#### **CLEARY GOTTLIEB**

# Cleary's Pharma Bites Contingent Value Rights (CVRs) in Pharmaceutical Deals



Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group May 2024 Update



# What are Contingent Value Rights?

Contingent Value Rights (CVRs) are used to provide additional value to stockholders of a target company upon the occurrence of specified future events.

CVRs are used regularly in pharmaceutical and biotech deals.

CVRs bridge the "value gap" attributable to uncertain future events that could change the valuation of a target business, sometimes drastically.

#### Most often seen types of CVRs include:

- Event-driven CVRs: payment triggered by a key event, often regulatory approvals for drugs, first commercial sale of a drug, etc.
- **Financial-driven CVRs**: payment based on sales of the target, often sales of a particular drug or a specific business line.
- Litigation CVRs: payment triggered by recovery (or sometimes absence of liability) from a key piece of litigation (e.g., a patent infringement suit)

# Mechanics of CVRs

CVRs are created by a Contingent Value Rights Agreement, usually agreed in form at the time of the signing of the transaction and entered into as of the closing.

A rights agent is appointed to manage the CVRs, facilitate payments and act in certain circumstances for the holders of the CVRs.

The milestones (whether for events, financial performance or otherwise) for payment are outlined in detail and the payment mechanics and timelines are established. CVRs may be settled in cash, stock or a mix, but most CVRs in the past 5 years involve payments exclusively in cash.

CVR Agreements often contain covenants by the acquirer, which can include efforts standards that the acquirer must perform in fulfilling the milestones and limitations on assignment or transactions concerning the business or drug molecule/line.

# CVRs allocate specific risks to offer additional deal certainty

#### BRIDGING VALUE GAPS

Where there are disagreements concerning valuation of an event, or an event is inherently speculative, a CVR can separate the event from the rest of the deal on which the parties have established an agreed valuation.

# REPLACING CLOSING CONDITIONS

Where an acquirer might otherwise wish to wait on a drug approval or some other event as a closing condition, a CVR can replace that uncertainty with a contingent payment.

# DEFERRED FINANCING

Because any payment associated with a CVR is delayed (sometimes by periods of 5-10 years or more), a CVR can act as a type of deferred financing for a transaction.

CVRs allow an acquirer to purchase a target business and leave the risk and uncertainty of a future event with the target's stockholders.

# ... but CVRs are not without drawbacks

CVRs are not appropriate for all situations, and typically there must be some significant value in the potential event or contingency for them to be worthwhile.

There is **increased cost and complexity** with respect to negotiating and drafting CVR Agreements, particularly when the CVRs are intended to be listed on an exchange.

Litigation risk exists in any situation where the CVR is not paid out in full.

Covenants or other restrictions can limit the acquirer's business.

The CVR shifts **significant risk to the target's stockholders**, who, unless the CVR is listed, generally cannot realize value for their rights until an event occurs and are subject not just to the risks of the event or contingency addressed by the CVR, but also to economic risks associated with the acquirer's fortune (e.g., bankruptcy).

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# **Key Statistics**

To better understand the CVR landscape, we analyzed public transactions in the pharmaceutical, biotech and medical technology industries since 2008 that included CVRs

**65** 

Pharmaceutical/ biotech/medical technology deals examined from 2008 to February 2024



#### 6 Listed

Average deal size in equity value of

~\$4.4B

(median \$1.7B)

#### 59 Unlisted

Average deal size in equity value of

~\$1.0B

(median \$453M)



Of the deals that have either fully or partially paid out or have expired (and for which payout information is available) (30 total), 4 have fully paid out to CVR holders, and 6 have made partial payment

4%-88%

Percentage representing the total consideration offered in the underlying deals represented by CVRs (assuming milestones fully paid)

25% - the mean potential payout

(median 19%)

# Approaches to Milestones

Pharmaceutical CVR
Agreements have
milestones that are based
on the occurrence of certain
events, the achievement
of financial goals or a
mixture of the two.

Of the deals in the survey, 36 had milestones based on events, 18 had milestones based on financials, and 11 had both.

