must show (1) irreparable injury; (2) inadequacy of legal remedies; (3) balance of hardships favors equitable relief; and (4) the public interest would not be disserved. District courts exercise equitable discretion.
- Rejection of categorical rules: The Court rejected both the Federal Circuit’s “general rule” favoring injunctions and the district court’s categorical denial based on willingness to license or non-practicing status

RESTORE Patent Rights Act

- Core change to § 283: Adds a short statutory provision creating a rebuttable presumption that a court “should grant a permanent injunction” after a final judgment of infringement.
- Burden shifting: Moves the initial burden to the adjudged infringer to rebut the presumption using equitable defenses; the patentee need not first prove irreparable harm to trigger the presumption.

Current Topics in Life Sciences IP:

Patent Eligibility Restoration Act

- Re-centers § 101 on practical applications. Eligibility would be assessed based on whether a claim is directed to a “useful” process, machine, manufacture, or composition, considered “as a whole”.
- Curtails judicial exceptions. Courts and the USPTO would be directed not to create or apply extra-textual eligibility tests (e.g., “inventive concept”/two-step framework).

Bayh-Dole

- On September 12, Commerce Secretary Howard Lutnick gave an interview in which he stated his view that the American taxpayer should receive half the benefit from federally funded inventions and that Bayh-Dole may be a tool the Department of Commerce could use to achieve that.
- While it is unclear whether and to what extent this reflects a change in policy, greater attention to Bayh-Dole compliance may be prudent, in particular the preference for manufacturing in the United States.

- NVCA - BOLT: Licensed Products shall be substantially manufactured in the United States to the extent (if at all) required by 35 U.S.C. Section 204.
- University license template - As a condition of the license granted hereby, LICENSEE acknowledges and shall comply with all aspects of the Federal Patent Policy applicable to the LICENSED INTELLECTUAL PROPERTY, including the obligation that LICENSED PRODUCTS used or sold in the United States be manufactured substantially in the United States.

Obligation to use Commercially Reasonable Efforts now appears to have some teeth..

- New Case Law:
- *Shareholder Representative Services, LLC v. Alexion Pharmaceuticals Inc.*
and
- *Fortis Advisors LLC v. Johnson & Johnson et al.*

Shareholder Representative Services, LLC v. Alexion Pharmaceuticals Inc.

- This case is about the acquisition, development, and eventual termination of research into a monoclonal antibody known first as SYNT001, and then ALXN1830, for various autoimmune indications.
- The Licensee deprioritized and ultimately terminated development in the face of mixed safety data and several obstacles to development.

Shareholder Representative Services, LLC v. Alexion Pharmaceuticals Inc.

- Alexion Def. of C.R.E:
- [U]sing such **efforts and resources typically used by biopharmaceutical companies similar in size and scope to [Alexion] for the development and commercialization of similar products at similar developmental stages** taking into account, as applicable, the Product's advantages and disadvantages, efficacy, safety, regulatory authority-approved labeling and pricing, the competitiveness in the marketplace, the status as an orphan product, the patent coverage and proprietary position of the Product, the likelihood of development success or Regulatory Approval, the regulatory structure involved, the anticipated profitability of the Product, and other relevant scientific, technical and commercial factors typically considered by biopharmaceutical companies similar in size and scope to [Alexion] in connection with such similar products. **The obligation to use such efforts and resources, however, does not require that [Alexion] or its Affiliates act in a manner which would otherwise be contrary to prudent business judgment** and, furthermore, the fact that the objective is not actually accomplished is not dispositive evidence that [Alexion] or any of its Affiliates did not in fact utilize its Commercially Reasonable Efforts in attempting to accomplish the objective.

Shareholder Representative Services, LLC v. Alexion Pharmaceuticals Inc.

- Alexion found in Breach
- “SRS has proven Alexion’s 2020 deprioritization of ALXN1830 fell short of the commercially reasonable efforts it agreed to use. A hypothetical company similar to Alexion, taking into account factors typically considered by such companies, would not have drastically reduced funding for a product like ALXN1830.”
- The Alexion Court then reviewed each of safety, efficacy, order of entry, and the likelihood of regulatory approval, ultimately determining that Alexion’s termination of the program was also a breach of Commercially Reasonable Efforts.

Fortis Advisors LLC v. Johnson & Johnson et al.

