



Highlighting the patent law developments you should know in biotech, biologics and pharmaceutical cases, legislation and federal agency actions in September 2019, including:

- An analysis of early entry triggers in an ANDA settlement agreement
- The patent venue statute does not require a nexus between the “established place of business” and the alleged acts of infringement
- The dismissal of “sham” litigation antitrust counterclaims



Any questions? Contact  
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## Federal Circuit

### State Sovereign Immunity Does Not Trump Patent Venue Statute

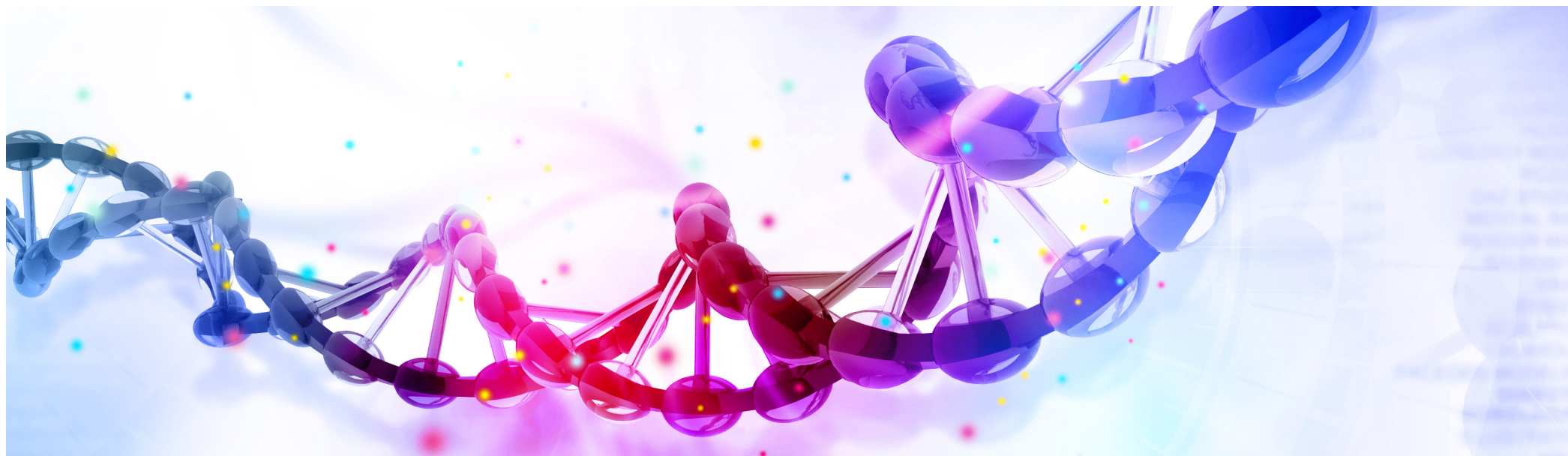
*Board of Regents of the University of Texas System v. Boston Scientific Corp.*, No. 2018-1700 (Fed. Cir. Sep. 5, 2019)

The appellants filed this patent infringement suit in the Western District of Texas. The district court found improper venue, and transferred the case to Delaware. The university appealed the transfer order. The Federal Circuit held that sovereign immunity does not apply and cannot be asserted to challenge a venue decision where a state acts only as a plaintiff.

### District Court Did Not Abuse Discretion in Excluding Expert’s Infringement Opinion

*Phigenix, Inc. v. Genentech, Inc.*, Nos. 2017-2617, 2018-1042 (Fed. Cir. Sep. 5, 2019)

The district court excluded plaintiff’s expert’s infringement opinion for failure to timely disclose a new (and narrower) infringement theory, and then granted summary judgment of no infringement based on the resulting lack of direct infringement evidence. The Federal Circuit held that the district court did not abuse its discretion in excluding the expert report and affirmed the grant of summary judgment.



