

COLLABORATION & LICENSING DISPUTES

How they develop. How the drafting decides them. What to do before positions harden.

Ryan Murr · Mary Beth Maloney · Karen Spindler

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Speakers and Roadmap

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Mary Beth Maloney

Partner, New York. Trial lawyer focused on complex commercial disputes, including life sciences licensing, collaboration, milestone and royalty disputes in court and arbitration.

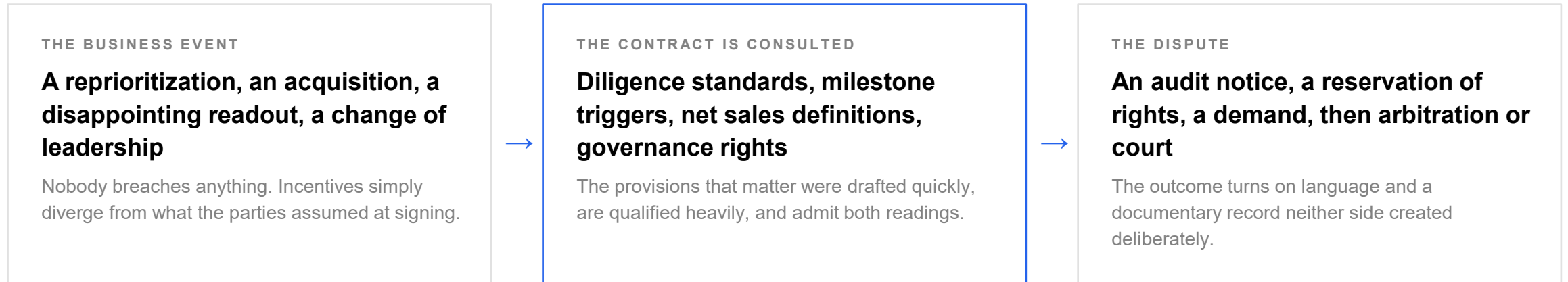
Karen Spindler

Partner, San Francisco. Life sciences transactional lawyer focused on licensing, collaboration and royalty-finance transactions, including diligence, milestone and governance architecture.

I	Welcome, speaker introductions and framing	Ryan Murr	0:00 – 0:05
II	Anatomy of a collaboration dispute: flashpoints, escalation, the record	Mary Beth Maloney	0:05 – 0:15
III	Drafting against the dispute: CRE, milestones, royalties, governance	Karen Spindler, with Mary Beth Maloney	0:15 – 0:28
IV	Dispute resolution provisions: forum, arbitration, expert determination	Both, moderated	0:28 – 0:38
V	When strain emerges: audits, escalation, privilege, the record	Mary Beth Maloney, with Karen Spindler	0:38 – 0:48
VI	Resolution: what we would draft differently	Both	0:48 – 0:52
VII	Q&A and closing	Ryan Murr	0:52 – 1:00

Why These Disputes Are Predictable

Collaboration disputes rarely begin with bad faith. They begin with a business decision that the agreement did not clearly permit or prohibit, and language that cannot resolve which it was.



Throughout the hour, we will keep coming back to two questions: what should have been in the contract, and what do you do now?

The Running Hypothetical: NovaRx / Meridian

We follow one collaboration through the hour. The facts are illustrative and do not describe any client matter.

THE DEAL

NovaRx, a clinical-stage biotech, licenses NVX-301, a Phase 2 asset in a rare autoimmune indication, to Meridian Pharma. Worldwide rights ex-Japan. \$40M upfront, \$310M development and regulatory milestones, \$500M sales milestones, tiered 8–14% royalties.

THE MILESTONE ARCHITECTURE

Two triggers matter: \$120M on “the first Regulatory Approval of the Licensed Product,” drafted when full approval was the only contemplated route; and \$90M on a label reflecting a specified magnitude of benefit “as a result of” a registrational study named in a schedule.

