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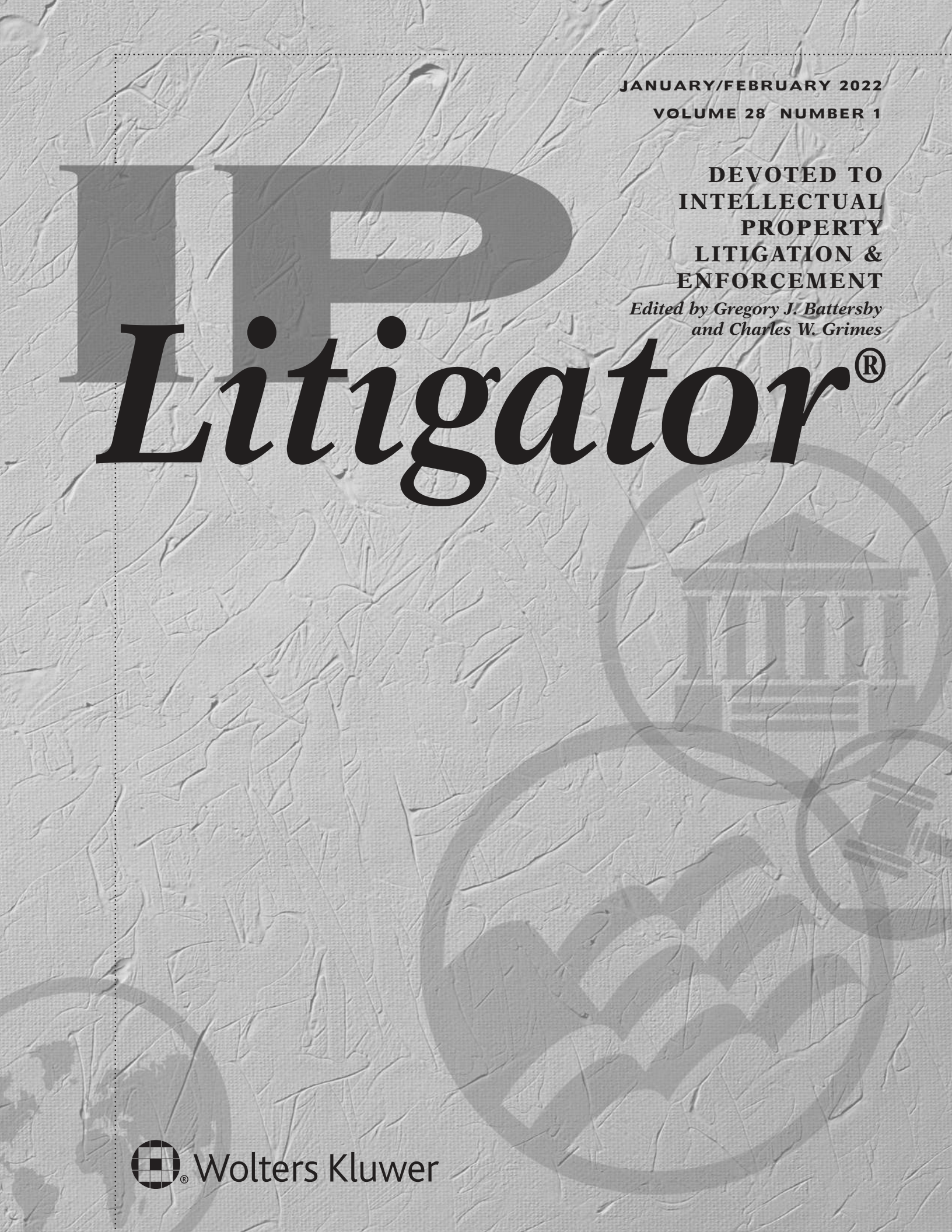

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2021 Year in Review: Noteworthy Precedent for Patent Litigators

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As the world marched forward in the face of the lingering coronavirus disease 2019 (COVID-19) global pandemic, the Supreme Court and Federal Circuit followed suit, issuing several noteworthy decisions of which patent litigators should be aware in 2022. Selected decisions are summarized below.

Supreme Court Declines Opportunity to Dismantle Patent Trial and Appeal Board: *U.S. v. Arthrex* (No. 19-1434)

In June 2021, the Justices issued a ruling on the highly anticipated challenge to the constitutionality of the U.S. Patent Trial and Appeal Board. Specifically, the Court addressed whether administrative patent judges are constitutionally appointed, evaluating whether the judges are "principal officers" that must be appointed by the President and confirmed by the Senate, or "inferior" officers who require supervision by a principal officer.

