

Buchanan • **LIFE SCIENCES**

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**2nd ANNUAL BUCHANAN
LIFE SCIENCES SUMMIT**

WEDNESDAY, SEPTEMBER 20 | 9:30 A.M. – 3:30 P.M.

CYTO PHL | PHILADELPHIA, PA

Opening Remarks



Jason Parish

Shareholder, Life Sciences Industry Group
Co-Leader and Life Sciences Litigation
Practice Group Leader
Buchanan



Tina Hu-Rodgers

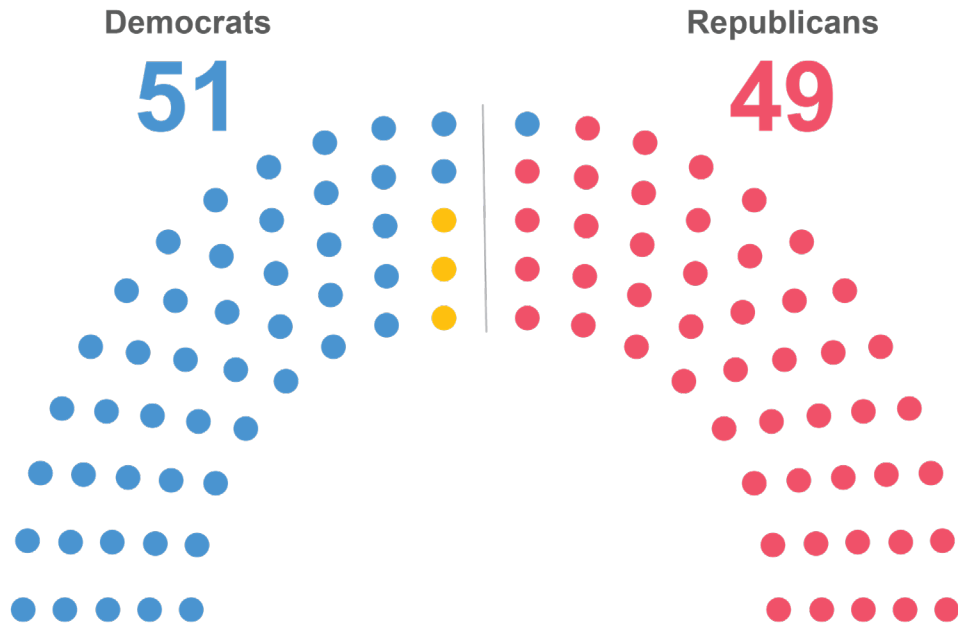
Counsel and Life Sciences Industry Group
Co-Leader
Buchanan

