No. 19-

IN THE

Supreme Court of the United States

BRIGHAM AND WOMEN'S HOSPITAL, INC.
AND INVESTORS BIO-TECH, L.P.,

Petitioners,

v.

PERRIGO COMPANY AND L. PERRIGO COMPANY,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Patent Act expressly provides for compensatory damages. 35 U.S.C. § 284. When the issues of patent infringement and compensatory damages are tried before a jury, judgment as a matter of law setting aside the jury's verdict is only appropriate if no reasonable jury could have come to the same verdict.

In addition to a jury's award of compensatory damages, the court post-judgment may award interest, costs, attorney fees, and enhanced damages (expressed as a multiplier of up to three times compensatory damages). The damage multiplier (i.e., enhancement) and the award of attorney fees for an "exceptional" case are both punitive in nature and determined in the district court's discretion in light of a litigant's misconduct. The questions presented by this petition for writ of certiorari are:

1. Whether the punitive enhancement under 35 U.S.C. § 284 is *collateral* to, and therefore not a *merits* ruling necessary for final judgment under this Court's reasoning in *Budinich v. Becton Dickinson & Co.*, 486 U.S. 196 (1988) (attorney fee award is "collateral").

2. Whether this Court should exercise its supervisory powers to stop the alarming trend of the Federal Circuit's setting aside patent infringement jury verdicts by not applying deferential appellate review that requires consideration of both sides' evidence, and precludes independent "weighing of the evidence" and making "[c]redibility determinations," contrary to *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000).

PARTIES TO THE PROCEEDING BELOW AND RULE 29.6 STATEMENT

The caption of the case contains the names of all the parties to the proceeding.

Petitioner Brigham and Women's Hospital, Inc. is wholly owned by Partners Healthcare System, Inc. Partners Healthcare System, Inc. has no parent corporations and no publicly held company owns 10 percent or more of its stock.

Petitioner Investors Bio-Tech, L.P. has no parent corporations and no publicly held company owns 10 percent or more of its stock.

RULE 14.1(b)(iii) STATEMENT

The proceedings in federal trial and appellate courts identified below are directly related to the above-captioned case in this Court.

Brigham and Women's Hospital, Inc. and Investors Bio-Tech, L.P. v. Perrigo Company and L. Perrigo Company, Case No. 1:13-cv-11640-RWZ (D. Mass). The United States District Court for the District of Massachusetts entered judgment regarding Petitioners' patent claims in this matter on December 19, 2016.

Brigham and Women's Hospital, Inc. and Investors Bio-Tech, L.P. v. Perrigo Company and L. Perrigo Company, Case Nos. 2017-1950, 2017-2021, 2017-2555, 2018-1243 (Fed. Cir.). The Federal Circuit entered judgment in this matter on February 28, 2019. The Federal Circuit denied Petitioners' combined petition for panel rehearing and rehearing en banc on May 2, 2019.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Brigham and Women's Hospital, Inc. and Investors Bio-Tech, L.P. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The merits opinion of the Federal Circuit is reported at 761 Fed. App'x 995 and reprinted at App. 1a-22a, *infra*. The order of the court of appeals denying rehearing is not reported and is reprinted at App. 83a-84a. Single judge and motions panel jurisdictional opinions of the Federal Circuit are unreported and are reprinted at App. 62a-66a, 51a-61a.

The Rule 50(b) opinion of the district court is reported at 280 F. Supp. 3d 192 and reprinted at App. 23a-50a. The district court's untimeliness opinion is reported at 251 F. Supp. 3d 285 and reprinted at App. 67a-81a. The final judgment is not reported and is reprinted at App. 82a.

JURISDICTION

The Federal Circuit issued its opinion on February 28, 2019. It denied rehearing and rehearing en banc on May 2, 2019. This Court has jurisdiction under 28 U.S.C. § 1254(1). This Court granted Petitioners' motion for an extension of time. *See* Order, Case No. 19A75 (July 19, 2019).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

U.S. Constitution, Amendment VII, provides:

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules of the common law.

35 U.S.C. § 284 provides:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.
>
> When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d).
>
> The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

35 U.S.C. § 285 provides:

> The court in exceptional cases may award reasonable attorney fees to the prevailing party.

28 U.S.C. § 1292(c)(2) provides:

> The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—(2) 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.

28 U.S.C. § 1295(a)(1) provides:

> The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—(1) of an appeal from a final decision of a district court of the United States, … in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents or plant variety protection.