These CVRs have an average of over 2 milestones per CVR, though may have as many as 6 milestones.

# **Event-based Milestones**

#### **Event-based CVR examples** include:

- **Regulatory approval** (most common).
  - Can include approval by one or more regulators, including the FDA, EC and/or others.
  - Instead of approval, milestones may be linked to notice (e.g., that a drug is "therapeutically equivalent" to another) or receipt of specific labeling.
  - Payment may vary based on DEA scheduling (e.g., more if unscheduled, and lower payments if Schedule IV instead of V).
- **First commercial sale** after a drug is approved.
- Success or progress against certain metrics in a clinical trial.
- Others: achievement of production goals or a certain number of clinical treatment visits by patients.

## Financials-based Milestones

#### Financials-based CVR examples include:

- Achievement of a sales targets during a certain measurement period, which triggers a fixed payment.
- Variable payments equal to a portion of certain sales. May be:
  - fixed (e.g., pay 40% of net sales over a certain dollar threshold)
  - progressive (2.5% of sales in a certain range, 5% of sales in a higher dollar range)
- Others:
  - variable payments based on payments due under a license agreement
  - EBITDA performance

# Crafting Milestones: Crucial to Success

#### Milestones must be carefully crafted to capture the intended outcome

#### OVERLY NARROW/SPECIFIC MILESTONES?

#### Case Study of SARcode Bioscience/Shire (2013)

- Shire purchased SARcode in 2013 for an upfront payment of \$160M, with significant additional payments possible based on commercialization of Lifitegrast.
- The shareholder's representative sued for \$425M in payments that it alleged had been triggered because the drug had been approved.
- The language of the milestone was contingent on certain endpoints being reached in a specific study, and because that particular study missed one of the endpoints, the Delaware court ruled that the milestones had not been triggered despite the fact that other studies demonstrated the endpoint in question and the drug was eventually approved.
  - The milestone was too specific to cover the drug approval path taken which differed from expectations.
- Product ultimately sold to Novartis for \$3.4B (plus \$1.9B in potential milestone payments).

#### **VAGUE MILESTONES?**

#### Case Study of Gilead/Calistoga (2011)

- Gilead acquired Calistoga for upfront payment of \$375 million and up to \$225 million based on milestones.
- Shareholder representative asserted that a \$50M milestone based on EC approval of a specified drug as a first-line treatment for a hematologic cancer indication was triggered.
- Court held meaning of "indication" to be ambiguous and context specific, requiring examination of parole evidence. Ultimately, determined parties intended term to be mean "disease", meaning milestone was not triggered based on EC approval of the drug only for a sub-population with a specified genetic mutation.

### Listed and Unlisted CVRs

CVRs can be **tradeable** or **non-tradeable**.

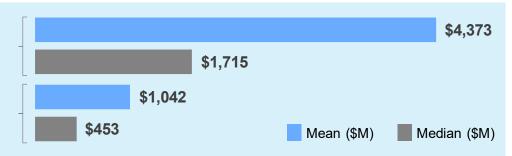
- In our sample, all tradeable CVRs were also listed on an exchange.
- Tradeable CVRs are required to be registered with the SEC, increasing complexity and costs.

< 10%

of the CVRs in the sample were tradeable

DEAL SIZE Listed/tradeable involve significantly larger deals

Listed CVR Unlisted CVR



#### **MILESTONE TYPE**

Listed CVRs are more likely to have both financial and event-driven milestones; of listed CVRs, 3 of 6 (50%) had both types, while only 8 of 59 (14%) unlisted had both

#### **INCREASED LITIGATION RISK?**

A third of listed CVRs in the sample have resulted in some litigation or investigation.