+ The Bottom Line | Impacts of Drug Pricing Legislation and Beyond

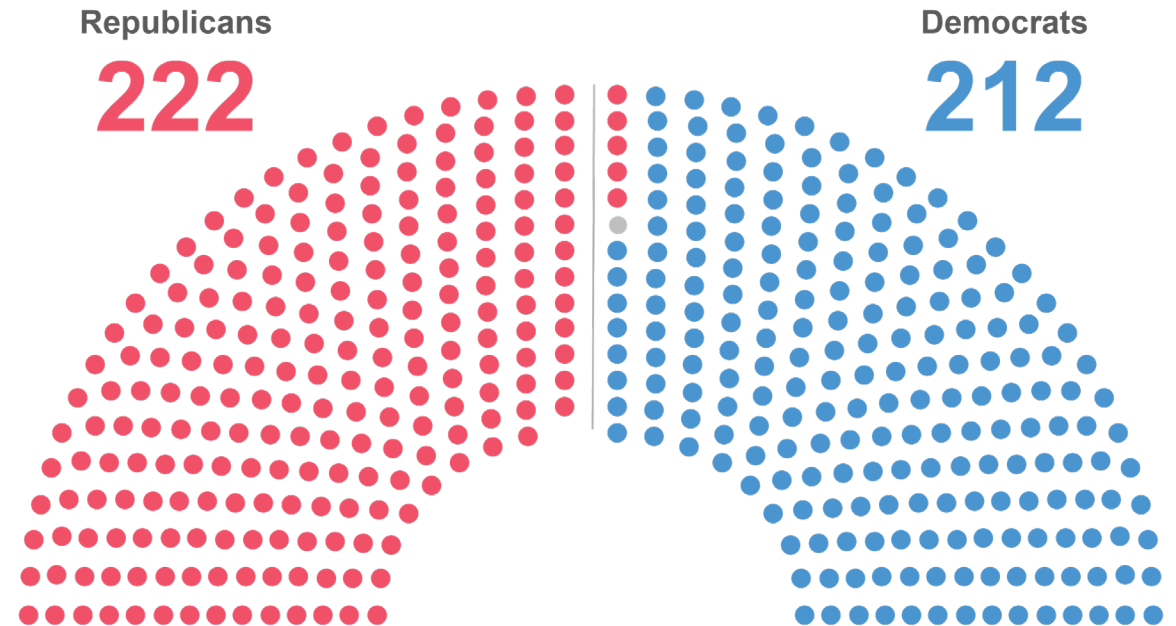


Michael Strazzella
Healthcare Industry Group Co-Leader and
Federal Government Relations Co-Chair
Buchanan

+ 118th Congress Balance of Power



Senate Party Breakdown :
51 Democrats (including 3 Independents)
49 Republicans



House Party Breakdown :
221 Republicans, 212 Republicans, 2 Vacancies (Seat of former Reps. David Cicilline (D-RI) and Chris Stewart (R-UT))

+ House and Senate Committee Focus



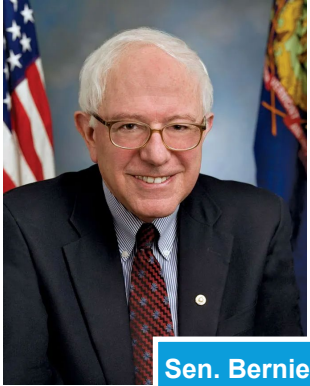
Sen. Ron Wyden (D-OR)
Chairman

- Chairman Ron Wyden (D-OR) wants PBM overhauls included in bipartisan drug pricing bill
- In July, Committee approved a bill to delink PBM income from drug prices and rebates, prohibit spread pricing in Medicaid, require more PBM reporting
- Cross-border Rx: Pharmaceutical Manufacturers and U.S. International Tax Policy



Sen. Mike Crapo (R-WY)
Ranking Member

Senate Health, Education, Labor, and Pensions (HELP) Committee



Sen. Bernie Sanders (D-VT), Chairman

- Chairman Bernie Sanders (I-VT) has been working on legislation to address health care workforce shortages
- Antimicrobial Resistance
- Mental Health
- Pandemic and All-Hazards Preparedness



Sen. Bill Cassidy (R-LA)
Ranking Member

+ House Energy & Commerce Committee



Rep. Cathy McMorris
Rodgers (R-WA), Chair

- Chair Cathy McMorris Rodgers (R-WA)
- Healthcare Transparency
- PBMs
- User Fees
- Drug Shortages
- Medicare Coverage: Innovative Drugs
- SUPPORT Act: Opioid Legislation



Rep. Frank Pallone, Jr.
(D-NJ), Ranking Member

+ House Ways & Means Committee



Rep. Jason Smith (R-MO), Chair

- Chairman Jason Smith (R-MO)

Key issues:

- No Surprises Act
- Price Transparency
- Healthcare Consolidation



Rep. Richard Neal (D-MA), Ranking Member

+ Fiscal Year 2024 Budget

- Congress must fund the government by September 30th each year
 - With less than two weeks left in the fiscal year, Congress has passed none of the 12 appropriations bills (only the House has passed the Military Construction-Veterans Affairs bill)
- Options:
 - Pass all 12 Appropriation bills by September 30th with FY24 funding levels
 - Pass a Continuing Resolution (CR): Extends FY 23 levels (might have tweaks)
 - Pass some Appropriation bills and CR for rest
 - Government Shutdown

