LIFE SCIENCES CLE WEBCAST · PART III OF III

Proving the Case

Science, patents, and damages in life sciences collaboration and licensing disputes

PRESENTERS

Charlotte Jacobsen · Mary Beth Maloney

Moderated by Ryan Murr

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Speakers and Roadmap

Ryan Murr MODERATOR
Partner, San Francisco. Co-Chair, Life Sciences Practice Group. M&A, capital markets and royalty-finance transactions.

Charlotte Jacobsen
Partner, New York. First-chair patent litigator with advanced technical degrees and a deep understanding of biology, chemistry, and FDA-regulated product development. Specializes in patent litigation and life sciences disputes.

Mary Beth Maloney
Partner, New York. Trial lawyer for life sciences licensing, collaboration, milestone and royalty disputes in court and arbitration.

#	THE CONVERSATION
1	NovaRx / Meridian: the dispute so far
2	Proving the milestone
3	Proving an efforts breach
4	Patents in a license dispute
5	What the patents prove
6	Experts: who, and what holds up
7	Damages: valuing a milestone never paid
8	The proof plan, and questions

NovaRx / Meridian: A Collaboration in Trouble

The hypothetical we have followed since September. All entities are fictional.

THE DEAL

The parties. NovaRx, a Nasdaq-listed clinical-stage biotech, licensed NVX-301, a Phase 2 asset for a rare autoimmune disease, to Meridian Pharma.

The economics. $310M in development and regulatory milestones, $500M in sales milestones, royalties of 8 to 14%.

The two triggers. $120M on the first Regulatory Approval. $90M on a label showing a specified benefit “as a result of” the registrational study named in a schedule.

The agreement. A License Agreement governed by New York law, with ICC arbitration and carve-outs to court.

WHAT WENT WRONG

- Meridian was acquired by a large public pharma with a competing program.
- Phase 3 slipped twice and the study was redesigned. The JSC stopped meeting.
- Royalty reports show one net number. NovaRx’s audit found deductions it cannot reconcile.
- Meridian served notice that the redesigned study is the Registrational Study and no $90M is payable.
- NovaRx’s royalty financing depends on the $90M label milestone, and its lenders are asking when it will be paid.

THE CLOCK FDA’s decision on the label from the redesigned study is less than nine months away. Every choice runs against that date.

Three New Facts, Three Questions

After Part II: a court claim on the $90M, arbitration on diligence, and an expert to decide the royalty deductions.

NEW FACT (ILLUSTRATIVE)	THE QUESTION IT RAISES
Meridian says FDA asked for the redesign, so the redesigned study is the Registrational Study.	**Is the $90M milestone owed?**
A former Meridian program lead says NVX-301 ranked behind the parent's competing program.	**Did Meridian use the efforts it promised?**
NVX-301 is approved but sales are slow. Meridian says the NovaRx patents are invalid and it owns the later patents.	**Can Meridian cut royalties to the know-how rate?**

NovaRx and Meridian are fictional.

TODAY'S QUESTION For each question: what must NovaRx prove, what shows it, who says it, and what is it worth?

Proving a Milestone

Four layers of proof, in the order a court or tribunal reaches them.

1. **The words.** The trigger and every defined term inside it. Decision makers start here.
2. **The structure.** What the schedule names, what it leaves out, and how the other milestones are drafted.
3. **The regulatory record.** What FDA was asked, what it said, and when: correspondence, minutes, protocol amendments, label drafts.
4. **The parties' conduct.** Reports, JSC minutes and public statements. Used only if the words leave a gap.

FROM THE CASE STUDY

Four features of one clause produced a $300 million dispute: a rate that outcome studies report several ways, no use of "primary endpoint," and payment keyed to the label.

The case settled nine months after filing.

Facts are from public filings and announcements.

THE PRACTICAL POINT Regulatory documents answer a contract question only when a qualified witness explains them. Name that witness before the first brief.

Proving an Efforts Breach

The proof depends on how the clause measures effort.

OUTWARD-FACING STANDARD

What a similarly situated company would do.

Proof: an industry practice expert, comparators, and the buyer's decisions measured against peers.

Alexion (Del. Ch. 2024). Funding was cut for an internal launch target, then the program was ended under an acquirer's synergy mandate. The court found both reasons idiosyncratic and held the termination breached the clause.

INWARD-FACING STANDARD

Efforts comparable to the buyer's own priority products.

Proof: the buyer's own records of how it treats priority assets.

J&J v. Fortis (Del. 2026). Breach affirmed where J&J set up an internal competition against its own device, merged teams, dropped the regulatory strategy and changed milestone incentives.

RECORDS THAT CARRIED BOTH CASES Portfolio reviews, probability models, budgets, incentive plans, milestone liability write-down.

Delaware decisions. Their reach elsewhere depends on the governing law and the wording of the clause.

THE PRACTICAL POINT The buyer's reasons are proved with the buyer's own records. Courts credited documents written for other purposes before any dispute existed.

Where Patents Enter a License Dispute

Five contract terms that turn on patent law.

1. **Valid Claim.** Royalties depend on a Valid Claim. The definition can exclude claims held invalid and include pending applications.
2. **Covered by.** Whether the product falls within a claim depends on how the claim is construed.
3. **Ownership.** Turns on who made the invention.
4. **Royalty term.** Royalties run to the last Valid Claim or a fixed term, and step down to a know-how rate when there are no patents.
5. **Challenge rights.** A licensee can challenge validity without ending the license. The contract sets where and what that costs it.