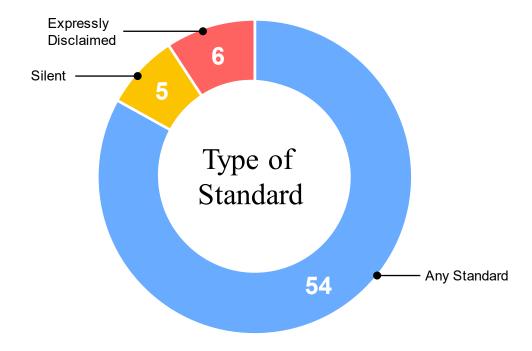
# Inclusion of an Efforts Standard

83%

of examples contain a standard that mandates a certain level of effort that the acquirer must use in pursuit of the milestones.

17%

are silent or expressly disclaim any effort required to meet the milestone(s).

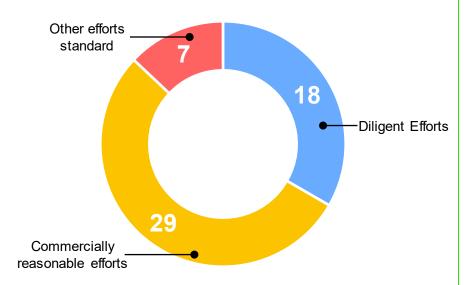


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# Considerations for Including an Efforts Standard

STANDARD	PROS	CONS
Efforts Standard	<ul> <li>Protection and value preservation for CVR holders</li> <li>For an acquirer, may be acceptable for a particular asset that it strongly desires to monetize</li> </ul>	<ul> <li>Adds litigation risk in the event that the milestones are not met or are only partially met – CVR holders can argue that acquirer did not use require level of effort in pursuit of the milestones</li> </ul>
Silence	<ul> <li>Lack of a standard may be easier to negotiate, particularly for an acquirer seeking to avoid an effort standard</li> </ul>	<ul> <li>Court may find a standard was implied even if not expressly stated (and litigation risk may exist because of the ambiguity)</li> <li>Less clarity for all parties concerning expectations</li> </ul>
Expressly Disclaim	<ul> <li>Provides clarity that there are no specific expectations on future actions</li> <li>For certain milestones, efforts standards may be unnecessary (e.g., financially-driven milestones shared between the parties may provide sufficient incentives)</li> <li>Increases acquirer freedom to operate its business, particularly when prioritizing different drug candidates</li> </ul>	<ul> <li>Less protection for CVR holders</li> <li>Target will typically resist</li> </ul>

# Types of Efforts Standards



- Factors in evaluating efforts include:
  - Acquiror's size, resources and geographic location
  - Product's market potential, developmental stage / costs, life-span and proprietary position
  - Competitiveness of alternative third-party products
  - Regulatory environment and regulatory treatment of similarly situated products
- Some definitions affirmatively require that the acquiror take or abstain from certain actions (e.g., minimum spend obligations), and some expressly disclaim certain actions from being required (e.g., commercially reasonable efforts shall not require the issuer to initiate additional clinical trials).
- CVRs may include mixed efforts standards (e.g., diligent efforts for regulatory milestone, commercially reasonable efforts for financial milestone) or an expenditure obligation in pursuit of the milestones.

Of the examples requiring a certain level of effort that the acquirer must use in pursuit of the milestones, 54% required commercially reasonable efforts, 33% required diligent efforts and 13% require other types of efforts, including mixed efforts standards

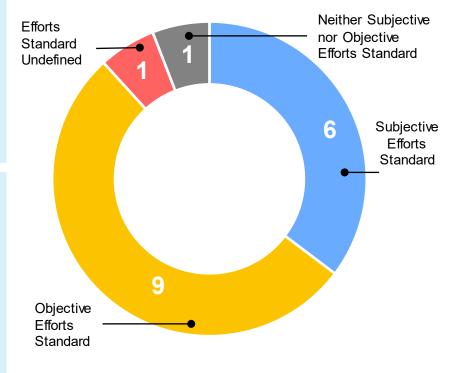
# Types of Efforts Standards

In deals since January 1, 2023:

SUBJECTIVE VS.
OBJECTIVE

In deals since January 1, 2023 that imposed an efforts standard on the issuer, 6 CVRs (35%) used a **subjective efforts standard** (e.g., "consistent with the general practice followed by Parent in the relevant jurisdictions"), 9 CVRs (53%) used an **objective efforts standard** (e.g., efforts "commensurate with the level of efforts that a pharmaceutical company of comparable size and resources would devote"), 1 CVR (6%) did not use a relative efforts standard and 1 CVR (6%) did not define the efforts standard.