## District Court

### Court Rejects Overly Strict Reading of Definiteness Requirement for Measurement Claims

*Vifor Fresenius Medical Care v. Lupin Atlantis Holdings SA*, C.A. No. 18-390-LPS (D. Del. Sep. 5, 2019)

In this ANDA litigation, the court construed claim terms and rejected defendants' indefiniteness arguments. The court first rejected defendants' argument that the term "essentially non-bioabsorbable" is indefinite because the patent specification provided sufficient guidance to one skilled in the art that they would know the bounds of the claim with reasonable certainty. Regarding a claim to "iron release rate," the court rejected an "overly-strict reading of *Nautilus*: one requiring that patentees who claim a measurement must also clearly and unambiguously identify a single method of measurement expressly tied to the claim limitation, with implicit or explicit disavowal of all other methods." The court also disposed of indefiniteness arguments relating to other limitations.

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### Substantial Evidence Supported Jury Verdict

*Vectura Ltd. v. GlaxoSmithKline LLC*, Civil Action No. 16-638-RGA (D. Del. Sep. 10, 2019)

A jury found defendant liable for infringement and awarded a 3% running royalty. The district court denied defendant's motion for judgment as a matter of law and for a new trial on issues of infringement, obviousness and damages. Substantial evidence in the record supported the jury's findings.

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### No Nexus Required Between Established Place of Business and Acts of Infringement for Venue

*Genentech, Inc. v. Eli Lilly and Co.*, No. 18-CV-1518 JLS (S.D. Cal. Sep. 12, 2019)

The district court denied Lilly's motion to dismiss or transfer for improper venue. The court found plaintiff's general allegations of infringement, followed by factual examples of alleged infringing activity, were more than sufficient to meet the pleading standard for venue purposes. The court also rejected Lilly's argument that a nexus is required between alleged acts of infringement and the defendant's established place of business. The plain language of the patent venue statute requires no such nexus and the court declined to read one into the statute. The court did dismiss plaintiff's willful infringement claim because the allegations of the complaint, taken as true, did not rise to the level of egregious conduct.

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### Court Will Not Entertain Summary Judgment Motion Close to Eve of Trial

*Takeda Pharmaceutical Co. v. Torrent Pharmaceuticals, Ltd.*, Civil Action No. 17-3186 (SRC) (D.N.J. Sep. 13, 2019)

Plaintiffs' moved for summary judgment on infringement and validity. Defendants asked the court to decline to entertain the motion, arguing that less than two months remained until trial. The court agreed that it was "too close to the eve of trial to adjudicate this motion" and the "better course" was to proceed to a full trial. Accordingly, the court dismissed the summary judgment motion.

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### No Early Entry Trigger Under ANDA Settlement Agreement

*Amgen Inc. v. Amneal Pharmaceuticals LLC*, Civ. No. 16-853-MSG (D. Del. Sep. 18, 2019)

Defendant Sun Pharmaceuticals and Amgen had previously settled ANDA litigation with an agreed upon entry date, subject to certain acceleration clauses. Following that settlement, another defendant (Teva) engaged in an at-risk launch, followed five days later by a settlement in which Teva agreed to cease its sales. Sun sought to enforce its settlement agreement, arguing that the at-risk launch triggered early entry. More specifically, Sun argued that in addition to settling with Teva, Amgen should have contracted with downstream distributors to "effectuate a cease and desist regarding the selling of Teva's product." After finding that it had jurisdiction over a ripe dispute, the court addressed the merits, holding that Amgen's obligations to Sun applied only to sales by those engaged in an at-risk launch – and not to distributors and resellers. Accordingly, Sun has no license to enter the market at this time.