IN NOVARX

Meridian says the early NovaRx patents are invalid and it owns the later patents, so royalties fall to the know-how rate. Four questions:

1. Does Valid Claim require a final ruling, or only a challenge?

2. Who decides validity?

3. Who invented the later patents?

4. What happens to royalties paid or withheld while the challenge runs?

THE PRACTICAL POINT Read Valid Claim like a litigator. One definition decides whether a patent challenge is a defense, a counterclaim or a termination event.

What the Patents Prove

The patent files are evidence on every claim, not only on the royalty rate.

ADMISSIONS IN THE FILINGS

What Meridian and its parent told the patent office about NVX-301 and the competing program: efficacy, utility, timing. Statements made to obtain a patent can contradict positions taken in the dispute.

PATENT STATUS AS AN EFFORTS FACTOR

Market-standard efforts clauses let the licensee weigh patent position (Part I). An invalidity claim that cuts royalties can also justify deprioritizing the drug. Test whether it came before or after the decision.

PATENTS VS. REGULATORY EXCLUSIVITY

If regulatory exclusivity outlasts the early patents, those patents cost Meridian royalties and protect nothing. That explains the attack. Term matters as much as validity.

WHO INVENTED THE LATER PATENTS

Lab notebooks, JSC minutes and the data NovaRx shared under the license. Inventorship and derivation turn on records made before the dispute.

THE PRACTICAL POINT Pull both companies' patent files before the first letter. Most are public, and they were written before the dispute under a duty of candor.

The Experts Licensing Disputes Typically Require

Consulting experts before notice, under privilege. Testifying experts once the theory is set.

SCIENTIFIC AND CLINICAL

What the data show, and what a redesign changes.

REGULATORY

What FDA asked for, what a label statement means, and what a sponsor would do at each decision point. Often a former FDA official.

INDUSTRY PRACTICE

What similarly situated companies spend, staff and decide at this stage. Selects the comparators.

PATENT

Claim scope, coverage and validity.

VALUATION AND ACCOUNTING

Probability of success, timing and discount rate. Gross-to-net deductions in royalty reports.

WHAT HOLDS UP

Rule 702 (amended 2023) requires a reliable method, reliably applied. In Alexion the buyer's own contemporaneous numbers beat later estimates.

THE PRACTICAL POINT Identify and consult with experts as soon as practicable. They will be essential to both developing and proving the case.

Valuing a Milestone Never Paid

Delaware courts now value unreached milestones as expected value.

WHAT DELAWARE AWARDS

The expected value of the lost milestones at the time of breach: each amount, weighted by its chance of success.

No need to prove the milestone would have been reached.

WHOSE NUMBERS WIN

In Alexion the court used the buyer's own probability estimates from before it ended the program.

It set aside later, lower estimates made once the buyer wanted out.

$180.9M

Expected-value award for the remaining milestones in Alexion (Del. Ch. 2025), on top of $130M for the first milestone.

ALSO PRICE Royalty underpayments with interest. Consequential damages exclusions and caps decide whether NovaRx's financing costs are recoverable.

THE PRACTICAL POINT The damages case is built during the liability case. Relevant probabilities sit in the buyer's documents from before the dispute.

Back to NovaRx: The Proof Plan

CLAIM	WHAT WE MUST PROVE	KEY EVIDENCE	WITNESSES AND VALUE
$90M milestone	What “Registrational Study” and “as a result of” mean after the redesign.	Schedule, protocol amendments, FDA minutes.	Regulatory expert, biostatistician. Value: $90M, weighted if not yet due.
Diligence	Efforts fell below those of a similarly situated company.	Portfolio reviews, budgets, probability models, incentive plans.	Industry practice expert, former program staff. Value: expected value of unreached milestones.
Deductions	Deductions fall outside the permitted categories.	Royalty reports, audit data.	Accounting expert. Value: underpayment plus interest.
Patent	A Valid Claim still covers NVX-301.	Claim construction, prosecution history, prior art.	Patent expert. Value: rate difference over the royalty term.

WHAT WE NEED FROM YOU Authority to retain consulting experts, a clean team protocol with Meridian’s parent, and a decision on which track files first.

Proving the Case: Four Things to Remember

1. **Prove the words first.** The contract, the schedule and the defined terms come before the science.

2. **Find whose records carry the case.** In an efforts dispute they belong to the buyer. Start with public sources and the contract's information rights.

3. **Read the patent files.** They were written before the dispute, under a duty of candor, and most are public.

4. **Value the claim while building it.** Probability, timing and discount rate come from the record.

FIVE DOCUMENTS FOR A FIRST READ

- The agreements, amendments and milestone schedule.
- The last four JSC minutes and development reports.
- Royalty reports and any audit report.
- Correspondence and notices from the counterparty.
- The dispute resolution clause in each agreement.

THE SERIES Part I covered the agreement, Part II the forum, Part III the proof. Recordings and slides for Parts I and II are on demand.

QUESTIONS

Ryan Murr · RMurr@gibsondunn.com
Charlotte Jacobsen · CJacobsen@gibsondunn.com
Mary Beth Maloney · MMaloney@gibsondunn.com

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