MILESTONE PAYMENTS AS A FACTOR 10 out of 15 (67%) such CVRs with subjective or objective efforts standards expressly prohibited the consideration of milestone payments in evaluating whether commercially reasonable, diligent or other efforts standards are met, with the remainder silent on the topic.



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#### Outcomes

#### CVRs can be risky

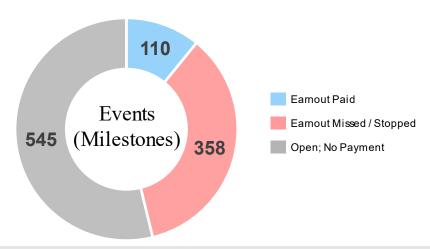
33% of CVRs in the sample that have either fully or partially paid out or have expired (and for which payout information is available) have resulted in a payout. Most of the payouts have been only for a portion of the milestones

#### In our sample of 63 completed CVR deals:



- Of the four full payments, one was based on achievement of net sales, two were based on drug approval and one was a reverse CVR (which paid out because a milestone failed)
- Partial payouts were based on regulatory milestones or partial achievement of sales milestones
  - Deals with 3 or more milestones facilitate partial payouts

#### Private deal earnout data shows similar risk:



- In a study covering 128 deals with 1,013 possible earnout milestone events, approximately 11% had paid out, 36% were missed or the program had been stopped, with the rest pending
- Of milestones due in by mid-2023, about 22% had paid out versus the remainder that were missed or pending

# Litigation

Litigation risk exists in any situation where the CVR is not paid out in full.

Cases involving CVRs have alleged claims for securities fraud or breach of contract.

Although a number of cases involving CVRs have been dismissed, parties in some cases have settled after partial denials of motions to dismiss.

A detailed discussion of key CVR-related litigation is available in <u>Annex A.</u>

# Other Typical Terms

# REDEMPTION RIGHTS

- While some agreements are silent on redemption rights, most explicitly state that they do not limit the issuer's ability to redeem the CVRs.
- When listed, redemption rights often need to be disclosed and are sometimes limited on price or only allowed when there are 50% CVRs outstanding.

#### ASSIGNMENT

- Nearly all CVR agreements permit assignment by the original issuer to an acquiror of the applicable product if the successor assumes the CVR obligations.
- Some agreements continue to make the original issuer liable and/or impose limitations on assignment (e.g., top companies in the pharmaceutical industry or companies with clinical development capabilities).

#### **AMENDMENT**

- Certain technical amendments can be made without the consent of the CVR holders as long as not adverse to the CVR holders.
- Other amendments require CVR holder approval (e.g., of 50% or 30% of holders); in some agreements, certain types of amendments require unanimous consent.

#### **GOVERNING LAW**

- Delaware law governs most agreements.
- <u>But New York law governs most CVRs that are listed and registered.</u>

# Some Law: Are CVRs a Security?

Depending on their features, CVRs may be considered **securities**, requiring registration under U.S. Securities Act.



To avoid treatment as a security, according to a series of SEC no-action letters, the following factors must apply:

- 1. the rights must be an integral part of the consideration to be received in transaction and granted pro-rata;
- 2. the rights must **not represent any ownership or equity interest** or carry voting or dividend rights or bear a stated rate of interest;
- 3. the rights must be non-transferable, except by operation of law or by will or intestacy;
- 4. the rights must not be evidenced by any form of certificate or instrument; and
- 5. any amount ultimately paid to the **holders must not depend on the operating results** of the surviving company or any constituent company to the merger.