INTRODUCTION

Notwithstanding a recent en banc effort, the Federal Circuit's struggle with final judgment has taken a new turn. By redefining compensatory damage "accounting" yet again, it preserved its jurisdiction in this case where none exists. The continued adherence to this approach interferes with a coherent final judgment process for the successful patentee – as evidenced in this case.

At trial, the jury rendered its verdict against Perrigo finding that it willfully infringed Brigham's U.S. Patent No. 5,229,137 ("Wolfe patent"), rejecting Perrigo's invalidity and laches defenses, and awarding $10.2 million in damages. After requesting entry of final judgment, Perrigo failed to file a notice of appeal or appeal-tolling motion within 30 days of final judgment and thus lost any right to appellate review. The Federal Circuit, however, rejected Brigham's motion to dismiss, and exercised jurisdiction over Perrigo's untimely appeal.

The Federal Circuit preserved Perrigo's appeal by classifying "enhancements" as a merits issue that tolled the final judgment under 28 U.S.C. § 1295. This required the Federal Circuit to disregard this Court's ruling in *Budinich v. Becton Dickinson & Co.*, 486 U.S. 196 (1988) and the long-standing treatment of post-judgment monetary awards as collateral to the merits. Post-judgment awards of attorney fees, costs, interests on the judgment and punitive enhancements of the judgment were collateral issues that did not "alter" or "moot" the judgment or toll the appeal process. *See generally* 7 Donald S. Chisum, Chisum on Patents § 20.03[4] (2019); *see also Budinich*, 486 U.S. at 199-200.

Instead of following *Budinich*, the Federal Circuit relied on the narrow jurisdictional exception provided by 28 U.S.C. § 1292(c)(2) ("§ 1292") authorizing appeals from judgments that are "final except for an accounting."

This reliance was misplaced for two reasons. First, the Federal Circuit mistakenly characterized a district court's post-judgment award of punitive enhancements as part of compensatory damage "accounting" under § 1292. This ruling cannot be reconciled with this Court's *Halo* decision that there is no compensatory role for enhancements and thus it cannot be considered damages for the infringement tort or part of an accounting. *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1932 (2016). It is, like an award of attorney fees, punitive – a penalty or fine collateral to the merits resolved post-verdict by the district court for egregious conduct. Thus, it is governed by this Court's *Budinich* decision.

Second, the expanded definition of "accounting" used to embrace post-judgment monetary awards such as "enhancements" does not (and cannot) act to convert that award from a collateral to a merits issue. This is true because the award does not "alter" or "moot" the merits judgment however it is labeled or classified. *See Ray Haluch Gravel Co. v. Cent. Pension Fund of Int'l Union of Operating Eng'rs & Participating Emp'rs*, 571 U.S. 177, 188 (2014) (rejecting how an issue is classified in "favor of an approach that looks solely to the character of the issue that remains open after the court has otherwise ruled on the merits of the case").

The improper exercise of jurisdiction here injects great uncertainty in the finality of patent judgments –

judgments that commonly involve some post-judgment monetary award such as enhancements or attorney fees. Final judgments for patentees will now be subject to confusing appellate deadlines governed by the changing views of what constitutes an "accounting" and which post-judgment monetary awards toll the appeal process.[1] *See generally Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305 (Fed. Cir. 2013) (en banc) (finding the issue of willful infringement is also within the § 1292 "accounting"). The divided *Bosch* court's open-ended view on what constituted a § 1292(c)(2) "accounting" provides future panels troubling little guidance and thereby risks further expansion of this narrow jurisdictional exception with wasteful piecemeal appeals.

The Court can bring both clarity and harmony back to final judgment rules. A punitive enhancement award, like an award of interest, costs and attorney fees, stands as a post-judgment monetary award that is collateral to the judgment. Because appeals of patent infringement cases are exclusive to the Federal Circuit, only this Court can rectify the chaos created by the decisions below.

After denying Brigham's motion to dismiss the appeal, the Federal Circuit disregarded the usual presumptions and evidentiary deference that normally flow from a jury verdict and reversed the infringement verdict. Contrary to this Court's long-standing mandate of restrictive evidentiary review, the Federal Circuit's credibility determinations and weighing of the evidence present

1. Expanding the definition of "accounting" acts to increase the number of immediately appealable interlocutory rulings – and promotes piecemeal appeals.

a serious erosion of Seventh Amendment right to trial by jury. It is part of a growing Federal Circuit trend of rejecting jury verdicts for patentees – a trend that diminishes the value of patents and motivates trial judges to take these cases away from jurors.

