# CONTRACT AMBIGUITY LEADS TO MISTRIAL IN $122M BIOTECH ROYALTY DISPUTE: LESSONS FROM GENENTECH V. BIOGEN

## The Mistrial and Its Significance

A California federal jury's inability to interpret standard patent licensing provisions has resulted in a mistrial that sends shockwaves through the biotechnology licensing community. On July 3, 2025, U.S. District Judge Yvonne Gonzalez Rogers declared a mistrial in *Genentech Inc. v. Biogen MA Inc.*, Case No. 4:23-cv-00909 (N.D. Cal.), after jurors deadlocked over whether Biogen owed $122 million in royalties for antibody drugs manufactured before patent expiration but sold afterward.

The case represents far more than a simple contract dispute between pharmaceutical titans. It exposes a critical ambiguity lurking in countless biopharmaceutical license agreements: precisely when does the obligation to pay royalties accrue? The answer to this seemingly technical question determines whether biotechnology companies owe millions in "tail royalties" on inventory manufactured under patent protection but commercialized after expiration.

For an industry that routinely stockpiles months or even years of drug inventory to ensure supply chain continuity, the stakes could hardly be higher. The dispute centers on U.S. Patent Nos. 6,331,415 and 7,923,221, part of the legendary Cabilly patent family that revolutionized antibody manufacturing and generated over $1 billion annually at its peak.

## Background: The Cabilly Patent Empire

Few patent families have shaped the biotechnology industry as profoundly as the Cabilly patents. Co-owned by Genentech and the nonprofit City of Hope, these patents claimed fundamental methods for producing therapeutic antibodies at commercial scale. Through a unique arrangement, Genentech controlled exclusive licensing rights and pursued an aggressive strategy that made these patents ubiquitous in antibody manufacturing.

The patents enjoyed an extraordinarily long life, not expiring until December 18, 2018, some 35 years after their priority date, due to patent term adjustments and extensions. By 2018, Genentech's share of Cabilly royalties exceeded $600 million annually, making them among the most lucrative patents in biotechnology history.

In 2004, as Biogen prepared to launch Tysabri (natalizumab) for multiple sclerosis treatment, it entered a license agreement with Genentech. The contract required Biogen to pay a mid-single-figure royalty on U.S. net sales and a lower royalty on international sales of any 'Licensed Product', defined as antibodies whose manufacture would infringe the Cabilly patents absent the license. From 2006 through 2018, Biogen dutifully paid over $750 million in royalties.

But when the patents expired, Biogen stopped paying, despite holding a substantial inventory of Tysabri, all manufactured using the patented process before expiration. Court proceedings revealed Biogen possessed 397,311 vials at the time of patent expiration. These vials, sold throughout 2019 and 2020, generated the current dispute.

## Competing Contract Interpretations

The litigation illuminates how standard licensing language can support diametrically opposed interpretations when millions hang in the balance. Both parties point to the same contractual provisions to support their positions, demonstrating the perils of imprecise drafting.

### *The Contractual Framework*

The agreement's royalty provision (Section 3.03) requires payment on "all Net Sales of all Licensed Product sold in the United States." The definition of "Licensed Product" encompasses any antibody "the making (or having made), using, selling, offering for sale or importing of which, but for the license granted under this Agreement, would infringe a Valid Claim of a patent included in Licensed Patents."

Critically, the agreement's term provision (Section 7.01) states the agreement continues "until the expiration of the last patent within the Licensed Patents," while the termination clause (Section 7.05) requires payment of "all fees and royalties that shall have accrued hereunder prior to the effective date of termination." Notably absent from the survival provisions: any explicit reference to the royalty obligation itself.

### *Genentech's Manufacturing-Based Theory*

Genentech's position centers on when the royalty obligation arises under the license agreement. The company contends that products become "Licensed Products" subject to royalties at the moment they are produced through the patented process or brought into the United States, regardless of when sales occur. This interpretation means that all Tysabri inventory existing at patent expiration on December 18, 2018, would remain subject to royalty payments upon subsequent sale, as these products were created using Cabilly-covered methods while the patents were still in force. Under this reading, the triggering event for royalty obligations is the use of the patented technology, not the commercial transaction.

This interpretation finds support in multiple sources. A Genentech senior executive testified that continuing royalties on pre-expiration inventory reflects standard industry practice for process patents. Perhaps more significantly, internal Biogen financial projections prepared by a senior accounting director after consultation with company lawyers showed anticipated royalty payments extending years past patent expiration, suggesting Biogen's own initial understanding aligned with Genentech's position.

### *Biogen's Sale-Based Theory*

Biogen counters with an equally plausible reading focused on the agreement's structure and plain language. Under Biogen's interpretation, royalties accrue only upon sale, and the agreement's termination upon patent expiry extinguishes all payment obligations. No sale after December 18, 2018, triggers royalties, regardless of when products were manufactured.