# Are CVRs a Security?

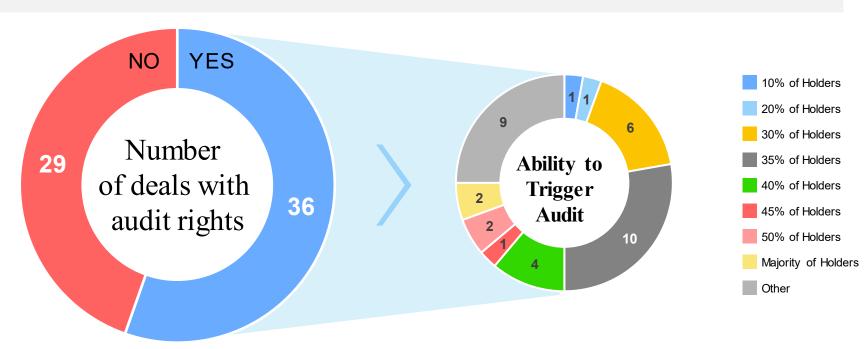
Transferability is the key feature determining whether a CVR will be treated as a security.

Though the staff has often provided no-action relief citing that a CVR is not dependent on operating results of a company, milestones are often structured to be dependent on a single product or some other narrower segment of sales:

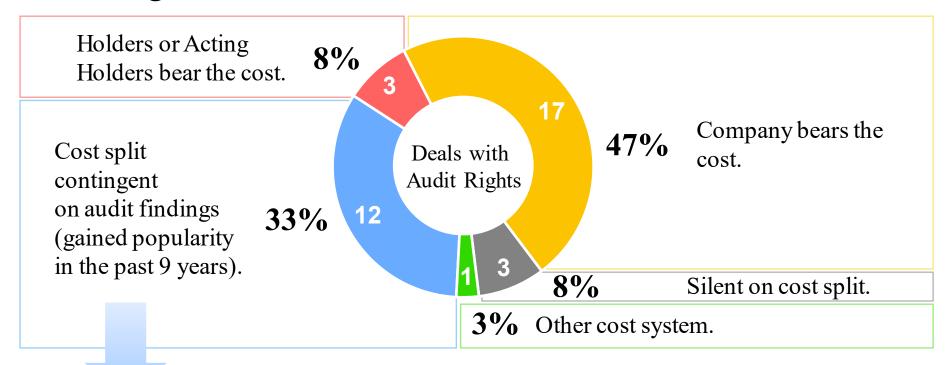
- In *Forest Laboratories/Clinical Data*, the company argued in its response to the SEC's inquiry that their CVR "will not depend upon the general operating results of Forest, Parent or Purchaser, but will only relate to the net sales, if any, of the Product."
- Financial milestones such as (i) a percentage of sales of a particular product over a threshold or (ii) a fixed payment in the event a sales threshold of a particular product is reached are generally not deemed to be general "operating results."
- Registered CVRs have occasionally had milestones that would likely be prohibited for an unregistered CVR, such as EBITDA of a holdco containing the target company.

# **Audit Rights**

- A majority of deals include an audit right, allowing an independent auditor (or in some cases, the holders or their agents) to verify the books and records underlying the acquiror's report on the milestones.
- Most frequently, action by 35% of the holders is required to trigger an audit, though there is significant variation in the sample



# Audit Rights – Who bears the costs of an audit?



#### APPROACH 1 OR APPROACH 2

Company bears all costs if and only if the audit identifies a CVR payment shortfall; **10** of **12** (83%) deals with cost split contingent on audit findings take this approach, and **3** require that the shortfall exceed a certain threshold ranging between 5-10% underpayment.

CVR holders and Company both bear the cost, based upon the percentage that the amount actually contested but not awarded to the holders or parent bears to the aggregate amount actually contested by the holder representative and parent; **2** of **12** (17%) deals with cost split contingent on audit findings take this approach.

