

2024

# BUSINESS IN 2023

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## **Gabriel S. Oberfield**

Senior Counsel

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New York, NY

# TODAY'S AGENDA

## Gabe Oberfield – (12:00PM-12:05PM)

- Intros / Agenda
- NYS Budget and Timing

## Colin Leonard – (12:05PM-12:15PM)

- NY WARN Act Proposed Regulations

## John Harras – (12:15PM-12:25PM)

- Proposed Forfeiture Regulations and Plan Sponsors

## Dustin Dorsino – (12:25PM-12:35PM)

- Update on Litigation Affecting NYS's Cannabis Licensing Program

## Bryan Smith – (12:35PM-12:45PM)

- Update on IP Litigation before SCOTUS

## G. Oberfield – (12:45PM)

- Wrap Up

# New York State Budget Negotiations...

Source: PoliticoPro

- No NYS budget, as yet
- The deadline was April 1, 2023 deadline to approve a new state budget
- Governor Hochul would with the legislature's support extend the ostensibly expired budget until April 10, 2023
  - No extender → delays in state payroll
- Chiefly contested issues remain:
  - Housing plan
  - Bail reform



New York State Capital – Office of General Services

# NY WARN Act – Proposed Revisions to Current Regulations



**Colin M. Leonard**

Member

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Syracuse, NY



# NY WARN Proposed Regulations

- Background on NY WARN
  - Enacted in 2009
  - Requires employers with 50 or more employees in New York to comply with NY WARN
  - 90 days notice prior to a “plant closing” or “mass layoff”

# NY WARN Proposed Regulations

- Plant Closing
  - Temporary or permanent shutdown of a single site of employment resulting in employment losses for 25 or more employees, excluding part-time employees
- Mass Layoff
  - Layoff of 250 employees, excluding part-time employees; OR if
  - Layoff of at least 25 employees, excluding part-time employees, where such number is at least 33% of the employees at the site

# NY WARN Proposed Regulations

- First set of revisions to the regulations since 2009
- Many revisions relating to process and procedure for compliance with NY WARN



# NY WARN Proposed Regulations

- Key Points: Sale of a Business
  - Important revisions that will apply in the context of the sale of a business
  - In order to take advantage of the exception to notice in the sale of a business, will need to include language in transactional documents
  - Impact: Likely to make it harder for sellers and buyers to come to terms on a deal without specific language transitioning employees to the buyer

# NY WARN Proposed Regulations

- Payments in Lieu of Notice

- Is a process where an employer is able to pay employees instead of continuing to employ them for the entirety of the 90 day notice period
- Revisions: Requires that an employer maintain a policy that requires notice in advance of a separation (e.g., two weeks, 30 days, 90 days?)
- Most employees in New York are “at will” – this would dilute that rule to require notice prior to separation

# NY WARN Proposed Regulations

- Changes to the Exceptions to Notice
  - Proposed regulations make significant changes to the substance and procedure required when trying to establish an exception to providing the 90 days of notice
    - Faltering Company – will only be available for a plant closing, not a mass layoff
    - Faltering Company and Unforeseeable Business Circumstance exceptions:
      - Employer must provide a signed affidavit under “penalty of perjury” that the information contained in the affidavit is “true and accurate.”
    - For all exceptions, can only be established upon a “determination” by the Commissioner of Labor.

# NY WARN Proposed Regulations

- Public comment period expires May 30, 2023
- Comments may be submitted to [regulations@labor.ny.gov](mailto:regulations@labor.ny.gov).
- Questions: Colin Leonard, [cleonard@bsk.com](mailto:cleonard@bsk.com)

# Proposed Forfeiture Regulations and Plan Sponsors



## John M. Harras

Senior Counsel  
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# Proposed Regulations on Plan Forfeiture Use

- Types of Forfeitures
- Use of Forfeitures
- Proposed Regulations on Forfeiture Usage
- Impact of the Proposed Regulations on Your Plan

# Types of Retirement Plan Forfeitures

- **Termination of Employment Without Cause**
  - Unvested Employer Contributions – Forfeited
- **Termination of Employment With Cause**
  - Unvested and Vested Employer Contributions – Forfeited
    - Need “bad boy” clause and accelerated vesting schedule
      - Terminated for “serious misconduct” or “post-termination competitive activities”
      - Generally, the vesting schedule must be shorter than 5 years