The decision, penned by Chief Justice Roberts, found that administrative patent judges "appear to be inferior officers," but held that the then-existing statutory regime permitting administrative patent judges to render a final decision on behalf of the United States without review by a principal officer was unconstitutional.

To remedy the constitutional violation, the Court partially invalidated Title 35 of the U.S. Code, Section 6(c), which provides that "[o]nly the Patent Trial and Appeal Board may grant rehearings," and severed it from the remainder of the statute. Absent that provision, the Court upheld the remainder of the statute and further instructed that "decisions by APJs must be subject to review by the Director." Accordingly, the Director may now review final PTAB decisions and, upon review, may issue decisions himself on behalf of the Board.

Thus, after *Arthrex*, the director of the U.S. Patent and Trademark Office now must have the opportunity to review *inter partes review* decisions before they become final. Despite that finding, the decision has had and will likely continue to have minimal practical effect. The opinion of the Court clarified that the Director "need not review every decision," but must "have the discretion to review decisions rendered by APJs." Because IPR decisions are appealable directly to the Federal Circuit, litigants have the option to bypass the new Director review process to expedite appellate review.

Doctrine of Assignor Estoppel Upheld at High Court: *Minerva Surgical Inc. v. Hologic Inc.*

Also in June, the Supreme Court upheld the validity of the doctrine of assignor estoppel. Assignor estoppel is a judicially created equitable remedy whereby an inventor is precluded from assigning her patent to another and later arguing that the patent is invalid during the course of litigation.

Justice Kagan, writing for the majority, affirmed that the doctrine of assignor estoppel applies when an "assignor's claim of invalidity contradicts explicit or

implicit representations the assignor made in assigning the patent." The Court rejected Minerva's challenge that the patent policy implications of "weed[ing] out bad patents" supported abrogation of the doctrine, and justified the "core of assignor estoppel" on traditional "fairness grounds," including a "demand for consistency in dealing with others." In so doing, the Court emphasized the importance of the assignee's justifiable reliance on the assignor's warranties, express or implied, that the patent at issue is valid.

Despite application of the doctrine by the Federal Circuit, the Supreme Court vacated the judgment of the Federal Circuit, which it characterized as "fail[ing] to recognize the doctrine's proper limits." Specifically, the Court remanded the case to the Federal Circuit for a determination whether the assignee had enlarged the patent claims after assignment such that the assignor did not warrant the new claims' validity.

Federal Circuit Imposes Limits on Antibody Patents: *Amgen Inc. v. Sanofi & Juno Therapeutics v. Kite Pharma*

The Federal Circuit issued multiple rulings in 2021 that impact the validity of patents relating to antibodies and antibody formulations.

In February, the Court issued the first of the two orders in the case of *Amgen Inc. v. Sanofi*, where the panel upheld the district court's invalidation of Amgen's antibody patents covering the cholesterol drug Repatha. Finding that the patents did not enable the full scope of the claims, the Court rejected Amgen and several major amici's plea to overrule the determination of the district court.

The Court held that a person of ordinary skill in the art would not be able to practice the full scope of the claimed invention without undue experimentation, rendering the claims non-enabled. Essential to the Court's finding was the broad scope of the claimed functional limitations and the unpredictability of the art. Because, as the panel ruled, the scope of the disclosed examples and guidance are too narrow to support the breadth of the claimed functional limitations, "[n]o reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments."

In June, the full Federal Circuit declined the opportunity to take the case up on rehearing and defended the enablement doctrine, stating that it was a part of the Court's jurisprudence "for good reason."

Not long after, the Federal Circuit issues another antibody decision in August 2021, reversing a district court's award of $1.1 billion to Juno Therapeutic against Kite Pharma for infringement of its cancer treatment drug, Yescarta. This time, the Court found that the patent's written description failed to demonstrate that the inventors possessed the full scope of the claimed invention.

The asserted patent claimed a nucleic acid polymer that encodes a chimeric T-cell receptor designed to program T cells to attack cancer cells in the body. One of the elements of the claimed receptor is a single-chain variable fragment (scFv), a protein that contains regions of antibodies for binding to target cells. When encoded by the polymer, the receptor is able to bind to its target and carry out the therapeutic function. The scFv was claimed according to this functional capability: "a binding element that specifically interacts with a selected target."