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## Court Dismisses Sham Litigation and Patent Misuse Counterclaims

*Duke University v. Akorn, Inc.*, No. 3:18-cv-14035-BRM (D.N.J. Sep. 16, 2019)

In this, the fourth in a series of litigations concerning bimatoprost, the court granted plaintiffs' motion to dismiss defendant's antitrust and patent misuse counterclaims and strike its related affirmative defenses. Concerning defendant's "sham litigation" counterclaims, although reciting the elements of a monopolization action, the facts as pled were "insufficient to vitiate the protections" of *Noerr-Pennington*. Prior litigations concerning bimatoprost were not objectively baseless when filed. The court also noted that courts in the prior cases had not found them to be "exceptional," a lower bar than the standard for sham litigation. The court likewise dismissed Akorn's conspiracy and patent misuse counterclaims/defenses, noting that, as a matter of law, sham litigation allegations cannot form the basis for a patent misuse claim. In addition, that defendant failed to plead the specifics of how there was an impermissible broadening of the physical or temporal scope of the patent also required dismissal.

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## Collateral Estoppel Does Not Bar Assertion of Narrower Claims in Subsequent Patent

*Duke University v. Sandoz, Inc.*, No. 18-cv-00997-MSK-KLM (D. Col. Sep. 18, 2019)

The district court denied defendant's motion for summary judgment that collateral estoppel bars plaintiffs' infringement claims. In prior litigation regarding a related patent with broader claims, the Federal Circuit held those broader claims invalid as obvious. However, the district court found that the instant patent claims, limited to the use of a single compound (bimatoprost), are not substantially identical to the broader claims of the prior patent concerning methods of treatment with multiple compounds. Accordingly, collateral estoppel did not apply.

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## District Court Denies Preliminary Injunction

*Waters Corp. v. Agilent Technologies, Inc.*, C.A. No. 18-1450 (MN) (D. Del. Sep. 20, 2019)

The district court denied plaintiff's motion for a preliminary injunction. Rejecting the argument that the term "substituent" did not include linkers between one chemical group and another, the court found plaintiff likely to succeed in proving infringement of the two asserted claims. However, defendant made a "compelling showing" that a prior art reference anticipated the chemical genus claim. Concerning obviousness of the method claim, "compelling arguments" on both sides rendered the court "unable to find Defendant's obviousness challenge lacks substantial merit." Accordingly, plaintiffs had not established a likelihood of success on the merits. The court also rejected plaintiff's irreparable harm arguments in view of its delay in seeking to enforce its patent rights. The alleged harm regarding downstream sales, market share and price erosion was also "too speculative," and, in any event, compensable with money damages. The balance of the equities slightly favored defendant, and the public interest in "having the continued presence of a product already validated for use in biologic drug development and FDA submission is a significant countervailing factor weighing against the public interest inherent in protecting patent rights." An injunction would require pharmaceutical companies using the defendant's product to revalidate their processes if forced to switch to the plaintiff's product, causing delays in drug development and regulatory approvals.

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## No Good Cause Shown to Amend Answer

*Iceutica Pty Ltd v. Novitium Pharma, LLC*, Civil Action No. 18-599-CFC (D. Del. Sep. 23, 2019)

The district court denied defendant's motion to amend its answer to assert an indefiniteness defense, as defendant failed to satisfy the "good cause" requirement of Fed. R. Civ. P. Rule 16(b). More specifically, defendant did not demonstrate diligence in asserting its new defenses and counterclaims. Defendant was on notice of plaintiffs' claim construction argument prior to the claim construction hearing, and parties are obligated to prepare for the possibility that the court might adopt the other party's construction.

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## Court Seemingly Interprets Section 102(f) to Require Joint Invention

*Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, CV 2:17-7639 SJO (C.D. Cal. Sep. 27, 2019)

The district court denied defendant's motion for summary judgment that a certificate of correction was invalid because disputed issues of material fact existed regarding whether the error in the as-issued patent would have been clearly evident to one skilled in the art. The court granted defendant's motion for summary judgment of no infringement under the doctrine of equivalents. The court also granted plaintiff's motion for summary judgment as to a section 102(f) defense. While declining to hold the defendant estopped by citation of a publication during an IPR, the district court appeared to hold that evidence of collaboration and joint invention is required under section 102(f). There was no evidence of joint behavior and, therefore, defendant was "precluded from pursuing its 102(f) defense."

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