# Audit Rights – Other Terms

- Audit requests typically must be submitted within a specified time window after **TIMING** delivery of statement confirming failure of milestones or the financials report. — Audit rights are generally available in connection with the determination of a milestone payment. **FREQUENCY** — When multiple audit rights are allowed, the frequency is typically expressly limited to a specific timeframe (e.g., once per year or once per milestone notice). SCOPE — 39% of deals limit the independent accountant's review to disputed items only. — 11% of deals allow Acquiror and CVR holders to submit comments to the **REVIEW &** independent accountant's preliminary findings, which the independent accountant COMMENT must take into consideration in good faith. — All deals require entry into a confidentiality agreement, except for one deal where CONFIDENTIALITY the CVR agreement includes a confidentiality requirement.



— Summaries of notable CVR/earnout decisions

# Jeff Himawan, et al. v. Cephalon, Inc., et al. (2024)

# **BACKGROUND**

- Cephalon acquired Ception Therapeutics in 2010, which had an antibody drug called Rezlizumab (RSZ) as its primary asset to treat eosinophilic asthma (EA) and eosinophilic esophagitis (EoE).
  - The merger agreement required Cephalon to use "commercially reasonable efforts" (CRE) to develop and commercialize RSZ to achieve regulatory milestones, with substantial payments owed upon regulatory approvals for each of EA and EoE.
    - Agreement included a "discretion clause" that provided that Cephalon would have complete discretion with respect to the business of Ception, and did not have any obligation to "(i) conduct clinical trials; (ii) pursue regulatory approvals; (iii) maximize payment to Ception stockholders; (iv) follow Ception's business plan; or (v) consult with Ception stockholders with respect to the business." This clause, however, was subjected to the CRE clause.
    - CRE defined objectively as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon], with due regard to the nature of efforts and cost required for the undertaking at stake."
- Cephalon spent over \$7.5 million trying to get RSZ approved for EoE but failed after multiple rejected proposals from the FDA.
- Teva acquired Cephalon in 2011 and prioritized the more promising EA indication over restarting efforts for EoE.
  - Teva succeeded in getting RSZ approved for EA (branded as CINQAIR) and paid the \$200M milestone (and close \$800M in others costs to bring EA to market), but it was commercially unsuccessful due to a black box warning and IV-only administration.
  - Teva later evaluated RSZ again for EoE but determined that it was impractical for a number of reasons, including commercial hurdles created by the black box warning and IV-only administration and in light of the related milestone payments.
- Plaintiffs sued for breach, complaining among other things that Cephalon and Teva's efforts paled in comparison to those utilized by other global pharma companies in developing their EoE products

#### **DECISION**

- The court initially rejected defendants' motion to dismiss
- After trial, the court found Cephalon and Teva acted reasonably given the regulatory hurdles for EoE and low commercial prospects even if approved, compared to their substantial efforts and spending on the EA indication.
- The "commercially reasonable efforts" clause did not require efforts contrary to the companies' economic interests, measured objectively against similarly-situated companies.
  - The Court declined to resolve the question of what size companies the CRE obligations would be measured against, as the record failed to demonstrate that a company even with Teva's resources—taking into account the low probability of achieving approval of an EoE treatment, the costs thereof, and the low probability of profitable commercialization—would find it in its economic interests to go forward

#### **KEY TAKEAWAYS**

- Discretion provision helpful, even when paired with CRE obligation.
- Factual nature of these types of disputes limit ability to dismiss before trial.
- A clear record of the buyer's efforts and decision-making process key to support a court's favorable analysis of its efforts.

#### Mercury Partners Management, LLC v. Valo Health, Inc. (Del. Ch. 2024)

#### **BACKGROUND**

- Plaintiffs, represented by Mercury Partners Management on behalf of the securityholders of Courier Therapeutics, were entitled to contingent value rights (CVRs) based on the FDA approval of a novel cancer therapeutic.
- Mercury alleged that Valo Health, Inc., the buyer of Courier Therapeutics, breached the Securities
   Purchase Agreement (SPA) by failing to use 'Commercially Reasonable Efforts' to develop and obtain
   FDA approval for the drug.
- The SPA defined "Commercially Reasonable Efforts" as efforts consistent with those a similarly situated, early-stage biotech company would devote to a similar product, considering various developmental and market factors.