Both issues are ripe for review by this Court.

STATEMENT OF THE CASE

A. The Patented Technology

Nearly three decades ago, a gastroenterologist practicing internal medicine at the Brigham and Women's Hospital in Boston, Massachusetts performed a series of clinical studies to explore the interactions between two acid reducing medicines – fast-acting antacids and longer duration histamine antagonists. At the time, these two medicines were *separately dosed* for acid-related stomach disorders as it was believed that antacids taken together with the histamine antagonists would interfere and deactivate the histamine antagonists and reduce their therapeutic value. Dr. Wolfe, the Brigham Gastroenterologist, sought to investigate this interaction.

In the treatment of episodic heartburn, Brigham and Dr. Wolfe's clinicals demonstrated that there was no inhibition of histamine antagonist by the antacids – even when dosed simultaneously. In fact, the combined dosing resulted in an unexpectedly *prolonged* duration of relief – beyond what the histamine antagonist would provide when dosed by itself. The surprising result achieved by Dr. Wolfe's new combination therapy was patented and a licensed version of the medicine approved by the FDA for

over-the-counter sales. The "Pepcid Complete"-branded treatment was sold by a joint venture between Johnson & Johnson, Co. and Merck, Inc. starting two decades ago and continues today.

In 2008, Perrigo launched Famotidine Complete, a generic version with the same active ingredients in the same amounts as Pepcid Complete. It was approved by the FDA as "bioequivalent" to the branded Pepcid Complete through an Abbreviated New Drug Application under the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. Brigham sued Perrigo in 2013 for infringing the Wolfe patent.

B. The Jury Trial

At trial, Brigham relied on its test data submitted to the FDA in gaining market approval for Pepcid Complete. Because this FDA testing data was generated using the same active ingredients and amounts found in the Perrigo accused formulation, this test data was powerful – but circumstantial – evidence that Perrigo's accused formulation provided the same clinical response as Pepcid Complete in terms of patient relief from episodic heartburn.

The core infringement dispute centered on the patent claim term "immediate" relief from heartburn pain – defined by the court as requiring "onset of relief in about 5 to 10 minutes" from dosing. The jury heard evidence that the claimed "immediate relief" of the Wolfe patent was a clinical attribute of Perrigo's accused formulation, including FDA testing data on (1) esophageal pH v. time measurements and (2) pain relief studies with supporting

testimony by Dr. Wolfe – Brigham's infringement expert. Heartburn is caused by stomach acid reflux (observed by a drop in pH) irritating the esophagus and thereby triggering inflammation. The evidence at trial showed that the accused formulation caused a jump in esophageal pH (i.e., lower acidity) *within two minutes of dosing*, just as with antacid. FDA pain relief studies demonstrated "adequate relief" within 15 minutes of dosing. Taken together, this is compelling evidence of "immediate" onset of relief – evidence sufficient to support the jury verdict of infringement. Fed. Cir. J.A. 6978, 6980-6981, 6982-7008, 7018, 7042-7045, 7063, 7065-7070, 7075, 7720-7721, 7298, 7302, 7554, 7847-7848, 8353-8354; *see also* Corrected Br. for Plaintiffs-Cross-Appellants at 29-39, *Brigham and Women's Hospital, Inc. v. Perrigo Co.*, No. 2017-1950, ECF No. 69 (Fed. Cir. Apr. 19, 2018).

Perrigo never contended that its accused product did not provide "immediate" relief but challenged Brigham's evidence as circumstantial. Contending that Brigham was required to directly test Perrigo's product and not rely on its own FDA clinicals, Perrigo argued at trial that the evidence of "immediate" relief was insufficient.

Perrigo concurrently argued that the Wolfe patent was invalid contending that all antacids provide immediate relief. In support of its invalidity position, Perrigo's expert, Dr. Tornay, testified that "immediate" onset of relief by acid neutralization is *an inherent property* of antacids:

> Q. How do antacids work to treat heartburn?
>
> A: They work, as we've heard, by neutralizing the stomach acid. *That's an inherent quality*

> *or characteristic of antacids: they neutralize acid.*
>
> Q. And how does neutralization of acid treat the heartburn?
>
> A. It treats it by decreasing the amount of acid present and therefore decreases the stimulus to the discomfort.

Fed. Cir. J.A. 8194 (emphasis added).

