



Jackrel Consulting, Inc.

# Willfulness

Recent Cases

# Halo Electronics v. Pulse Electronics (2016)



## – background

Supreme Court 2016

- Old test = (1) clear and convincing evidence that infringer acted despite “objectively high likelihood” of infringing a valid patent; and (2) clear and convincing evidence that “risk of infringement ‘was either known or so obvious that it should have been known’”
  - Parties relied heavily on opinions of counsel to avoid willful infringement
- Halo case facts
  - Halo offered to license patents to Pulse, but Pulse engineer concluded Halo’s patents were invalid and so Pulse continued to sell infringing product without a license
  - No opinion of counsel
  - Jury found there was a high probability Pulse had infringed willfully
  - Trial judge refused to award enhanced damages because Pulse had a defense that was not objectively baseless or a sham
- Stryker case facts (Stryker v. Zimmer)
  - Jury found Zimmer infringed Stryker’s patents on the devices and it was willful
  - Trial judge trebled damages under 284, finding that Zimmer had intentionally copied Stryker design
  - “All-but instructed its design team to copy Stryker’s products”, ”chosen a ‘high-risk/high-reward strategy of competing immediately and aggressively in the pulsed lavage market,’ while ‘opt[ing] to worry about the potential legal consequences later.”
  - No opinion of counsel

# Halo continued - Supreme Court statutory analysis



- Language of 284 does not have any limit or condition
  - 35 USC 284 “the court may increase the damages up to three times the amount found or assessed”
- But, discretion should be exercised in light of considerations underlying the grant of discretion and two centuries of case law requires that enhanced damages be reserved for “egregious cases of culpable behavior”

# Halo continued – Supreme Court on Seagate



- Test too rigid and insulates the worst offenders because it required objective recklessness
- The statute should allow for the subjective willfulness to be punished
- Clear and convincing burden is too high
- Also, decisions on enhanced damages should be reviewed for abuse of discretion, which is entirely different than the standard the Fed. Cir. was using
  - Under Seagate, the first step was reviewed de novo and the second step for substantial evidence and the ultimate decision for abuse of discretion



# Halo – Breyer concurrence

- “Court’s references to ‘willful misconduct’ do not mean that a court may award enhanced damages simply because the evidence shows that the infringer knew about the patent *and nothing more*”
- Cautionary statements about not overdoing the treble damages lest the decisions start to impede the progress of science and useful arts



# Halo Cont – did they pay

- Pulse did not pay treble damages – district court judge denied treble damages, finding Pulse did not act in an egregious manner
- Zimmer did pay enhanced damages – judge called it egregious piracy

# Overview

- Ravgen, Inc. v. Lab. Corp. of Am. Holdings
  - Huge award (\$100's of millions)
  - (Jan '25) CAFC affirmed the PTAB decisions on the same patent
  
- Provisur v. Weber
  - Jury found Weber willfully infringed, but...
  - (Oct '24) CAFC reversed
  - Provisur Technologies petition to the Supreme Court
  
- Lindis Biotech v. Amgen
  - Also big, \$50M --> \$150M due to willful infringement, but...
  - (Aug '25) Patents found unenforceable due to inequitable conduct during prosecution!

# Ravgen, Inc. v. Lab. Corp. of Am. Holdings

Fed. Cir. Jan '25



Huge award, and the CAFC just affirmed the PTAB decisions on the 7,332,277 patent

- Ravgen, Inc. owns the '277 patent – related to non-invasive methods for sampling DNA and detecting genetic disorders in a fetus. It describes analyzing fetal DNA (“cffDNA”) found in a blood sample drawn from a pregnant mother.
- In 2022 – Jurors found that Lab Corp did infringe Ravgen’s patent, and that the infringement was willful. **They awarded Ravgen its full royalty demand of \$272.5M in damages. Judge Alan Albright subsequently enhanced the jury award by \$100M.**
  - Labcorp argued that they did not copy the asserted patent or Ravgen’s method, Labcorp had a good faith belief in non-infringement and invalidity, Labcorp uses old technology, and Labcorp had no specific intent to infringe.
- CAFC affirmed that patents are valid, overcoming non-obviousness and motivation to combine issues
  - “copying is not required” for willful infringement – only that it is “deliberate or intentional”
  - “While Labcorp’s witnesses testified that the accused Labcorp products use a different approach from what is claimed in Ravgen’s patents, the jury was free to weigh the evidence and come to its own conclusion. ... (“The jury was entitled to hear the expert testimony and decide for itself what to accept or reject.”). Therefore, substantial evidence supports the jury’s willful infringement finding that Labcorp’s infringement was deliberate or intentional, and the Court declines to grant JMOL of no willful infringement.”