#### **DECISION**

- Specific performance was denied due to the indefinite nature of the obligation, the complexity involved in the business judgment, and potential notice requirements involved in overseeing the development and commercialization of a drug over the course of years (in contrast to, for example, closing a merger), making it impractical for the court to provide meaningful oversight or to foresee what actions might be deemed contemptuous.
- The ruling referenced prior cases, including Carteret Bancorp, Inc. v. Home Group, Inc. and 26 Capital Acquisition Corp. v. Tiger Resort Asia Ltd., acknowledging the difficulties of enforcing best efforts clauses in the context of evolving commercial realities.

#### **KEY TAKEAWAYS**

- This case illustrates the challenge of enforcing "best efforts" clauses in contracts, especially when they involve long-term, complex undertakings like drug development.
- The court is reluctant to issue specific performance orders that would require it to involve itself in ongoing business judgments or to oversee an extended developmental process that lacks definitive, measurable standards. This is relevant in cases where relief via specific performance would be too indefinite and supervision-intensive.

# Menn v. ConMed Corp. (Del. Ch. June 30, 2022)

#### **BACKGROUND**

- Pavel Menn, representing the former shareholders of Endodynamix, Inc., filed a lawsuit against ConMed Corporation for breach of contract. Menn claimed ConMed failed to use "commercially best efforts" to maximize sales of a medical device, SureClip, provide quarterly reports on its progress, and make the required payments. Additionally, Menn argued ConMed wrongly ceased development of SureClip, claiming it posed a safety risk, to avoid making acceleration payments.
- The stock purchase agreement between ConMed and Endodynamix included contingent payments based on the development and sales milestones of SureClip, which ConMed was contractually obligated to develop using commercially best efforts. Menn sought accelerated payments following ConMed's discontinuation of SureClip's development.

#### **DECISION**

- After a 7-day trial and extensive post-trial proceedings, the court found in favor of ConMed. The defendants successfully argued they had undergone significant efforts to develop Sureclip, but had to discontinue it SureClip due to technical challenges and legitimate safety concerns for patients (which was a contractually specified reason to stop development).
- The court ruled that ConMed did not breach their commercially best efforts obligation before deciding to discontinue the development of SureClip. Consequently, Menn's demands for acceleration payments were unfounded.

#### **KEY TAKEAWAYS**

- This case emphasizes the critical importance of defining "commercially best efforts in contractual agreements, especially when future development and sales milestones are linked to additional payments. It also It illustrates the autonomy companies can have under contract law when a clause gives them discretion, especially concerning decisions about product safety and viability.
- The court's decision reaffirms that legitimate safety concerns can justify the cessation of a product's development, in spite of the existence of best-efforts clauses, and even if it affects contingent financial obligations to former shareholders (such as unmet milestone payments).

# Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016)

# BACKGROUND

- Prior to 2011, Genzyme Corporation was the owner of a drug called Lemtrada which had shown potential as a treatment for multiple sclerosis. At least as far back as 2002, the FDA repeatedly expressed concern about Genzyme's use of single-blind clinical trials for Lemtrada and reiterated its preference for a double-blind clinical trial to obtain FDA approval.
- In 2011, Sanofi acquired Genzyme Corporation. In connection with the merger, Genzyme shareholders received a cash payment of \$75 per share, plus one CVR per share. The CVRs entitled its holder to \$1 per CVR if the FDA approved Lemtrada for treatment of multiple sclerosis by March 31, 2014 and certain additional cash payments upon the achievement of product sales and production milestones.
- In November 2013, the FDA rejected Lemtrada's initial application, with two of the reviewing physicians referencing the failure to use double-blind studies.
- Two securities fraud class action complaints were filed, alleging, among other things, that Sanofi made materially misleading statements of opinion to investors regarding the likelihood of meeting the FDA approval milestone. In particular, the plaintiffs alleged that Sanofi's failure to disclose the FDA's feedback regarding its use of single-blind studies in the Lemtrada clinical trials was an omission of material information.