+ Fiscal Year 2024 Budget

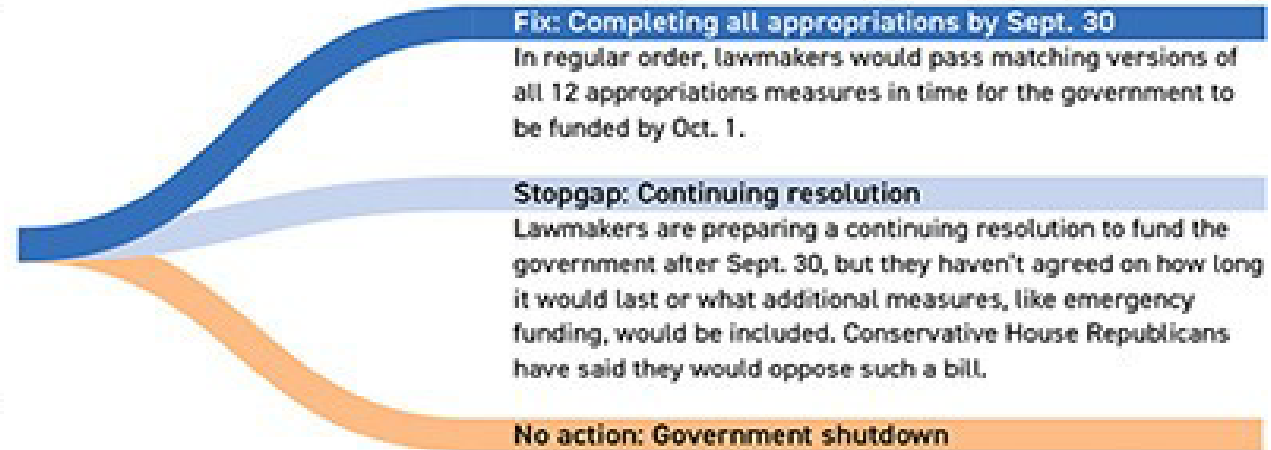
WHAT'S BEEN DONE

The House and Senate Appropriations committees have sent their drafts of 10 and all 12 funding bills, respectively, to the House and Senate floors. The House has passed its measure for Military Construction-Veterans Affairs, while the Senate has taken up a three-bill "minibus" package.

Complicating things are White House requests for aid to Ukraine and a disaster relief package. House Republicans want to separate Ukraine aid from the rest of the emergency funding; Democrats want to pass them together.

ISSUE

Appropriations for fiscal 2024



HOW IT COULD END

+ Lower Costs, More Transparency Act (H.R. 5378)

U.S. House will vote on Legislation this week

*Disagreements between Democrats complicating issues

- Extend funding for community health centers, National Health Service Corps, and special diabetes programs through calendar year 2025, teaching health center GME program through fiscal 2030
- Prohibit PBM spread pricing in Medicaid and limit payments for PBM services to an administrative fee; require additional PBM reporting on drug costs, coverage, and rebates
- Require providers and group health plans to disclose price of services and drugs to patients

+ Lower Costs, More Transparency Act (H.R. 5378)

- Require FDA to inform generic drug applicants of differences between their product and the brand-name drug in an effort to accelerate generic drug development
- Eliminate Disproportionate Share Hospital pay cuts for fiscal 2024 and 2025
- Reduce Medicare payment rates for off-campus hospital outpatient departments
- DROPPED: Medicare provision that bases patient cost-sharing on a drug's list price — rather than the net price paid by the health plan

+ Orange Book reform

Senator Elizabeth Warren (D-MA) and Rep. Pramila Jayapal (D-WA) letter to FDA Commissioner calling on reforms related to “anti-competitive behavior”.

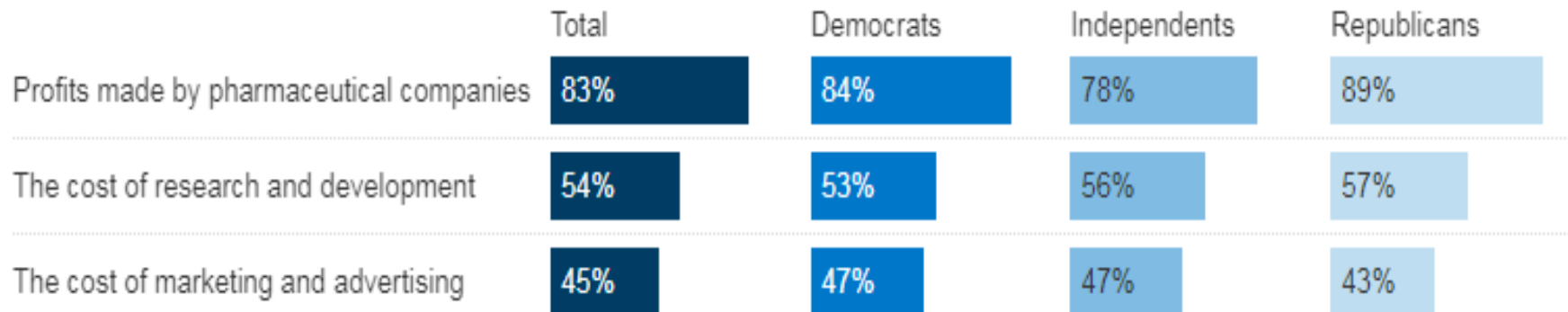
- Clarify guidelines for patents that can be listed in Orange Book
- Work closely with the USPTO to develop a review and validation system for every patent that is listed in the Orange Book
- Revise policies regarding ‘suitability petitions’
- Share chemistry, manufacturing, and control information provided by drug manufacturers in applications for Investigational New Drugs with the USPTO

+ Rx Price Negotiation

Figure 5

About Eight In Ten Across Parties Say Drug Company Profits Are A Major Contributing Factor To Prescription Drug Costs

Percent who say each of the following is a **major factor** contributing to the price of prescription drugs:



NOTE: See topline for full question wording.