# Types of Retirement Plan Forfeitures

- **Withdrawal of Mandatory Contributions**

- Unvested and Vested Employer Contributions – Forfeited
  - Plan has mandatory contributions from employees
  - Employee withdraws mandatory contributions and is less than 50% vested
  - Employee has ability to cure

- **Death**

- Unvested and Vested Employer Contributions – Forfeited
  - Plan must have policy providing for this forfeiture
  - Does not apply to survivor annuities

# Types of Retirement Plan Forfeitures

- **Multiemployer Plans – Special Rules**
  - Cessation of Contributions (e.g., sale of business, termination of CBA)
    - Benefits accrued prior to employer's obligation to contribute are forfeited.
      - Only applies if plan documents include this policy
  - Insolvency/Termination (i.e., plan assets less than benefits)
    - Plan Sponsor must amend the plan to reduce or suspend benefits

# Current Permissible Use of Forfeitures

- **Defined Benefit Plans (e.g., pension plans)**
  - Reduce Employer's Contributions under Plan "As Soon As Possible"
  - Pay Plan Administrative Expenses
    - Recordkeeping fees, third-party administrator fees, and reporting/testing fees
- **Defined Contribution Plans (e.g., 401(k) savings plans)**
  - Allocate "to participants' accounts in accordance with a definite formula."
    - Administrative Expenses?
      - Unclear
    - Separate suspense account?
      - IRS Newsletter - No

# New Proposed Regulations on Forfeiture Use

- **Defined Benefit Plans**

- Repeal requirement to apply forfeitures “as soon as possible.”
- Incorporate forfeitures into actuary’s reasonable underlying minimum funding level calculation.
- Proposed Effective date: first day of plan year on or after January 1, 2024.

- **Defined Contribution Plans**

- Plan may use forfeitures to:
  - Pay administrative expenses;
  - Reduce employer contributions; or
  - Increase benefits of other participants.
- Plan must use forfeitures within 12 months after close of plan year of forfeiture
  - No more separate accounts for forfeitures
- Transition Rule: pre-2024 forfeitures would be deemed to have occurred in 2024.

# Proposed Forfeiture Regs: The Impact on Your Plan

- **Effect of Proposed Regulations**

- Close Forfeiture Suspense Accounts – Allocate Contents by End of 2025
- Amend Plan Documents
  - Require Use of Forfeitures within 12 months
  - Identify Permissible Uses of Forfeitures
    - Pay expenses, reduce employer contributions, or increase benefits for participants
- Adjust actuary assumptions
  - Valuation of minimum funding level must include expected forfeitures

- **Timeline of Implementation**

- May 30, 2023 – Deadline for Comments

# Update on Litigation Affecting NYS's Cannabis Licensing Program



**Dustin M. Dorsino**

Associate

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Syracuse, NY

# Background

- New York's cannabis regulators opened retail applications first to “justice-involved” applicants under the Conditional Adult-Use Retail Dispensary (CAURD) Program
- To date, 66 CAURD licenses have been awarded (99 more were approved Monday). So far, only 7 CAURDs have opened.
- The application period for the remaining applicants is expected to open this Fall.



# Variscite NY One, Inc. v. State of New York

- Plaintiff: Michigan-based CAURD applicant. No “significant connection” to New York
- Argument: NY’s Cannabis Regulations violate Dormant Commerce Clause
- Decision: Preliminary Injunction granted on CAURD Program in Finger Lakes, Central New York, Western New York, Mid-Hudson and Brooklyn geographic areas

# Coalition for Access to Regulated & Safe Cannabis v. NYS Cannabis Control Board et al.

- Plaintiff: group of large multistate cannabis organizations and potential dispensary applicants
- Argument: NY cannabis regulators improperly assumed the role of the Legislature by allowing CAURD applicants to apply first
- Relief Sought: Declare CAURD Program unconstitutional; compel OCM to pursue civil penalties against illicit cannabis stores; open dispensary application period for everyone

# Update on IP Litigation before SCOTUS



**Bryan C. Smith**

Senior Counsel

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Rochester, NY

# Amgen, Inc. v. Sanofi

No. 21-757

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IN THE  
**Supreme Court of the United States**

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AMGEN INC., *et al.*,  
*Petitioners,*

*v.*

SANOFI, *et al.*,  
*Respondents.*

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ON WRIT OF CERTIORARI TO THE UNITED STATES  
COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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BRIEF OF LAW PROFESSORS  
JOSHUA D. SARNOFF, SHARON K. SANDEEN,  
AND ANA SANTOS RUTSCHMAN AS *AMICI*  
*CURIAE* IN SUPPORT OF RESPONDENTS

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# Patent Quid Pro Quo

35 U.S.C. §112(a) requires that a patent's specification must contain “a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.”