**CAFC confirmed the patents validity, and declined to grant JMOL of no willful infringement**

<https://imslegal.com/case-studies/ravgen-v-labcorp>

[https://www.cafc.uscourts.gov/opinions-orders/23-1342.OPINION.1-6-2025\\_2446357.pdf](https://www.cafc.uscourts.gov/opinions-orders/23-1342.OPINION.1-6-2025_2446357.pdf)

[https://www.govinfo.gov/content/pkg/USCOURTS-txwd-6\\_20-cv-00969/pdf/USCOURTS-txwd-6\\_20-cv-00969-6.pdf](https://www.govinfo.gov/content/pkg/USCOURTS-txwd-6_20-cv-00969/pdf/USCOURTS-txwd-6_20-cv-00969-6.pdf)

# Provisur v. Weber

Fed. Cir. Oct '24



- Jury found Weber willfully infringed Provisur’s patents
  - Provisur’s patents (US 7,065,936, 10,625,436, & 10,639,812) relate to food-processing machinery, e.g., high-speed mechanical slicers used in food-processing plants, e.g., for meats and cheeses.
  - Weber systematically tracked and rated Provisur’s patents “using software, assigning the highest possible relevance score.” However, did not seek advice of counsel.
- CAFC reversed the willfulness finding
  - 1. Section 298 says that the lack of an opinion of counsel cannot be used to prove willfulness
    - 35 U.S.C. §298 “the failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent ... may not be used to prove that the accused infringer willfully infringed the patent”
  - 2. Maintaining a patent matrix tracking potentially relevant patents is insufficient as a matter of law to establish willful infringement
    - “At most, the patent matrix demonstrates Weber’s knowledge of the asserted patents and their relevance to Weber’s business in general. The patent matrix and corresponding testimony do not provide any level of specificity as to the relevance of the tracked patents for any of Weber’s products. There is no dispute Weber knew of the asserted patents. ... The issue here is whether Weber knew of its alleged infringement and had a specific intent to infringe.”

**Should tracking patents, without seeking legal advice, and without taking any steps to avoid infringement be considered “willful”?**

# Provisur v. Weber

Fed. Cir. Oct '24



- The Seventh Amendment’s reexamination clause says that “no fact tried by a jury, shall be otherwise re-examined in any Court of the United States...”, seems at odds with the rules of civil procedure that allow CAFC to reject a jury verdict (via JMOL, Judgment as a Matter of Law).
- Provisur petitioned the Supreme Court (Dec '24) – arguing that the Federal Circuit improperly discounted significant evidence supporting willfulness, including:
  - Weber’s patent monitoring system that rated Provisur’s patents as highly relevant
  - testimony that Weber took no steps to avoid infringement.
  - Jury found that Provisur’s witnesses were dishonest when they testified that they had no knowledge of the patents.
  - → which provided support for the jury’s finding of “reckless disregard” sufficient for willfulness (under Halo Electronics, Inc. v. Pulse Electronics, Inc. , 579 U.S. 93 (2016))
- Petition also argued that there is a recent trend of the CAFC over-turning jury verdicts in patent cases.
  - exception to Seventh Amendment protections — giving wider discretion to reject jury findings when a case is likely too complex for an average juror to comprehend.
  - this exception is not found in the Constitution and has not been recognized by the Supreme Court.