#### **DECISION**

- The Second Circuit dismissed the claims on the basis that no reasonable investor would have been misled by Sanofi's optimistic statements regarding the approval of Lemtrada.
- Sanofi had no obligation to disclose public information regarding FDA interim feedback that tended to cut against their projections, particularly considering investor sophistication and customs and practices in the pharmaceutical industry (noting in particular that the FDA has long made public its preference for double-blind trials).

#### **KEY TAKEAWAY**

— Acquirors need not disclose a piece of information merely because it cuts against their projections.

# UMB Bank, N.A. v. Sanofi, No. 15-cv-8725 (S.D.N.Y. 2016)

#### BACKGROUND

- UMB Bank, as trustee, filed a lawsuit against Sanofi over alleged breach of a Contingent Value Rights (CVR) Agreement stemming from Sanofi's acquisition of Genzyme.
- Sanofi's acquisition of Genzyme was partly structured around the attainment of specific milestones associated with Lemtrada (a drug developed by Genzyme).
- UMB Bank received CVRs as part of the acquisition deal, which included milestones based on FDA approval and sales of a specific drug.
- The lawsuit centered on a breach of contract claim, in which UMB Bank accused Sanofi of failing to use diligent efforts to achieve certain milestones outlined in the CVR Agreement.
- UMB Bank sought a declaratory judgment on one count of its complaint, asserting Sanofi's failure to comply with contractual obligations regarding an independent audit of Lemtrada sales as stipulated in the CVR Agreement.

#### **DECISION**

- The court granted the UMB Bank's motion for partial summary judgment regarding a demand that the defendant submit to and pay for an independent audit of Lemtrada's sales. The court denied immediate enforcement of the judgment based on considerations of judicial efficiency and separability of claims. The audit claim was not found to be sufficiently independent from other claims to warrant an immediate judgment.
- The court recognized that UMB Bank alleged sufficient facts suggesting Sanofi's failure to diligently pursue the milestones.
- The dispute was ultimately settled for \$315 million, a fraction of the potential \$3.8 billion maximum obligation under the CVR Agreement.

#### **KEY TAKEAWAY**

— This case underscores the difficulties of enforcing CVRs and audit rights, while highlighting the judicial system's cautious approach towards granting immediate judgment to avoid piecemeal appeals and ensure comprehensive resolution of all intertwined legal issues.

# SRS v. Alexion, 768 A.2d 8 (Del. 2000)

# BACKGROUND

- SRS represented Syntimmune's Securityholders post-merger with Alexion Pharmaceuticals, Inc. Syntimmune was developing a pharmaceutical candidate for treating rare autoimmune diseases.
- The merger agreement included an upfront payment of \$400 million. In addition, up to \$800 million in contingent value rights (CVRs) were possible, based on achieving specific development milestones related to SYNT001.
- The CVRs were to be triggered by eight milestone events, including successful clinical trials and regulatory approvals, specified in the merger agreement.
- The breach of contract claim centered on Alexion's alleged failure to use commercially reasonable efforts to develop SYNT001. This claim was initiated after Alexion reported that the development of SYNT001 had fallen "significantly behind schedule."
- SRS alleged that Alexion ceased using commercially reasonable efforts as of October 4, 2019, contrary to the merger agreement stipulations, which required ongoing diligence for seven years post-merger. Alexion argued that the breach of contract claim was not ripe for judgment, asserting that the dispute was premature since the seven-year period during which it was required to use commercially reasonable efforts had not yet concluded.

#### **DECISION**

— Citing practical considerations (such as judicial economy), the court rejected Alexion's argument, ruling that the claim was ripe for adjudication. The court found that the alleged breach was based on past events and underlying static facts, which allowed the court to assess the merits of the case. The breach, if any, occurred when Alexion ceased to exert commercially reasonable efforts, and not at the end of the obligation period.

#### **KEY TAKEAWAY**

— Claims can ripen before the end of the obligated period, particularly if the facts are static and ascertainable. Contractual obligations to exert efforts within a specified time frame can be judged before the time frame has expired if a breach is alleged to have occurred. This is particularly relevant in scenarios where efforts are evidently falling short of contractual standards well before the deadline.