Kite argued that the claims describe "millions of billions" of scFvs, each of which "has a unique amino acid sequence that can dictate whether and how an antibody, and thus an scFv, binds to a target." The '190 patent, however, provided only two scFvs. The Court found persuasive Kite's arguments that only a fraction of the claimed scFv genus would function as claimed, and the patent-in-suit neither (i) disclosed a representative species, nor (ii) common structural features of the claimed scFv genus to identify which scFvs would function in accordance with the claim.

Both *Amgen* and *Juno* highlight the challenges patentees face defending broad functional claim limitations for antibody patents. A petition for rehearing is currently pending before the Federal Circuit in *Juno*.

GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.

In August 2021, a Federal Circuit panel issued the second of the two opinions concerning induced infringement as related to "skinny labels" authorized under 21 U.S.C. 355(j)(2)(A)(viii). The statute permits ANDA filers to "carve out" patented indications on the label of a proposed product (i.e., a "skinny label"), which the FDA will allow if the carved out indication "do[es] not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use." 21 C.F.R. § 314.127(a)(7).

After a jury returned a verdict for GSK, finding that, *inter alia*, Teva induced infringement of GSK's patent by marketing a generic version of GSK's Coreg® drug with a skinny label, the district judge granted Teva's JMOL motion on inducement. The Federal Circuit reversed in a first decision in October 2020, finding the jury's verdict was supported by the evidence of record.

Subsequently, the panel granted panel rehearing, where it reached the same conclusion: Teva induced infringement of the asserted patent. However, the Court corrected its October 2020 decision to eliminate the accusation that the prior decision "upset the careful balance struck with section viii carve-outs." Instead, the Court clarified that the decision was a "narrow, case-specific review of substantial evidence." The Court pointed to several key facts underlying the finding of induced infringement, such as (i) the alleged skinny label instructed doctors to perform patented methods, (ii) Teva's marketing materials could be viewed as promoting an infringing use, and (iii) Teva's press releases described the generic product as suitable for patented indications.

Federal Circuit Addresses the Pleading Standard for Patent Cases: *Bot M8 LLC v. Sony Corp.*

In July 2021, the Federal Circuit addressed the "stringency of pleading requirements" for patent cases. Plaintiff Bot M8 LLC had sued Defendant Sony Corp., asserting six patents that were directed to arcade and casino games as well as gaming machines. The district court had *sua sponte* directed Bot M8 to file an amended complaint specifying "every element of every claim that you say is infringed and/or explain why it can't be done"—an instruction challenged on appeal. The district court further instructed that if the product was available, the Plaintiff had to "buy [the product] on the market" and "reverse engineer" it. In response to the district court's order, Plaintiff Bot M8 filed a 223-page first-amended complaint, and Sony moved to dismiss.

In affirming the district court's dismissal of Bot M8's claims as to two patents-in-suit (the '540 and '990 patents) for failure to state a plausible claim of infringement, the Federal Circuit found relevant that the pleadings were "conclusory and at times contradictory." With respect to conclusory pleadings, the Court reiterated that "mere recitation of claim elements and corresponding conclusions, without supporting factual allegations, is insufficient to satisfy the *Iqbal/Twombly* standard." And with respect to contradictory pleadings, the Court emphasized that a plaintiff might "plead itself out of court" when the pleaded factual allegations are "actually inconsistent with and contradict infringement."

In spite of these findings, the Court noted that "a plaintiff's pleading obligations are not onerous." Accordingly, in reversing the district court's dismissal of Bot M8's claims as to two different patents-in-suit (the '988 and '670 patents), the Court found that the district court erred by instructing Bot M8 to "explain in [the] complaint every element of every claim that you say is infringed and/or explain why it can't be done." In so doing, the Federal Circuit reiterated that a plaintiff "need not prove its case at the pleading stage" and is "not required to plead infringement on an element-by-element basis." Rather, the level of detail required in each case depends on a multifactor analysis that accounts for, e.g., (i) the complexity of the technology, (ii) the materiality of any given element to practicing the asserted claim(s), and (iii) the nature of the allegedly infringing device. Applying this clarified standard, the Court found Bot M8's allegations regarding the '988 and '670 patents sufficient to survive a motion to dismiss.