**Provisur petitioned the Supreme Court to find out... but the petition was denied in Feb '24**

# Lindis Biotech v. Amgen

District court Aug '25



Original ruling (Dec '24) Amgen owed \$50M, and with willfulness --> \$150M, but district court found Lindis Biotech patents were unenforceable due to inequitable conduct

- Lindis Biotech patents (US 8,709,421 & 10,071,158) relate to cancer treatments (e.g., for lymphoma) using a bispecific immunostimulating antibody in combination with a glucocorticoid (which is a corticosteroid)
- Lindis sued Amgen, who earned \$800 million from U.S. sales of cancer immunotherapy drug Blincyto last year.
  - AI Overview – While corticosteroids have the potential to dampen the immune response that Blincyto (blinatumomab) depends on, *[[studies show that low-dose steroid use does not significantly reduce Blincyto's effectiveness??]]*. Corticosteroids are used alongside Blincyto to manage dangerous side effects, such as cytokine release syndrome (CRS) and neurological toxicities, that can occur when the immune system is activated too strongly.
- Jury found that Amgen infringed two Lindis patents covering immunotherapy innovations. And that Amgen's infringement was willful, which could lead the court to increase the damages award up to \$150.9 million.
- In a decision in August, U.S. District Judge invalidated the patents due to inequitable conduct related to withholding material information from the USPTO during prosecution

<https://www.reuters.com/legal/government/amgen-hit-with-503-mln-us-verdict-cancer-drug-patent-lawsuit-2024-12-18/>

<https://fingfx.thomsonreuters.com/gfx/legaldocs/xmpjbqazzpr/AMGEN%20LINDIS%20TRIAL%20verdict.pdf>

<https://www.wsgr.com/en/insights/lindis-v-amgen-inequitable-conduct.html>

<https://www.fiercepharma.com/pharma/amgen-skirts-50m-payout-blinicyto-patent-litigation-tiff-lindis>

# Lindis Biotech v. Amgen

District court Aug '25



- Quick and dirty tests (2002) showed that glucocorticoid premedication before immunostimulating antibodies, such as Herceptin and Rituxan, did not significantly reduce the specific immune activity directed against the tumor-cell antigen (EpCAM)
  - this data was in the app, and in prosecution it was used as a “surprising result” to overcome 103 rejections
  - April 2018, based on Applicants' arguments, the examiner withdrew the 103 and allowed the claims of the '158 Patent.
- However, the Trion report (2005) showed that dexamethasone inhibits tumor cell killing by Removab.
  - Two weeks after the Trion Report, he filed the priority patent application of the Asserted Patents.
- "To prove inequitable conduct, a party must show that the patentee withheld material information from the PTO, and did so with the specific intent to deceive the PTO."
  - Reasonable that Lindis (Dr. Lindhofer) knew the Trion/EMA Report was material, and also submitted it to the PTO for a different patent application.
  - Intent -- "To satisfy the intent requirement, the accused infringer must prove ... that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it. Inequitable conduct requires clear and convincing evidence of a specific intent to deceive the PTO..."
  - “Amgen makes the assertions that Lindis (Dr. Lindhofer) 1) knew of the Withheld References and 2) made a deliberate decision to withhold them from the PTO. Lindis does not dispute these assertions and, instead, only argues that Lindis (Dr. Lindhofer) believed that the Withheld References were not material. As a result, the Court accepts that Lindis (Dr. Lindhofer) knew of the Withheld References and made a deliberate decision to withhold them from the PTO.”

→ Patents invalidated due to inequitable conduct

<https://www.reuters.com/legal/government/amgen-hit-with-503-million-us-verdict-cancer-drug-patent-lawsuit-2024-12-18/>

<https://finqfx.thomsonreuters.com/gfx/legaldocs/xmpjbaqzzpr/AMGEN%20LINDIS%20TRIAL%20verdict.pdf>

<https://www.wsqr.com/en/insights/lindis-v-amgen-inequitable-conduct.html>

<https://www.fiercepharma.com/pharma/amgen-skirts-50m-payout-blincyto-patent-litigation-tiff-lindis>

**Cannot withhold “material information” from the PTO during patent prosecution  
→ inequitable conduct**



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Thank You