- This statutory requirement dictates that patent applications contain sufficient disclosure to allow one skilled in the relevant art to make and use the claimed invention ***without undue experimentation***. It is the essence of the quid pro quo bargain between the inventor and the government where a temporary right to exclude others from making or using the invention is granted to the inventor in exchange for the enabling description of their invention

# Underlying Technology - Problem

- Treatment for High LDL cholesterol (LDL-C)
- Dealing with PCSK9
  - PCSK9 is a naturally occurring protein that binds to and causes the destruction of liver cell receptors responsible for extracting LDL-C from the bloodstream
  - More PCSK9 protein in the body = fewer LDL receptors in the liver = higher LDL cholesterol levels

# Underlying Technology - Solution

- Antibodies (proteins that bind to target molecules) developed to treat cholesterol by inhibiting PCSK9
  - Antibodies bind to PCSK9 to **prevent PCSK9 from destroying the liver cell receptors** that extract LDL-C from the bloodstream
  - Made up of amino acid chains with unique sequences



# Amgen's Product

**AMGEN**

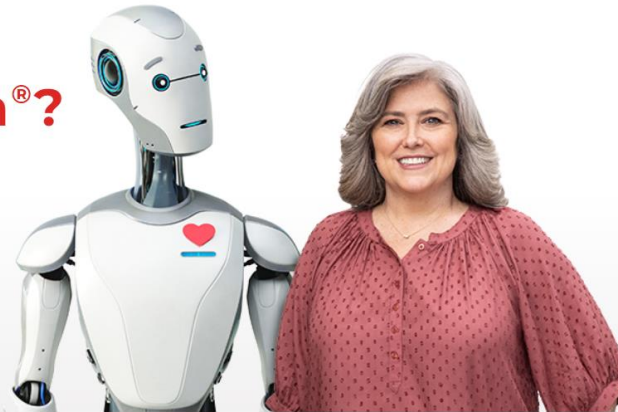
 **Repatha**  
(evolocumab) injection  
140 mg/mL

- \$1.296 billion in sales worldwide in 2022\*
- \$1.117 billion in sales worldwide in 2021\*

For adults with heart disease

## What Is Repatha®?

Repatha® is a breakthrough medicine that can help you dramatically **lower bad cholesterol and reduce your risk of heart attack.**



\* <https://www.amgen.com/newsroom/press-releases/2023/01/amgen-reports-fourth-quarter-and-full-year-2022-financial-results>

# Sanofi/Regeneron's Accused Product

sanofi

REGENERON®

- \$467 million in sales worldwide in 2022\*
- \$421 million in sales worldwide in 2021\*

## What is PRALUENT?

In adults with cardiovascular (CV) disease,

PRALUENT is proven to reduce the risk of having certain CV events (heart attack, stroke)

If you have heart disease, and your bad (LDL) cholesterol remains high, you're at risk for a CV event, like a heart attack, stroke, or certain types of chest pain conditions (unstable angina) requiring hospitalization.



Nearly 1 in 3 people who survived a heart attack or stroke suffered another cardiovascular event in the next 4 years.\*



Praluent®  
(alirocumab) Injection 75mg/mL  
150mg/mL

- \* <https://newsroom.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2022-financial>

# Amgen's U.S. Patents at Issue



- U.S. Patent No. 8,829,165
- U.S. Patent No. 8,859,741

(12) **United States Patent**  
**Jackson et al.**

(10) **Patent No.:** **US 8,829,165 B2**  
(45) **Date of Patent:** **\*Sep. 9, 2014**

(54) **ANTIGEN BINDING PROTEINS TO  
PROTEIN CONVERTASE SUBTILISIN  
KEXIN TYPE 9 (PCSK9)**

(71) Applicant: **Amgen Inc.**, Thousand Oaks, CA (US)

(72) Inventors: **Simon Mark Jackson**, San Carlos, CA (US); **Nigel Pelham Clinton Walker**, Burlingame, CA (US); **Derek Evan Piper**, Santa Clara, CA (US); **Wenyan Shen**, Palo Alto, CA (US); **Chadwick Terence King**, North Vancouver (CA); **Randal Robert Ketchum**, Snohomish, WA (US); **Christopher Mehlin**, Seattle, WA (US); **Teresa Arazas Carabeo**, New York, NY (US)