WHAT HAPPENED

Eighteen months in, Meridian is acquired by a company with a competing late-stage program. Phase 3 slips twice, the program pivots to a narrower population and the registrational study is redesigned. The JSC stops meeting; royalty reports show a single net figure.

WHY IT IS URGENT

NovaRx has a royalty financing that draws on the Phase 3 milestone. A slipped milestone is a funding event, not a delayed payment.

TWO QUESTIONS, EVERY SEGMENT

THE DRAFTING QUESTION

What should have been in the contract?

THE LITIGATION QUESTION

What do you do now?

SECTION II · MARY BETH MALONEY

ANATOMY OF A COLLABORATION DISPUTE

The recurring flashpoints, how they escalate, and what the record looks like when outside counsel gets a call.

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Seven Recurring Flashpoints

Nearly every collaboration and licensing dispute we handle traces back to one of these seven provisions, and most trace back to the first three.

01

Diligence obligations

What “commercially reasonable efforts” means, and what it is measured against

02

Milestone triggers

Achievement events that do not survive a development or regulatory pivot

03

Royalty calculation

Net sales deductions, stacking relief, offsets and step-downs

04

Governance deadlock

JSC and JDC decision rights, final say, and escalation that goes nowhere

05

IP and improvements

Ownership of what the partner invents while running your program

06

Termination and reversion

Getting the asset back in a condition in which it can still be developed

07

Change of control

A new parent with different priorities and, often, a competing program

TODAY'S FOCUS

Sections III and IV draft against 01 through 04. Change of control runs through the hypothetical all hour.

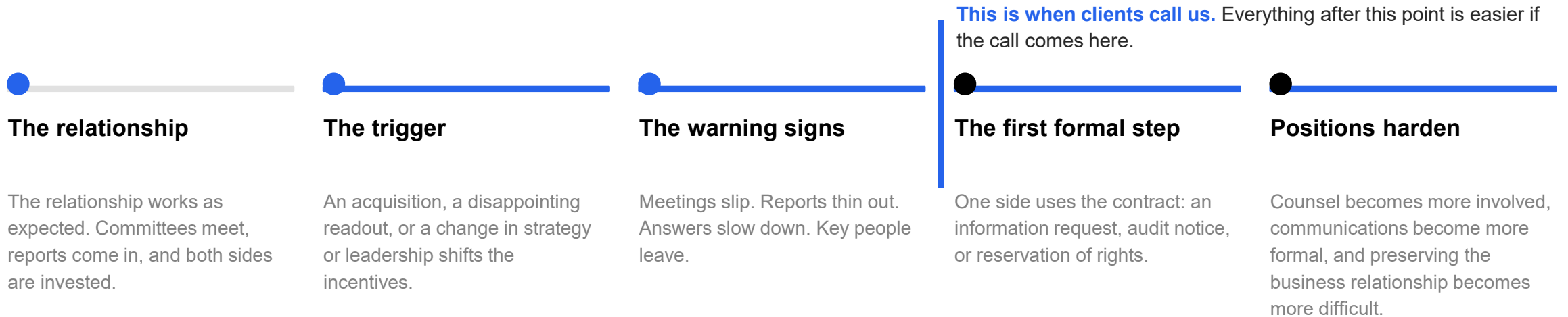
Termination and reversion: Karen touches on it today.

IP and improvements: Session 3 of this series, November 19, with Charlotte Jacobsen.

Every one of the seven has produced matters for our team.

How a Collaboration Dispute Escalates

The dispute usually starts long before anyone calls it one.



The practical point: do not wait for a demand letter. The earlier the issue is identified and managed, the more options remain for protecting the relationship and the record.

What the **Record** Usually Looks Like

By the time outside counsel is involved, the key documents already exist. The question is whether they help or hurt.