Biogen's position gains strength from the termination clause's conspicuous omission of royalty obligations from the survival provisions. If the parties intended royalties to survive termination, Biogen argues, they would have explicitly said so. Moreover, Biogen presented evidence that among dozens of Cabilly licensees with "virtually identical" contract language, only a handful actually paid tail royalties, undermining Genentech's industry custom argument.

## Trial Proceedings and Deadlock

The three-day trial before Judge Gonzalez Rogers showcased the complexity of patent licensing disputes. Despite clear presentations from counsel on both sides, jurors struggled to parse the competing interpretations.

Initial jury deliberations revealed a 5-3 split, with positions shifting as discussions progressed. Ultimately, the jury deadlocked 7-1 in Genentech's favor, falling one vote short of the required unanimity. Post-trial discussions with jurors confirmed what many practitioners suspected: complex commercial disputes involving technical patent and contract interpretation issues may exceed the comfort zone of lay jurors.

Judge Gonzalez Rogers's post-mistrial comments proved particularly telling. When Genentech proposed retrying the case as a bench trial, the judge expressed openness, acknowledging that "these are difficult cases for jurors to parse through." Her willingness to consider a bench trial reflects growing judicial recognition that certain commercial disputes require specialized expertise.

## Implications for the Biotechnology Industry

The mistrial's immediate impact extends beyond the parties. Genentech has filed similar suits against other Cabilly licensees, including Millennium Pharmaceuticals (now Takeda) regarding Entyvio, where 2019 sales of $3.1 billion could yield even larger royalty claims. The combined value of these disputes likely exceeds $200 million, making the interpretation question critical for multiple industry players.

More broadly, the case highlights an ambiguity often seen in biopharmaceutical license drafting. Despite involving sophisticated parties, experienced counsel, and enormous financial stakes, the Genentech-Biogen agreement did not explicitly address a predictable scenario. Given that pharmaceutical companies routinely maintain substantial safety stock, often several quarters of inventory, the treatment of pre-expiry manufactured products deserves explicit attention.

This issue also sits adjacent to longstanding U.S. Supreme Court precedent restricting post-expiration royalties. In Kimble v. Marvel Entertainment, LLC, 576 U.S. 446 (2015), the Court reaffirmed that royalties tied solely to sales occurring after patent expiration are unenforceable under Brulotte v. Thys Co., 379 U.S. 29 (1964). However, Kimble left room for royalty obligations that accrue based on pre-expiration acts, such as manufacturing or importation, if clearly stated in the agreement. The Genentech-Biogen dispute thus underscores how careful drafting can preserve enforceability while navigating the constraints imposed by Kimble and Brulotte.

### *Practical Guidance for License Drafting*

**1. Address Tail Royalties Explicitly:** Never rely on implication or industry custom. State clearly whether royalties apply to products manufactured or imported during the patent term but sold afterward. Consider formulations like: "Royalties shall be payable on all Licensed Products manufactured or imported into the United States during the term of the Licensed Patents, regardless of when such Licensed Products are sold."

**2. Define Accrual Precisely:** Specify when royalty obligations accrue: upon manufacture, sale, or another triggering event. Eliminate interpretive ambiguity by stating: "The obligation to pay

royalties on each unit of Licensed Product accrues upon the earliest of: (a) manufacture, (b) importation into the Licensed Territory, or (c) commercial sale or use of such unit."

**3. Draft Comprehensive Survival Clauses:** Explicitly list all provisions that survive termination, including payment obligations for accrued royalties. Do not assume courts will infer survival based on context or commercial logic.

**4. Consider Inventory Provisions:** Clarify treatment of end-of-term inventory. Options include royalty step-downs, wind-down windows, or royalty exemption periods for products in the pipeline at patent expiration.

**5. Evaluate Dispute Resolution Mechanisms:** Given the complex interplay of patent law and contract language, consider specifying arbitration by panels with technical expertise or permitting court resolution via bench trial.

## The Path Forward

With a retrial potentially scheduled for July 14, 2025, the parties face strategic decisions. Accepting Judge Gonzalez Rogers's invitation for a bench trial might streamline proceedings and increase predictability. Alternatively, settlement discussions may intensify now that both parties understand the litigation risks.

The case's ultimate resolution will reverberate throughout the biotechnology industry. A Genentech victory would validate tail royalty provisions and potentially trigger retroactive payment obligations for other licensees. A Biogen victory would encourage strict construction of license terms and might prompt licensors to revise their standard agreements.

Whatever the outcome, *Genentech v. Biogen* has already succeeded in highlighting a critical issue for biotechnology licensing. In an industry where patent cliffs can devastate revenue streams overnight, the precision of contractual language becomes paramount. The $122 million question before the court serves as an expensive reminder that ambiguity in license agreements is a luxury the industry can no longer afford.

As biotechnology companies continue to build their businesses on complex webs of intellectual property licenses, the lessons from this mistrial are clear: explicit drafting trumps assumed understanding, boilerplate provisions demand scrutiny, and the cost of ambiguity can be measured in hundreds of millions of dollars. For an industry built on scientific precision, perhaps it's time for equal precision in contractual drafting.

This article reflects information available as of July 8, 2025, and does not incorporate developments occurring after that date.