SOURCE: KFF Health Tracking Poll (July 11-19, 2023) • PNG

KFF

+ Rx Price Negotiation

The List is Out!

- Eliquis, a blood thinner
- Xarelto, a blood thinner
- Januvia, a diabetes drug
- Jardiance, a diabetes drug
- Enbrel, a rheumatoid arthritis drug
- Farxiga, a drug for diabetes, heart failure and chronic kidney disease
- Imbruvica, a drug for blood cancers
- Entresto, a heart failure drug
- Stelara, a drug for psoriasis and Crohn's disease
- Fiasp and NovoLog, for diabetes
- \$50.5 Billion or 20% of Part D Spending (June 1, 2022 to May 31st, 2023)

+ Rx Price Negotiation



What will the 10 do?

- Have 30 days to sign agreement
-Or Face tax penalty

Lawsuits....will they be decided in time?

- 2027 15 more drugs
- 2028 20 more drugs

+ Rx Price Negotiation

Inflationary Rebate

- 34 drugs identified by CMS
 - invoiced in 2025 (for 2023 and 2024)
- Part B beneficiary coinsurance lower between Oct. 1 – Dec 31

One more lingering thing.....



Biden Impeachment Inquiry



Regulatory and Legal Enforcement in Life Sciences | Trends to Watch



George Karavetsos
Shareholder, White
Collar Defense,
Compliance, and
Investigations
Practice Group Leader
Buchanan



Jason Bologna
Shareholder, White
Collar Defense,
Compliance, and
Investigations
Buchanan



Allison Borgatti
Shareholder, White
Collar Defense,
Compliance, and
Investigations
Buchanan



Mark Kasten
Counsel, Litigation
Buchanan



Megan Scheib
(Moderator)
Senior Attorney,
Litigation
Buchanan

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Break | 11:00 a.m. – 11:15 a.m.

+ Prioritizing the Priorities | Lessons Learned as + a Life Sciences Company's General Counsel



Kimberly Banks MacKay
SVP, General Counsel and
Corporate Secretary
West Pharmaceutical
Services, Inc.



Linda Pissott Reig
Shareholder, FDA &
Biotechnology
Buchanan



Jennifer Sanfilippo
General Counsel & Chief
Compliance Officer
Melinta Therapeutics



Risky Business | Strategies for Managing Essential Life Sciences Partnerships



Rob Holland

Director, Associate General
Counsel
BD&L, Strategy and
Portfolio
Sandoz Inc.



Jason Parish

Shareholder, Life Sciences
Industry Group Co-Leader
and Life Sciences Litigation
Practice Group Leader
Buchanan



Tina Hu-Rodgers

Counsel and Life Sciences
Industry Group Co-Leader
Buchanan



Needs from Partnerships

Big Company

- Comprehensive understanding, qualifications and expertise in development and manufacturing
- Data Management
- Manufacturing and packaging capabilities and expertise
- Understanding, qualification and/or expertise in development and manufacturing for specific products

Small Company

- Up-front capital
- Facility, equipment and staff capabilities
- Distribution and commercialization capabilities and expertise
- Quality considerations
- Sophisticated quality or pharmacovigilance (“PV”)
- Compliance infrastructure and other institutional controls



Addressing Antitrust Risk

- Antitrust should be front of mind in any discussion of a partnership with an actual or potential business competitor
 - Does a merger analysis apply? Is an HSR filing required?
 - Is the partnership itself “legitimate”?
 - Does operation of the partnership violate the antitrust laws?
- See: FTC / DOJ Antitrust Guidelines for Collaboration Among Competitors
 - www.ftc.gov/os/2000/04.ftcdojguidelines.pdf
- Engage antitrust counsel at the beginning!