WHAT HURTS

- Minutes that miss the real disagreement
- Internal speculation about the partner's motives
- Royalty reports that show only a net number
- Amendments that reset rights or deadlines
- Emails that excuse the very conduct later challenged

WHAT HELPS

- Contractual requests and responses
- Development reports in the form the agreement requires
- Audit findings with underlying data
- Prompt written corrections to minutes
- Factual, disciplined internal assessments

The practical point: when outside counsel gets involved, the first step should be a focused review of the key internal communications, the parties' communications, and the documents tied to the disputed obligations. That usually reveals where the real risk lies, and where the leverage is. Almost everything in the right column exists only because the agreement required it.

SECTION III · KAREN SPINDLER, WITH MARY BETH MALONEY

DRAFTING AGAINST THE DISPUTE

Diligence, milestones, royalty mechanics, audit rights and governance: what to put on the page, and how each provision performs when it is finally tested.

“Commercially Reasonable Efforts,” as Usually Drafted

AN ILLUSTRATIVE MARKET-STANDARD DEFINITION

“The level of efforts and resources that a similarly situated company would devote to a product of similar commercial potential at a similar stage of development, taking into account all relevant factors, including safety and efficacy, product profile, competitive position, patent status, regulatory environment and profitability.”

IN OUR HYPOTHETICAL

Meridian never stopped work. It completed the required toxicology package, kept the IND open, attended every scheduled JSC meeting and filed its reports on time. On this language that is a defensible record, and NovaRx has no agreed metric with which to contradict it.

FOUR WAYS IT FAILS THE LICENSOR

“Similarly situated company”

Whose baseline: the mid-cap licensee you signed with, or the global acquirer that now owns the program? Both readings are available, and each side will choose one.

“All relevant factors”

A standard that admits every factor admits every explanation. The qualifier is broad enough to swallow the obligation it modifies.

“Profitability”

Left unqualified, this permits the licensee to count the milestones and royalties it owes the licensor as a cost that justifies deprioritizing the asset.

Nothing is measurable

With no countable anchor, breach becomes a contest between industry-practice experts: slow, expensive, and genuinely uncertain in outcome.

Anchoring the Standard to Something Countable

01 Fix the benchmark

Efforts consistent with the licensee's own products at a similar stage and of similar potential, and in no event less than a stated floor. Two reference points, not one.

02 Strip the self-serving factor

Expressly exclude amounts payable to the licensor from any profitability assessment. One sentence, and it removes the most common defense.

03 Add anchors that do not move

Minimum annual program spend. A dedicated program team. Phase 3 initiation within a stated period of a positive readout. Filing within a stated period of database lock. Launch within a stated period of approval and reimbursement.

04 Keep the obligation product-level

The duty runs to the Licensed Product, not to the franchise or the therapeutic area. Portfolio-level framing is where individual assets are quietly shelved.

05 Anti-deprioritization

The obligation is unaffected by the licensee's acquisition of, merger with, or in-licensing of a Competing Product, a defined term, drafted at signing.

06 Make failure visible

Development reports on a fixed cadence with specified content, plus a live program review right. An obligation that is never measured is effectively unenforceable.

A WORD OF CAUTION

Objective benchmarks help, but a licensee can satisfy a checklist on paper. Keep the broader diligence standard alongside them.

IN A DISPUTE

Numbers beat adjectives. A spend floor or dated trigger is far easier to enforce than “commercially reasonable efforts.”

The Single-Trial Default Breaks **Phase Triggers**

In February 2026 FDA made one adequate and well-controlled pivotal trial, supported by confirmatory evidence, its default basis for approving novel drugs. Milestone event triggers across the market were drafted on the opposite assumption.