- Entering the surgical robotics market was vital for J&J. Yet J&J's Verb robot was falling increasingly behind the schedule J&J had announced to the market, despite J&J's colossal investments. J&J looked to Auris, a startup and competitor in the space, as a solution. Auris product is the iPlatform.
- Auris agreed to an earnout component after securing J&J's commitment to devote commercially reasonable efforts befitting a "priority medical device" in furtherance of the milestones.
- J&J's promise to Auris was broken almost immediately after closing. Instead of providing efforts and resources to achieve the regulatory milestones, J&J thrust iPlatform into a head-to-head faceoff against Verb called "Project Manhattan."

Fortis Advisors LLC v. Johnson & Johnson et al.

- A “Priority Medical Device” was an internal term and product designation within J&J that allowed the court a yardstick to measure against J&J’s conduct.
- The Fortis Court held that forcing Auris’ iPlatform into a showdown with Verb was the antithesis of the commercially reasonable efforts expected for a priority medical device. This was a breach and J&J is liable for certain milestones unmet as a result of J&J’s breach.

NVCA Template – Know-How Product

- **“Know-How Product”** means (a) any product, method, or service that is Covered by Licensed Know-How, but excludes Patent Products and (b) which has been nominated as a development candidate within [5] years from the Effective Date.
- Classic Royalty Step-down for Know-How Products - For Know-How Products, Licensee shall pay Licensors $[\frac{1}{2}] \times$ % of Net Sales.
- Alternative, no Know-How Products, use this definition of Licensed Product:
- **“Licensed Product”** means any and all products which (a) the manufacture, use, sale, offer for sale, importation, or marketing of which in a country with a Valid Claim of the Licensed Patents would constitute infringement (direct or indirect) of that Valid Claim, and/or (b) the manufacture, use, sale, offer for sale, importation, or marketing of which would constitute infringement (direct or indirect) of a Valid Claim in the United States and is manufactured, used, sold, offered for sale, imported or marketed in a country in the Territory in which such product is not covered by a Valid Claim of the Licensed Patents.

Contractual Protections for IP

Contracting Basics Overview

- **OWN YOUR IP! MANY SMART PEOPLE GET THIS WRONG!!!**
 - The default is generally that the company creating the IP owns the IP unless the IP is specifically assigned to the other party
 - The company paying for the services in many (most) cases should be the owner of the intellectual property created
- Assignment
 - For you to own IP that has been created for you by someone else, the contract must say (i) that you own it, AND (ii) “We, the contractor, hereby assign all rights in the intellectual property underlying the deliverable to you.”
- Exclusivity
 - Can the contractor reuse the IP they create for their own internal purposes? Can they reuse a deliverable that you paid for when working with other clients?
 - If you’re licensing IP to someone else, can they sublicense? Did you retain the right to license the IP to others at the same time?
 - Did you sufficiently limit what the licensee can do with the IP?

Typical Considerations

Confidentiality Agreements

- A recipient of information shared without restriction can use that in any manner they want
- Confidentiality agreements impose limitations but they also grant permissions – make sure the recipient has a prohibition on nondisclosure AND use, and make sure there is an obligation to protect
- Check the length of the obligation
- If not comfortable, don't disclose--absolutely permitted to provide info in stages as you get more comfortable

Typical Considerations

Material Transfer Agreements

- Confidentiality Agreements are insufficient to protect materials
- A recipient of materials shared without restriction can use those materials in any manner they want
- Generally:
 - Restrict the use to a specified research plan or very narrow purpose and prohibit human use
 - Prohibit commercial use of materials
 - Limit the use of the results
 - Limit the ability of recipient to share materials and derivatives
 - Address who should own results and arising IP
 - Prohibit reverse engineering

Typical Considerations

Services/Consulting Agreements

- Make sure you have an assignment of any IP that is created
- Make sure the description of the work to be done is very specific.
 - Mid-project approvals?
 - Final acceptance criteria?
- Make payment provisions specific
 - Amount and timing.
 - How measured? What evidence needed?
- What is the other side putting you on the hook for
- What kind of quality are you getting? Who's doing the work?

Typical Considerations

License grants

- Typical agreements requiring a license grant--Manufacturing, Clinical Trial, Development, Consulting, Sponsored Research, Material Transfer, Distribution
- Keep as narrow as possible
 - Limit the field to specific indications, specific territories, specific uses
 - Limit rights to further sublicense if possible
 - Specifically specify exactly what licensee can do with the intellectual property and prohibit other uses
- Is there a need for a license FROM the other party?
- Licenses can give rise to their own group of reps and warranties and indemnification provisions

Contracting Tips

- Everything is up for negotiation
- Watch out for what's NOT in the contract, but should be
- Keep a library of all contracts you enter
- Detail the deliverables fully
- Tie payments to very clear deliverables or points in time
- Don't rely on contracts too heavily — with a strong enough relationship with your partner, you'll never need to refer to the contract

Questions or Comments?