Common Problems in Partnerships



Standard “Transition to a New Supplier” is Not Practical

- Tech transfers can take time
- May not meet qualification standards



Questionable Causes

- Development delayed/significantly impacted for unknown or unreasonable causes
- Reporting requirements



Negative Consequences of Enforcing Contract

- Could terminate or otherwise impact business relationship
- Decreased Profits

Solution: Develop Strategic Business Alliances



- Hedging risk
- Due Diligence
 - Resources/Support Needed
 - Company Culture
 - Collaboration Experience
 - Compliance Infrastructure and Expertise
- Strong rights to terminate and other contractual language (e.g., to protect intellectual property rights)
- Specific and granular development plans



Solution: Manage Effectively

- Know what each partnership entails
 - Obligations
 - Responsibilities
 - Rights
- Consider how each partnership may affect other partnerships/agreements
- Be vigilant





Networking Lunch | 12:15 p.m. – 1:15 p.m.

+ Optimizing Clinical Trials | Maximizing Value from Concept to Implementation



**Barbara Binzak
Blumenfeld, Ph.D.**
Shareholder and FDA
& Biotechnology
Section Co-Chair
Buchanan



**Michelle Garvey
Brennfleck**
Shareholder and
Healthcare Industry
Group Co-Leader
Buchanan



Jennifer Minter
Shareholder and
Corporate Section
Chair
Buchanan



Lauren Misztal
Senior Vice President,
General Counsel
Clario



Duane Stewart
Shareholder,
Intellectual Property
Buchanan+

Clinical Trial Pillars



- Design the trial
- Consider subject recruitment
- Identify trial funding opportunities and related requirements
- Develop reimbursement strategy
- Select service providers
- Address data ownership, data sharing, and IP protection
- Address subject data privacy
- Consider possible future use of data or subject samples/craft informed consent language
- Oversee the service providers
- Monitor for fraud
- Inform site investigators, IRB, and FDA of information as needed
- Address data breaches

Clinical Trials Scenario Exercise

Use the QR Code to submit your thoughts!



+ Trade Secrets & Life Sciences | Protecting Value from Walking Out the Door



Marjorie Adams
Head of Employment &
Litigation/Associate General
Counsel
Ferring Pharmaceuticals, Inc.



Jonathan Janow
Shareholder, Litigation
Buchanan



Jason Murtagh
Shareholder, Labor &
Employment
Buchanan



James Wilcox
Counsel, IP Litigation
Buchanan



+ The Rise of Trade Secret Litigation - Impact on Life Sciences Companies

- 2016 Defend Trade Secrets Act
 - After the DTSA was introduced, federal trade secret case filings rose by 30 percent;
 - Today courts are dealing with roughly 1,400 cases a year.
- Employment Issues Impacting Trade Secret Protection
 - Employment Contracts;
 - Non-disclosure agreements;
 - Invention agreements; and
 - Inevitable disclosure doctrine.
- Intellectual Property Issues Impacting Trade Secret Protection
 - Interplay between patents and trade secret protections.

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TRADE SECRET PRIMER

+ What Laws Are Applicable for Trade Secret Litigation?

- The Defend Trade Secrets Act of 2016 (DTSA):
 - Provides a federal, private civil cause of action for misappropriation of a trade secret related to a product or service used or intended for use in interstate or foreign commerce.
 - Three-year statute of limitations from date misappropriation is discovered or should have been discovered.
 - DTSA sought conformity with the Uniform Trade Secrets Act.
 - Since 2016, DTSA interpretation and application is still being developed.
 - Growing legal certainty should engender more DTSA litigations in the future.
- State Law Misappropriation of Trade Secret Claims:
 - DTSA does not preempt state law claims.
 - 48 states adopted the Uniform Trade Secrets Act, with some modifications.

+ The DTSA Trade Secret Definition - 18 U.S.C. § 1839(3)

- “[A]ll forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if —
 - (A) the owner thereof has taken reasonable measures to keep such information secret; and
 - (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information”

+ What Is Misappropriation under the DTSA?

- Acquisition of another's trade secret by improper means; or
- Disclosure or use without express or implied consent by a person who used improper means to acquire knowledge of the trade secret,
 - who knew or had reason to know that the knowledge of the trade secret was-
 - derived from or through a person who had used improper means to acquire the trade secret;
 - acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret; or
 - derived from or through a person who owed a duty to the person seeking relief to maintain the secrecy of the trade secret or limit the use of the trade secret; or
 - knew or had reason to know that the trade secret was a trade secret and had knowledge that the trade secret had been acquired by accident or mistake.
- Improper Means equals theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage.
 - Improper means is not reverse engineering, independent derivation, or any other lawful means of acquisition.

+ Compare DTSA to California's Trade Secret Definition - Cal. Civ. Code § 3426.1(d)

- “Trade secret” means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
 - (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
 - (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
- California is broader than the DTSA as it does not call out categories of information as the DTSA does:
 - DTSA specifically calls out financial, business, scientific, technical, economic, or engineering information.