WHAT BREAKS IN THE LEGACY AGREEMENTS

- Triggers keyed to a second pivotal or confirmatory Phase 3 study. If the sponsor takes the single-trial path, initiation, enrollment and completion may never occur: the payment is not delayed, it is unreachable
- Triggers keyed to “initiation of a Phase 3 Clinical Study.” A seamless Phase 2/3 adaptive design has no clean boundary between dose-finding and pivotal confirmation, so there may be no identifiable moment when Phase 3 began
- Approval milestones conditioned on a stated number of pivotal studies: they describe a path the sponsor may no longer take
- Fees tied to Phase 3 enrollment counts, or to endpoints a single adaptive trial may never separately report

HOW TO DRAFT NOW

- Define triggers by regulatory function rather than phase label: the first Clinical Study intended to support an application for Regulatory Approval, however designated by the sponsor or the agency
- Add the equivalence catch-all: “or any study serving the equivalent function under the applicable regulatory pathway”
- Deemed achievement where the sponsor's chosen development path bypasses the trigger entirely
- Treat the policy as reversible. It arrived without guidance or rulemaking and can change without process, so language keyed to function survives either default
- In diligence, ask directly whether the target's in-licenses and out-licenses are calibrated to a two-trial assumption that no longer applies

The economics moved with the policy: a second pivotal trial can cost hundreds of millions of dollars and add two to four years. Compressing that changes valuation, earnout thresholds, and the point at which a royalty stream becomes monetizable.

See Gibson Dunn, *Biotech Briefings*, “One and Done: FDA’s New Single-Trial Default and What It Means for Drug Developers, Investors, and Counsel” (March 2026); Prasad & Makary, *N. Engl. J. Med.* (Feb. 18, 2026).

How **One Sentence** Produced a \$300 Million Dispute

A publicly filed milestone dispute in the Southern District of New York (2023). Our team represented the licensor. The facts below are drawn from the public filings. Four features of a single milestone provision account for the entire disagreement.

01

It assumed the study would produce one number

The trigger spoke of cardiovascular risk reduction correlating with the relative risk reduction rate. Outcomes studies report several rates: composite endpoints of differing composition, and individual components. The clause offered no rule for choosing among them.

02

It never used the words “primary endpoint”

Two readings of one sentence. The licensee read the industry term of art into the provision. The licensor read the provision as written. No tribunal ever had to choose, and the drafting lesson is that the agreement never did either.

03

It pointed outward to a schedule

The study was identified by reference to a development plan schedule. That schedule described this study by its design and other studies by their endpoints. A tribunal will draw an inference from that contrast, in whichever direction it happens to cut.

04

It keyed payment to the label, not the data

The obligation arose on regulatory approval of a label containing the figure. The label had not yet been granted, so the disagreement surfaced before the triggering event occurred, and before any notice or invoice obligation was engaged.

Back to NovaRx: its \$90M milestone points “as a result of” a study named in a schedule, a study that has since been redesigned. Same structure, same exposure, and nobody has looked at it yet.

Royalty Mechanics: Where the Money Moves

Most royalty disputes come down to deductions, reductions, and whether the reporting lets you see what happened.

Net Sales

The deduction list is the entire dispute. Close “other similar deductions.” Name the categories expressly: rebates, chargebacks, government program discounts, wholesaler and GPO fees, returns, copay and patient assistance, each capped, or capped in the aggregate as a stated percentage of gross.

Combination Products

Put the allocation formula in the agreement, then answer the question the formula cannot: what happens when a component has no standalone price. A fallback of good-faith negotiation followed by expert determination is far better than silence.

Reductions

Third-party stacking relief, pro rata or fixed. Generic-entry step-downs defined by unit share over a stated measurement period. Patent-expiry and know-how-only tails, drafted with royalty-term limits in mind.

THE ONE NUMBER

A cumulative floor

A single cap on all reductions taken together, in no event below a stated percentage of the royalty otherwise payable. Without it, stacking relief and step-downs compound to a number nobody modeled at signing.

REPORTING GRANULARITY

Require deductions itemized by category. A single net line is not a report, and you cannot audit what you were never shown. This is also the provision royalty purchasers price most closely in a monetization.

IN A DISPUTE

One net number on a royalty report means the audit is the case. More than one of these has been resolved through the audit right alone, with deduction-level data in hand and no demand letter ever sent. That path exists only if the report and audit provisions were drafted to produce data, not conclusions.

The Right That Is Usually **Narrower Than It Looks**

The value of the audit right depends on what you are entitled to see.