(73) Assignee: **Amgen, Inc.**, Thousand Oaks, CA (US)

7,261,893 B2	8/2007	Veldman et al.
7,300,754 B2	11/2007	Abi Fadel et al.
7,368,531 B2	5/2008	Rosen et al.
7,411,051 B2	8/2008	Rosen et al.
7,456,264 B2	11/2008	Keler et al.
7,482,147 B2	1/2009	Glucksmann et al.
7,572,618 B2	8/2009	Mintier et al.
7,776,577 B2	8/2010	Kapeller-Libermann et al.
7,968,689 B2	6/2011	Rosen et al.
8,030,457 B2	10/2011	Jackson et al.
8,062,640 B2	11/2011	Sleeman et al.
8,080,243 B2	12/2011	Liang et al.
8,168,762 B2	5/2012	Jackson et al.
8,188,233 B2	5/2012	Condra et al.
8,188,234 B2	5/2012	Condra et al.
8,344,114 B2	1/2013	Sparrow et al.
8,357,371 B2	1/2013	Sleeman et al.
8,399,646 B2	3/2013	Liang et al.
8,420,098 B2	4/2013	Camphausen et al.
8,426,363 B2	4/2013	Lianz et al.

# Functional Genus Claims (Example)

1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

- Broadly claims a genus of antibodies that provide the recited function
  - Antibody that blocks binding of PCSK9
  - Specific sequence is not required to infringe claim
- Amgen holds separate patent on sequence of specific antibody employed in the commercial product
  - Sanofi product does not infringe that patent
  - Sanofi conceded infringement of the broad genus claim

# First Jury Trial

- Amgen sued Sanofi for patent infringement in October, 2014
- Sanofi stipulated to infringement of the asserted patents but asserted various invalidity defenses
- Jury denied invalidity defenses
- Federal Circuit vacated and remanded based on evidentiary issue

## Second Jury Trial

- Jury denied invalidity challenges
- District Court granted JMOL of invalidity based on enablement
  - Found undue experimentation would be required to enable the full scope of the claims

# Federal Circuit Upholds Invalidity Finding

- Federal Circuit held the genus claims were not enabled
  - Found the disclosure did not reach the full scope of the claimed embodiments
  - Skilled artisans would have to generate and then screen every theoretical candidate antibody to determine if it was within the scope of the claims
  - Millions of candidates would have to be tested
  - Antibody arts are unpredictable
  - Patent did not provide adequate guidance beyond 26 working examples



# Questions Presented on Appeal to Supreme Court

## QUESTION PRESENTED

Section 112 of the Patent Act provides that a patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it," sufficient "to enable any person skilled in the art \* \* \* to make and use the" invention. 35 U.S.C. § 112(a). The requirement that the specification teach skilled artisans "to make and use" the invention is referred to as the "enablement" requirement. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996). The question presented is:

Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without "substantial time and effort," Pet. App. 14a (emphasis added).

# Quid Pro Quo Balancing Act

- Competing goals:
  - Providing broad coverage for inventions to encourage innovation
  - Ensuring that the disclosure provides enough information to make and use the invention without undue experimentation

# What will Supreme Court do?

- Will the Supreme Court alter the landscape of enablement?
  - Will the Federal Circuit's enable the full scope of the claimed invention test survive?
  - Will the Supreme Court provide further guidance on how much experimentation is undue?
- Decision may have major impacts on research and development in the life sciences
  - What scope of invention can companies obtain patent protection for in life sciences and chemical fields?
  - How will genus claims be impacted?

# Amici in Support of Amgen



abbvie



ACS  
Chemistry for Life®



InstilBio



# Amici in Support of Sanofi

**Genentech**  
A Member of the Roche Group

AstraZeneca



**Pfizer**

**GILEAD**  
Creating Possible

Johnson & Johnson

*Lilly*

**UnifiedPatents®**

**Arnold  
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**aam®**  
Association for Accessible Medicines

Public Interest Patent Law Institute

**VIATRIS™**

**AIPLA**  
American Intellectual Property Law Association

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& KING ATTORNEYS

# Your Questions



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### **New York Employment Law: The Essential Guide**

NYS Bar Association Members can buy the book from the bar [here](#).

Non-NYS Bar Association Members can purchase through Amazon [here](#).

# Thank You

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It is not to be considered as legal advice.  
Laws can change often, and information may become outdated.

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