Federal Circuit Affirms that Direct Evidence of Deceptive Intent Not Necessary to Prove Inequitable Conduct: *Belcher Pharmaceuticals LLC v. Hospira Inc.*

In September 2021, the Federal Circuit considered the heightened standard for proving inequitable conduct outlined in *Therasense, Inc. v. Becton, Dickinson & Co*. The Court concluded that Judge Stark, presiding in the District of Delaware, did not abuse his discretion in holding the patent-in-suit unenforceable for inequitable conduct. The panel reviewed the district court's factual findings regarding materiality and intent and concluded that the facts adequately supported the finding of inequitable conduct.

In a unanimous panel decision authored by Judge Reyna, the Federal Circuit affirmed the district court's finding that the Chief Scientific Officer of Belcher Pharmaceuticals engaged in inequitable conduct by withholding material prior art from the USPTO. To prevail on an inequitable-conduct defense, a defendant must establish (i) the materiality of the withheld reference and (ii) the applicant's intent to deceive the USPTO. With respect to materiality, the district court found the element satisfied because the claims had been invalidated as obvious in view of the withheld reference (an epinephrine product meeting the claimed pH range). The invalidity finding was not challenged on appeal. The Federal Circuit reiterated that invalidation of the patent in view of the withheld prior art renders the withheld prior art "necessarily material to patentability."

The panel also examined the district court's finding that the accused Chief Scientific Officer intended to deceive the USPTO by withholding material references. Despite no "direct evidence" of deceptive intent, the Court found

no error in the district court's determination that intent deceive was the "only reasonable inference" that could be drawn. Integral to the Court's reasoning was the CSO's conflicting actions before the FDA (where the objective was approval of Belcher's drug product) and the USPTO (where the objective was patent issuance). Specifically, the Court cited the CSO's assertion to the USPTO that the claimed pH range of the drug product was a "critical" innovation yielding "unexpected results," despite having knowledge that during development, Belcher had reverted to the claimed pH in its drug product based on the withheld prior art drug product to expedite FDA approval.

Given the strict standard set forth in *Therasense* for proving inequitable conduct, *Belcher* represents an increasingly rare affirmance of a finding of inequitable conduct, and provides guidance on the proofs necessary to support such a finding. Though direct evidence of deceptive intent is rare, *Belcher* reinforces that patent challengers may prove inequitable conduct when deceptive intent is the "only reasonable inference" that can be drawn from an applicant's conduct.

The Federal Circuit's Jurisdiction Over Interlocutory Orders: *Mondis Technology Ltd. v. LG Electronics Inc.*

Pursuant to 28 U.S.C. § 1292(c)(2), "[t]he United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction of an appeal from a judgment in a civil action for patent infringement which would otherwise be appealable to the United States Court of Appeals for the Federal Circuit and is *final except for an accounting*" (emphasis added). However, as recently highlighted by Judge O'Malley, "it is becoming increasingly unclear exactly when a decision becomes final except for an accounting such that the time to file a timely appeal begins."

In dissenting from the denial of rehearing en banc in *Mondis Technology Ltd. v. LG Electronics Inc.*, Judge O'Malley disagreed with the panel's finding that the Federal Circuit might have had jurisdiction to hear an interlocutory appeal when a trial on damages was still outstanding. Because "a trial on damages is not an 'accounting,'" Judge O'Malley explained that she would have reheard the case "to explain that [the Federal Circuit] do[es] not have jurisdiction to hear LG's appeal under § 1292(c)(2) until the damages trial is no longer outstanding … ."

Judge O'Malley also found that the *Mondis* panel compounded its error by misinterpreting Federal Rule of Appellate Procedure 4(a)(4)(A) (which suspends the time to appeal while several specifically enumerated motions are pending) to mean that the enumerated motions therein "can only toll the time to appeal if they relate to the interlocutory judgment such that the judgment is not final except for an accounting." In other words, a "judgment is final except for an accounting where a variety of motions remain to be decided, so long as an appellee can convince th[e C]ourt that those outstanding motions are not related to the interlocutory appeal." Judge O'Malley cautioned that the panel's interpretation is unsupported and will "require [the Court] to delve into the merits of an appeal to determine whether motions are related to the interlocutory appeal before determining jurisdiction, reversing the normal course of analysis."

To preserve the opportunity for an interlocutory appeal under § 1292(c)(2), parties should file a notice of appeal after the district court decides liability-related post-trial motions under FRAP 4(a)(4)(A), even if damage-related post-trial motions remain pending. Failure to do so could bar parties from pursuing an interlocutory appeal, thus preventing appellate review until all issues of damages are adjudicated.