Scope and lookback

Records for a stated period, once per calendar year, on reasonable notice.
Confirm the lookback period is at least as long as your limitations period.

Sublicensee reach

Either a direct audit right or a flow-down obligation with a right to compel. Most of the sales that matter will not be the licensee's own.

The auditor's report limitation

If the auditor may report only the net discrepancy, you have bought a number rather than a record, and you cannot brief a dispute on it. Negotiate for the underlying findings.

Cost shifting and interest

The licensee pays the audit cost above a stated discrepancy threshold, plus interest on underpayments running from the original due date.

Underlying data, not summaries

Gross-to-net build-ups, rebate and chargeback detail, contract pricing.
Summary schedules simply reproduce the licensee's own conclusions in a new format.

What happens afterwards

Route the post-audit disagreement to expert determination on a defined scope, rather than to full arbitration, which will cost more than the discrepancy.

IF THE ROYALTY STREAM IS MONETIZED

Make sure the purchaser or lender has the same audit rights you do. A narrower downstream right will be priced.

IN A DISPUTE

Use the audit right early and deliberately. A request after years of silence signals a dispute, so time it. Most windows are annual and close quietly, and a complete production can resolve the issue fast; a delayed or incomplete one tells you something too.

Decision Rights, Final Say, and the **Deadlock You Will Hit**

Decision rights only work if the agreement also addresses deadlock, escalation, and the record.

- **Committee mechanics.** Set composition, quorum, cadence, and what happens if meetings stop.
- **Decision rights.** Use a clear decision matrix: what the committee decides, what one party decides, and what requires consent.
- **Final say.** Limit it. It should not increase the other party's obligations, reduce amounts owed, override an express term, or require a breach of law or of a third-party agreement.
- **Escalation.** Time-box it and name the offices, not "senior executives of each party."
- **Deadlock.** Pick a real mechanism by category: status quo, casting vote, expert determination, or buy-out.

HOW IT READS LATER

Committee minutes are often the first exhibit.

Negotiate the right to prepare or correct them at signing. It costs nothing and it changes the record.

IN A DISPUTE

Final say does not end the fight. It shifts the question from who had authority to whether that authority was exercised for a proper purpose, which is harder to resolve early, not easier.

SECTION IV · BOTH, MODERATED

DESIGNING THE DISPUTE RESOLUTION PROVISION

Court, arbitration, and expert determination serve different purposes. The agreement should say which applies, and when.

Match the Mechanism to the Dispute

Do not treat governing law, forum, and process as one boilerplate choice.

THREE SEPARATE CHOICES

Governing law

What law governs the parties' substantive rights.

Forum or seat

Where the dispute is heard and which court supervises the process.

Rules and administrator

Who runs the proceeding, how much disclosure is available, and how quickly it moves.

KEEP THE DEAL FAMILY CONSISTENT

The license, supply, quality, and financing documents should not send related disputes to different forums.

THE PRACTICAL POINT

If the clause is vague or inconsistent across agreements, the first dispute may be about where and how to litigate rather than the merits.

MATCH THE PROCESS TO THE ISSUE

Royalty and accounting disputes

Expert determination. Fast, narrow, and usually cheaper, if the scope is drafted tightly.

Valuation disputes

Final-offer or baseball arbitration. Best when the dispute should end in a number.

Everything else

Court or arbitration, depending on confidentiality, discovery, appellate rights, interim relief, and whether a public record matters.

What You Are Choosing Between

The right process depends on the issue you are trying to resolve.