**WHAT ARE EXAMPLES OF TRADE
SECRETS WE ARE SEEING IN LIFE
SCIENCES LITIGATIONS?**

+ High Level Examples of Trade Secret Information Related to Life Science Companies

Categories of Trade Secret Information (When Confidential with Reasonable Efforts)

Product Design	Manufacturing Procedures	Distribution Information	Pricing Strategies and Projections	Sales and Industry Relationships
Proprietary Business Information and Plans	Patient Data	Customer Lists	Marketing Materials and Research	Non-public Drug Sales Data
Data regarding Physician Prescribing Habits	Analyses of Prescriber/Patient Data	Industry Competitive Intelligence	Analyses between Products	Risk Evaluation and Mitigation Strategy Research
Software and Code	Technology Initiatives	Go-to-market Strategies	Emerging Growth Area Research	Product Development Priorities and Pipelines

+ High Level Examples of Trade Secret Information Related to Life Science Companies

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+ Medical Device Trade Secrets - Insulet Corp. v. EOFlow, Co. Ltd. et al.

- Insulet alleges EOFlow copied the design for its Omnipod patch pump that is a compact, wearable, waterproof, adhesive medical device that delivers insulin to diabetics.
 - The Omnipod adheres directly to the skin and doses insulin through a tiny needle, unlike traditional pumps that send insulin into the body via a tube.
 - Insulet alleges EOFlow hired several Insulet former senior executives and started working with Insulet's primary manufacturer.
 - Insulet argues EOFlow's rapid development of a patch pump virtually identical to Omnipod, and the complex manufacturing process required to produce it where others have failed is no accident.
 - Insulet notes that Medtronic, who is seeking to acquire EOFlow, has been unable to develop the patch pump on its own.
- Insulet now seeks a preliminary injunction before the Medtronic acquisition.

+ What Relief Is Available for Trade Secret Misappropriation Claims?

- Preliminary injunctive relief available to prevent any actual or threatened misappropriation. The court can:
 - Order the misappropriation to stop;
 - Order to protect the secret from public exposure; and/or
 - Order the seizure of the misappropriated trade secret in extraordinary circumstances.
- At the conclusion of trial, the court can award:
 - Damages;
 - Court costs;
 - Reasonable attorneys' fees; and/or
 - A permanent injunction.

+ Key Takeaways

- Whether it is a trade secret or not depends on your actions:
 - Did your company develop information that is not publicly available or reasonably ascertainable by the public;
 - Is this information valuable to your company?
 - Does your company take action to protect it from being disclosed?
 - To protect your trade secret in litigation, you will likely need to convince a jury, and not a judge, that your information is proprietary, valuable, and that you took measures to maintain its secrecy.



THE INTERPLAY BETWEEN EMPLOYER TRADE SECRET PROTECTION AND EMPLOYEE CONTRACTS





HOW DOES THE ABILITY TO MAINTAIN A TRADE SECRET DEPEND ON YOUR EMPLOYMENT AGREEMENTS?



+ What Do Employee Agreements Have to Do with Protecting Trade Secrets?

- Employee agreements affect the scope of an employer's trade secret protection;
- Draft employment agreements to expressly contain provisions to safeguard employee developed information and innovations;
- Define confidential information in the agreement;
 - E.g., “the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.”

+ What Do Employee Agreements Have to Do with Protecting Trade Secrets?

- Prohibit the use and disclosure of confidential company information for any reason except for the benefit of the employment both during employment and after employment has ended;
 - Draft agreements such that there is no temporal limitation on confidentiality obligations;
 - Draft agreements so that this obligation does not depend on the reason for an employee's departure.
- Require disclosure of employment agreement to future employers to inhibit future employer foul play.
- Understand the law governing your employment agreements.
 - Pay close attention to state specific laws.

+ How Do You Ensure Your Company Owns the Innovation, and Does Not Miss the Innovation?

- Require employee disclosure of inventions:
 - Employee shall promptly disclose to the Company any and all intellectual property, discoveries, inventions, technological innovations, improvements and copyrightable works conceived or made by employee, solely, jointly or commonly with others, during employee's employment with the Company, whether or not conceived or made during working hours, relating in any manner to the business, business plans, or development plans of the Company.
 - Incentivize disclosures - cash rewards and/or recognition per disclosure/application/patent.
- Assignment provision specifies employer ownership of all innovations/advancements:
 - All such discoveries, inventions, technological innovations, improvements and copyrightable works, **whether patentable or not patentable**, shall be the sole and exclusive property of the Company with respect to any and all countries.
 - Contractual language where employee "agrees to and does hereby grant and assign" was "not merely an agreement to assign, but an express assignment of rights in future inventions"
 - Require employee to execute the necessary documents.