Perrigo's expert confirmed before the jury that the antacids at issue provide the "immediate" relief:

> Q. And how long do the antacids normally work to treat heartburn.
>
> A. They work, *the onset is what we would call immediate.*

Fed. Cir. J.A. 8196 (emphasis added).

The jury concluded that Perrigo's Famotidine Complete willfully infringed.

C. Verdict and Post-Trial Proceedings

In December 2016, an eight-person jury returned a verdict for Brigham and final judgment against Perrigo was entered on December 19, 2016. As of January 18, 2017 (30 days after entry of judgment), neither party had filed a notice of appeal or an appeal-tolling motion. The merits dispute was thus over – and appeal foreclosed.

See Fed. R. App. P. 4(a)(1)(A); *Bowles v. Russell*, 551 U.S. 205, 207 (2007). Nevertheless, Perrigo filed post-trial motions under Rules 50 and 59 on January 24, 2017 per a schedule extension – an extension, however, precluded by the Federal Rules. Fed. R. Civ. P. 6(b)(2).

On February 17, 2017, Perrigo filed an *untimely* Notice of Appeal (App. No. 2017-1950) and moved the district court for an *ex post* extension of time. Perrigo also challenged the finality of the December 19, 2016 Final Judgment.

On April 24, 2017 the district court rejected Perrigo's motion for an extension of time and ruled that the December 19, 2016 Judgment was "final" under § 1292. *See* App. 69a-77a, 82a. The district court also denied Perrigo's post-trial motions under Rules 50 and 59 as untimely, and Brigham's motions against Perrigo for an "exceptional" case and "enhancements." *See* App. 77a-81a. On May 11, 2017, Perrigo filed a second Notice of Appeal (App. No. 2017-2021). Shortly thereafter on May 19, 2017, Perrigo filed a second round of post-trial motions—motions essentially identical to its previous untimely motions denied by the district court.

Brigham's motions to dismiss Appeal No. 2017-1950 and to limit the issues in Appeal No. 2017-2021 were denied on June 21, 2017. The Federal Circuit motions panel denied Brigham's motion for reconsideration, reversed the district court's April Order, and ruled that the December 19, 2016 Judgment was not "final" under § 1295 because enhancements was a merits issue that had not been resolved by the district court. App. 51a-61. The Federal Circuit deactivated the appeals pending the

district court's resolution of Perrigo's second round of post-trial motions. App.62a-66a.

On November 17, 2017, the district court granted judgment as a matter of law ("JMOL") against Brigham on its infringement claim; rejecting Brigham's evidence demonstrating that Perrigo's product provided "immediate" relief as insufficient to support the jury verdict. App. 23a-50a. The Federal Circuit affirmed and denied Brigham's request for panel and/or en banc rehearing. App. 83a-84a.

In finding that Brigham's evidence on "immediate" relief was insufficient as a matter of law, the Federal Circuit independently weighed the FDA test data, declined to consider the admissions of Perrigo's expert and challenged the credibility of Dr. Wolfe's testimony, stating it was "uncorroborated, conclusory and interested." App. 21a.

REASONS FOR GRANTING THE PETITION

FOR PURPOSES OF FINAL JUDGMENT, PUNITIVE ENHANCEMENTS SHOULD REMAIN WITH ALL OTHER POST-JUDGMENT MONETARY AWARDS – AS *COLLATERAL* RULINGS BY THE COURT

A. Exceptional Case and Damage Multiplier for Enhancements are Collateral Issues that Cannot "Alter" or "Moot" Final Judgment on the Merits

This Court's rulings in *Budinich*, *Halo*, and *Octane Fitness* mandate a dismissal of Perrigo's notice of

appeal filed more than 30 days after final judgment. The Federal Circuit ruling indefinitely tolling Perrigo's appeal deadline was improper and creates an unsettling and chaotic process for triggering appellate review in a patent dispute.

Perrigo's time to appeal was not tolled. After judgment, the court in an infringement suit may award collateral monetary awards in the form of interest and costs, increased damages (i.e., enhancements), and/or attorney fees. *See* 7 Chisum on Patents § 20.03[4]; *see also* Donald S. Chisum, *Remedies for Patent Infringement*, 13 AIPLA Q.J. 380 (1985). The grant of a post-judgment monetary award is recognized as a collateral ruling to the merits judgment. *See Budinich*, 486 U.S. at 200-01. Enhanced damages under 35 U.S.C. § 284 and attorney fees under 35 U.S.C. § 285 are both issues that are collateral to the merits in a patent dispute. Pending collateral issues do not toll the deadline for an appeal. *See id.* at 202-03.