	COURT LITIGATION	INSTITUTIONAL ARBITRATION	EXPERT DETERMINATION
Typical duration	Often years; faster where the dispute is suited to early summary judgment or expedited declaratory relief.	Often 12 to 24 months.	<i>Not mediation. An independent expert decides a defined issue, usually on a binding basis.</i> Often a few months.
Cost profile	High; discovery drives much of the cost.	High but more compressed; tribunal and institution fees add.	Lower for a narrow technical or accounting issue.
Confidentiality	Public unless sealed.	Generally confidential by agreement and rule.	Confidential and private.
Disclosure	Broad.	More limited and tribunal-controlled.	Usually limited to the documents needed to answer the defined question.
Dispositive motions	Available and often important.	Available, but less central.	Not usually part of the process.
Review	Full appellate review.	Very limited grounds to vacate.	Usually final except for narrow contractual grounds.
Best suited to	Injunctions, IP disputes, and clear contract-interpretation issues.	Cross-border, technical, or relationship-sensitive disputes.	Royalty calculations, net sales, accounting, and valuation inputs.

The practical point: match the process to the problem. A royalty calculation should not require the same proceeding as a major contract or IP dispute. Session 2 of this series, October 15, with Lindsey Schmidt, takes the comparison in depth.

In the case study: the agreement chose New York courts and no arbitration. That made expedited declaratory relief available on a payment not yet due, and produced a resolution in nine months. For a listed company the public forum is a disclosure decision as much as a litigation one; choose it on purpose.

SECTION V · MARY BETH MALONEY, WITH KAREN SPINDLER

WHEN THE RELATIONSHIP STARTS TO FRAY

Use the contract, protect the record, and preserve room to solve the problem before positions harden.

How These Disputes Usually Get Resolved

Most can be resolved before filing if counsel gets involved while the relationship still has value.

THE FIRST MOVE

Usually an audit notice or a contractual information request, rather than a demand letter.

THE RESOLUTION

Usually an amendment: clearer diligence obligations, better reporting, a corrected milestone, or an orderly return of the asset.

THE LEVERAGE

Often comes when the counterparty needs something: a consent, an extension, a new territory, or another amendment.

Our team has resolved more than a dozen licensing and collaboration disputes before a complaint was filed.

THE PRACTICAL POINT

The window closes once positions are committed to writing. Before then, there is still room to investigate the facts, use the contract, and solve the problem without turning it into litigation.

The First Thirty Days

Start with the contract, the record, and the deadlines, rather than a demand letter.

DO

- Read the reporting, audit, notice, committee, and information provisions first
- Use contractual rights to ask the questions that need answering
- Put disputed issues on the committee agenda and confirm the outcome
- Calendar every notice, cure, audit, and limitations deadline
- Have counsel direct the factual review
- Preserve the relevant documents early

DO NOT

- Speculate in writing about the counterparty's motives
- Let business teams make legal conclusions in internal documents
- Escalate informally if the agreement requires formal notice
- Sign an amendment without checking what rights or deadlines it changes
- Send the angry email
- Assume an audit or notice right will still be available later

THE PRACTICAL POINT

Contractual rights are not accusations. Used early, they let you get the facts, build a clean record, and preserve the commercial relationship at the same time.

Protecting the Record and the Privilege

Copying counsel is not a privilege strategy

Privilege protects communications seeking or providing legal advice. A business document does not become privileged because a lawyer was copied, and reflexive copying weakens the position on the documents that genuinely are privileged.

Know what is never privileged by design

Committee minutes, joint working group materials, alliance documents and anything prepared for the counterparty are shared by design. They should be written as though they will be read aloud, because they will be.

Define the circle, and keep it small

Identify who is inside the assessment. Have counsel direct the factual gathering so that work product protection attaches to the analysis rather than to the underlying business facts.

Label accurately, not automatically

Blanket marking invites a challenge to every designation. Accurate, selective labeling is more defensible and far cheaper to maintain through a review.

Separate the channels

The conversation with the partner is one channel. The internal assessment of whether there is a breach is another. Mixing them is how a party ends up producing its own analysis.

Watch the monetization channel

Where royalties have been sold or pledged, information may have to flow to a purchaser or lender. Work out the common interest position early rather than after the fact.

The instruction that actually works: do not tell the business team to stop talking to the partner. Tell them to stop speculating in writing.

Finding the **Leverage** to Solve It

Leverage in a collaboration is not constant. It spikes when the counterparty needs something, and that is when contract language actually gets fixed.