+ How Can You Utilize Restrictive Covenants to Protect Trade Secrets?

- Limit former employee's ability to compete against his or her former employer for a reasonable period and within a reasonable geographic area.
 - Considerations
 - Does the nature of this business warrant post-employment restrictions?
 - What level of employees should be required to enter such a covenant?
 - Is this a jurisdiction that recognizes such a covenant? If so, are there limitations?
- But are non-compete agreements are falling out of favor?
 - On July 9, 2021, President Biden issued his "Executive Order on Promoting Competition in the American Economy"
 - Purpose – to "curtail the unfair use of noncompete clauses" to empower workers to find better jobs and strengthen their bargaining position when it comes to negotiating pay.



**IF NON-COMPETE PROTECTION FADES,
CAN I KEEP MY EMPLOYEE FROM
WORKING FOR A COMPETITOR?**



+ What Is the Inevitable Disclosure Doctrine?

- Allows a court to enjoin a former employee temporarily from working for his or her employer's competitor because of the threat of disclosure or use of the trade secrets the employee learned while employed by his or her former employer.
 - The doctrine relies on the premise that the employee has gained knowledge of confidential information while working for the former employer; and
 - The employee cannot forget or refrain from relying on that knowledge during his or her new employment with the competitor.
- The doctrine requires a court to consider:
 - The protection of employers' rights in their trade secrets on the one hand versus the right of the individual to exploit his talents, use matters of general knowledge, and pursue his calling without undue hindrance from a prior employer.

+ Where Is the Inevitable Disclosure Doctrine Applicable?

- State courts are split on the application of the inevitable disclosure doctrine.
- The DTSA does not preempt, influence, or modify applicable state law governing when an injunction should be applied.
 - Injunctions are more likely to be issued where state and DTSA claims are brought together.
- 17 states have adopted the inevitable disclosure doctrine in one form or another:
 - Arkansas, Connecticut, Delaware, Florida, Indiana, Illinois, Iowa, Minnesota, Missouri, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Texas, Utah and Washington.
- 5 states have rejected the inevitable disclosure doctrine:
 - California, Colorado, Louisiana, Maryland and Virginia.

+ Key Takeaways

- Don't let poorly drafted employment agreements disrupt your trade secrets:
 - Draft with an eye toward employer ownership of employee created trade secrets and innovation;
 - Particularize employment agreements based on the location and duties of a given employee.
 - Require the employee to take all steps or acts to vest the right of those trade secrets and innovations with the employer;
 - That do not have loopholes to the employee's obligations to maintain the confidentiality of those trade secrets; and
 - Don't solely depend on non-compete agreements from keeping your employees from moving to competitors in the future, even if they provide you with value today.



THE INTERPLAY BETWEEN PATENT AND TRADE SECRET PROTECTION



+ What Is the Relationship between Patent and Trade Secret Protection?

- Trade secret protection is a compliment to patent protection.
- Trade secret protection is broader than patent protection because it extends to information or technology that may not be patentable.
 - Patents require the inventor to provide a detailed and enabling public disclosure about the invention in exchange for the right to exclude others from practicing the invention for 20 years from the filing date.
 - Life Sciences companies are facing issues with fully enabling the scope of their claims given extensive disclosures are required to fully enable broad claims those companies seek.
 - Claims should be drafted to specific embodiments disclosed in a patent specification especially where products that would fall under a claim's scope would require substantial trial and error to be developed.
 - Seek layered patent claim scope protection through multiple patent filings.



WHAT IS MORE VALUABLE: A TRADE SECRET OR A PATENT?



+ What is the Relationship between Patents and Trade Secrets?

	Patent	Trade Secret
Subject Matter	Process, machine, manufactured item, or composition of matter	Information, including a formula, pattern, compilation, program, device, method, technique, or process
Legal threshold for protection	Useful, new, non-obvious	Reasonable efforts made to maintain and protect secrecy
Term	20 years	As long as secret is maintained
Violation	Infringement by making, using, selling, offering for sale, or importing claimed invention	Misappropriating the trade secret
Costs	High cost to obtain patents and enforce those patents	Costs to maintain secrecy
Remedies	Damages for reasonable royalties, lost profits, willful infringement, attorney's fees, injunction	Damages, punitive damages, attorney's fees, injunction
Risks	Patent invalidation, high cost to overcome IPR and litigation invalidity proceedings	Disclosure of secret, reverse engineering

+ Patent vs. Trademark Considerations:

- How **important** is the invention? The more important the invention generally is, the more important it is to obtain a patent.
- The ease of **reverse engineering** and likelihood of **independent discovery** of the invention.
- **Enforceability**: Can you prove patent infringement or discern an unlawful user of the trade secret.
- Can you **keep the secret**? Who needs to know the secret for commercial success?