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Meet The Faculty

Jay Reilly - jreilly@foleyhoag.com



Jay is a partner at Foley Hoag, representing biotech, medical device, diagnostic and software companies, as well as universities and nonprofits, in strategic transactions in the life sciences industry, particularly complex collaborative arrangements and technology acquisitions and dispositions. Jay has extensive experience negotiating and closing joint ventures, licensing arrangements, mergers and acquisitions, and venture capital financings. He also handles day-to-day agreements such as manufacturing, clinical trial, consulting and sponsored research agreements.

Gillian Fenton - gillian@lifesciencetransactions.com



Gillian M. Fenton, Esq., CLP recently became the founder and managing director of LST Strategies LLC, a specialty law practice dedicated to life science transactions (<https://lifesciencetransactions.com>). She is also a Practitioner in Residence at the Center for Intellectual Property x Innovation Policy (<https://cip2.gmu.edu/>), hosted by George Mason University. Previously, she served GSK (GlaxoSmithKline) as Vaccines Special Counsel for Innovation and Government Collaborations. Gillian supported a wide variety of international business development transactions, R&D collaborations and strategic alliances to feed the pipeline for GSK's vaccines and infectious diseases business segment. She also negotiated and managed GSK Vaccines' R&D U.S. Government Contracts, patent licenses, and scientific collaborations with NIH/NIAID, BARDA, DARPA, CARB-X and NIIMBL. Before joining GSK, Gillian was VP, Chief Intellectual Property Counsel at Emergent BioSolutions Inc., where she founded the IP department and supported all IP aspects of the company's IPO and subsequent 9 years of growth through M&A in the vaccines, biodefense, and global health fields. Gillian also spent over twelve years in private practice at law firms in Boston, MA and Washington, DC.

Jorge Contreras - jorge.contreras@law.utah.edu



Jorge L. Contreras is a Distinguished University Professor, the James T. Jensen Endowed Professor for Transactional Law and Director of the Program on Intellectual Property and Technology Law. He teaches and researches in the areas of intellectual property, property law, technical standardization, antitrust and science policy. In 2020 he received the University of Utah's Distinguished Research Award and is an elected member of the American Law Institute. He has testified before the U.S. Senate and House Subcommittees on Intellectual Property, and was awarded the Rossman Memorial Award by the Patent & Trademark Office Society in 2022.

Professor Contreras has written or edited fourteen books and published more than 150 scholarly articles and chapters. His book, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA* (NY: Hachette/Algonquin, 2021), has been praised by the NY Times, Wall St. Journal, Nature and numerous other outlets, and was named "Best Patent Law Book of the Year" by the international IPKat blog. His scholarly articles have appeared in leading scientific, legal and policy journals including Science, Nature, NYU Law Review, Georgetown Law Journal, Iowa Law Review and Antitrust Law Journal. [Read More](#)

Erin M. Foley, Ph.D. - efoley@foleyhoag.com



Erin Foley designs and implements global intellectual property strategies for early-, mid-, and late-stage companies across diverse technology sectors, including gene editing, gene therapy, viral vector engineering, RNA-based therapies, monoclonal antibodies, CAR-T therapies, stem cell therapies, vaccines, antimicrobial therapies, DNA sequencing, and food science. Her practice focuses on devising and implementing global patent and exclusivity strategies, leading IP diligence for both target-side and buyer-side companies and providing patent support in partnership and licensing negotiations.

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Justin Crotty - justin.crotty@saul.com



Justin Crotty brings both a scientific and business sensibility to his work helping clients protect their intellectual property through patent prosecution, inter-partes review proceedings and litigation, particularly for the pharmaceutical, medical device and biotechnology industries. His experience also includes drafting freedom-to-practice, non-infringement and invalidity opinions.

Prior to law school, Justin earned both a bachelor's degree and doctorate in chemistry and, as a graduate fellow, lectured on topics at the interface of biology, mathematics and physics. His interest in the path from laboratory to commercial product stems from a fellowship in a university technology transfer office, where he evaluated technologies for their potential commercial value. His work there also involved researching prior art to determine the feasibility of patenting technologies. [Read More](#)

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