AT SIGNING

Highest

Everything is negotiable and nothing has been relied upon. This is where the diligence, milestone and reporting architecture has to be won.

STEADY STATE

Lowest

The counterparty needs nothing. Requests to amend read as distrust and are declined politely.

THE COUNTERPARTY NEEDS SOMETHING

Spikes

A territory or field expansion, a supply extension, a regulatory transfer, a consent, an affiliate restructuring after an acquisition. This is the window.

OPEN DISPUTE

Adversarial

Amendments are now settlement terms. Everything is priced, and the relationship value is already impaired.

WHAT TO TRADE FOR

A tightened diligence benchmark. Deduction-level reporting. A cumulative royalty floor. Change-of-control consequences. Minute procedure. All small asks in isolation.

PRESERVING OPTIONALITY

Tolling and standstill agreements stop the clock without escalating. Raise them early, while they still read as housekeeping, and remember the counterparty is often your partner on other programs.

How These Disputes End

The legal issue may be narrow. The resolution often resets the business relationship.

CASE STUDY

The parties settled nine months after filing.

- \$100 million paid before the European label decision
- \$25 million paid after the label decision
- The licensee assumed European manufacturing and supply
- The litigation was dismissed and the collaboration continued

A dispute over one milestone provision ended in a \$125 million settlement and a broader commercial resolution.

BACK TO NOVARX

What NovaRx never had:

- A measurable diligence benchmark
- A rule for which study result counts
- A floor under royalty reductions
- Protection against change-of-control deprioritization

Its best remaining leverage may be an amendment negotiated when Meridian's new parent needs something from NovaRx.

THE PRACTICAL POINT

The earlier the problem is identified, the more ways there are to solve it without forcing the parties into an all-or-nothing litigation posture.

Case study facts are drawn from the parties' public filings and announcements. NovaRx / Meridian is illustrative only.

Collaboration and Licensing Disputes: The Checklist to Keep

DRAFT IT BEFORE THE PROBLEM

- 01 Diligence.** Anchor the obligation to something measurable; “commercially reasonable efforts” alone is rarely enough.

- 02 Profitability.** Do not let amounts payable to the licensor become a reason to deprioritize the asset.

- 03 Milestones.** Define the event and the measure; never let a payment obligation borrow a study’s ambiguity.

- 04 Royalties.** Put a cumulative floor under reductions before stacking and step-downs compound.

- 05 Reporting.** Require deduction-level detail; if you cannot see the math, the audit right is theoretical.

- 06 Dispute process.** Match the process to the issue; a royalty calculation should not need the same proceeding as an IP dispute.

- 07 Change of control.** Assume the partner will be acquired and draft the consequences while you still have leverage.

WHEN THE RELATIONSHIP STARTS TO FRAY

- 01 Start with the agreement.** Read the reporting, audit, notice, committee, and information provisions before anyone sends an email.

- 02 Use the contract.** Ask for what you need under a named provision; it is an entitlement, not an accusation.

- 03 Protect the record.** Keep the business team talking and stop the speculation in writing.

- 04 Protect the deadlines.** Calendar every notice, cure, audit, and limitations period immediately.

- 05 Find out what the case really is.** Have outside counsel run a short, focused review of the internal communications, the parties’ communications, and the documents tied to the disputed obligations.

- 06 Preserve the relationship and the leverage.** Before positions harden, look for the amendment, consent, or extension that can solve the problem.

Three Things to Remember

Use the contract. Protect the record. Preserve your options.

The earlier those three things happen, the more likely the dispute can be understood, and often resolved, before the relationship and the record make the choices for you.

NEXT IN THIS SERIES

Session 2 · October 15 Arbitration or Litigation? How life sciences collaboration disputes actually play out, with Lindsey Schmidt and Mary Beth Maloney.

Session 3 · November 19 Proving the Case When the Science Is Complex, with Charlotte Jacobsen and Mary Beth Maloney.

Questions

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