Key Takeaways



- Catalog your innovations so you understand what you have;
- Determine the value (potential value) of your innovations;
- Determine whether those innovations are patent protectable;
 - A thorough prior art search, before filing a patent application, may inform you that it is better to keep your “not so new” technology secret.
- Don't keep information known to be required to practice a patent pending innovation secret as a future patent may be invalidated as non-enabled.
 - Focus on trade secret development for innovations that are already patent pending for the strongest complimentary trade secret protection.
 - The facts on the development of your technology will come out in discovery.



PRACTICAL GUIDANCE



+ What Are Employer Practices to Preserve Trade Secret Confidentiality?

- **Be proactive** in identifying trade secrets.
 - Document/itemize identified trade secrets and take proactive steps to maintain their secrecy.
 - Documentation includes identifying who developed the trade secret and when it was developed.
 - Label or stamp documents that contain trade secrets with words such as “confidential” or “trade secret.”
 - Visibly label areas of the workplace which contain trade secrets with signs or labels indicating the same.
 - Promote naming conventions for documents that make it easy to identify which documents contain trade secret material.

+ What Are Some Reasonable Measures Employers Can Use to Preserve Trade Secret Confidentiality?

- Employ reasonable measures to maintain secrecy:
 - Require participation in confidential education programs that inform employees on company practices;
 - Develop, maintain and circulate an institutional policy regarding trade secrets and require employees to certify that they read and understood the policies.
 - Physically lock the areas in the institution where the trade secrets (or documents containing them) would reside.
 - Limit access, employ passwords, and maintain detailed records of who has access to trade secrets and when they access that information (keep document control logs).
 - Maintain firewalls between the internet and computer systems that contain trade secrets.
 - Limit remote access to trade secrets in computer files.

+ What Employment Practices Can be Utilized to Preserve Trade Secret Confidentiality?

- Use performance reviews to remind employees of confidentiality obligations.
 - Cultivate a confidentiality culture by incorporating education and training during onboarding, performance reviews, special education programs, and at time of departure such that employees may be regularly reminded of their obligations and the consequences of disclosure.
- Educate employees on risks of disclosure in telework and work from home environments.
 - Misappropriation can occur between spouses, roommates, or shared workspaces.
- Provide employees with copies of their contract agreements at the time of departure.
 - Draft contracts to maintain duty of confidentiality after term of employment no matter what the reason for departure.
 - Check for suspicious user activity of departing employees.

+ Is Utilizing Artificial Intelligence a Trade Secret Disclosure Risk?

- **YES!** The secrecy of information is determined by circumstances surrounding any disclosure.
 - The heart of a trade secret's status is secrecy.
- Entrusting confidential information to an AI chatbot may destroy the trade secret status.
 - There is a loss of control as to what the AI chatbot may or may not do with the information. There is a risk the AI chatbot may publish or share your information with others.
 - At a minimum, there needs to be contractual agreements with any company offering AI services that require the AI to keep any information input confidential.
- The development of a company's own dedicated AI may reduce these risks.

+ What Are Strategies for Complementary Patent and Trade Secret Protection?

- Do not disclose your trade secrets in patent applications or scientific journal articles.
 - Consider the risk of failure to enable or disclose the best mode of your invention in your patent application if your trade secrets are withheld at the time of filing.
 - Strategy: Define and develop trade secrets that advance a patent pending invention after the date the patent has been filed.
- Trade secrets will be ascertainable from a patent disclosure if it makes the trade secret **“generally known”** or **“explicitly disclosed”** such that any reasonably skilled artisan could have developed the trade secret from the disclosure.

+ Key Takeaways

- The things in your company's control are:
 - Employment agreement language;
 - Security measures to maintain secrecy including ongoing education for your employees;
 - An understanding your innovations and their expected value;
 - Your response to accidental releases of information; and
 - Active monitoring for trade secret misappropriators.

Closing Remarks



Joseph Dougherty
Chairman and CEO
Buchanan



Networking Reception | 3:30 p.m. – 4:30 p.m.