In *Budinich*, the district court issued an order awarding attorney fees authorized by statute, after a merits ruling resolving the dispute. Within 30 days of the fees award, but long after the merits ruling, plaintiff appealed all issues. This Court ruled that there was no appellate jurisdiction on the merits because the fees award was "collateral" to the merits and more than 30 days had passed since the final judgment on the merits.

A collateral court ruling is one that cannot "alter the [merits] order or moot or revise decisions embodied in the [merits] order." *Id.* at 199. An award of attorney fees to the prevailing party in litigation, while monetary,

is collateral to the merits because it "does not ***remedy the injury*** giving rise to the action, and indeed is often available to the party defending against the action." *Id.* at 200 (emphasis added).

As noted in *Halo*, enhancements similarly does not provide a ***remedy for the injury*** of infringement – it has no compensatory objectives, but is instead punitive, corresponding to an award of attorney fees. *See Halo,* 136 S. Ct. at 1929, 1932. Enhancements, like a fees award, is a punitive collateral court ruling that is not a true "damage" to the infringement tort and will not toll the time for filing a Notice of Appeal. *See Budinich*, 486 U.S. at 202-03.

The award of attorney fees in a patent dispute is authorized by 35 U.S.C. § 285 premised on a district court finding that a case is "exceptional." *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 545, 548-49 (2014). Following *Budinich*, the Federal Circuit has correctly recognized that an attorney fees award based on an exceptional case determination is "collateral" to the merits, because it cannot "alter the [merits] order or moot or revise decisions embodied in the [merits] order." *Raniere v. Microsoft Corp.*, 887 F.3d 1298, 1308 (Fed. Cir. 2018) (citing *Budinich*, 486 U.S. at 199).

Three features of exceptional case jurisprudence link it to the enhancement multiplier of 35 U.S.C. § 285. First, an exceptional case with an award of attorney fees is also purposely punitive in nature. *See Octane Fitness*, 572 U.S. at 554 n.6.

Second, exceptional case and enhancement awards involve common foundations in evidence and are often

considered and granted together to the patentee where willful infringement is found – the mandated predicate to an enhancement. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 858-59 (Fed. Cir. 2010), *aff'd*, 131 S. Ct. 2238 (2011). District courts determine whether a case is "exceptional" by considering the "frivolousness, motivation, objective unreasonableness" of the losing party's position. *Octane Fitness*, 572 U.S. at 554 n.6 (quoting *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 534 (1994)). Or, more generally, the weakness of its litigation position. For enhancements, the district court considers, *inter alia,* the infringer's behavior as a party to the litigation, the closeness of the case and the infringer's motivation for harm. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 827-28 (Fed. Cir. 1992).

Third, both exceptional case and enhancement awards are solely the province of the district court post-verdict. In fact, much of the evidence for both issues is excluded from the jury during trial (e.g., litigation misconduct) and the district court makes its supplemental monetary award decisions post-trial. A finding of willful infringement not only allows for the court's consideration of enhancements, in many instances it becomes the foundation for both enhancements and an exceptional case ruling with an award of attorney fees. A case involving a willfully copied invention is often "weak" and "stands out" – and thus "exceptional." *Spindelfabrik Suessen-Schurr Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik AG*, 829 F.2d 1075, 1085 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1063 (1988) ("Where a finding of willful and deliberate infringement and a collateral finding of exceptional circumstances are premised on the same basis, this court has found no abuse of discretion in awarding both increased damages and attorney fees.")

The district court grant of enhanced damages is not a true *damage* but a penalty or fine for a litigant's misconduct and designed to deter that misconduct in the future. *Halo*, 136 S. Ct. at 1932 ("Awards of enhanced damages under the Patent Act over the past 180 years establish that they are not to be meted out in a typical infringement case, but are instead designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior."); *see Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 506-07 (1964); *see also* 7 Chisum on Patents § 20.03[4][b][iii]. In practice, the post-judgment-award of enhancements is not even considered absent a merits finding of willful infringement and cannot be considered until compensatory damages is determined. *Pyle Nat. Co. v. Lewin*, 92 F.2d 628, 631-32 (7th Cir. 1937).

1. The Federal Circuit Determination That *Enhancements is Accounting* Was Flawed

In this case, the Federal Circuit recognized the conflict its ruling creates with *Budinich* and attempted to distinguish it by noting that compensatory "damages" and "enhancements" are both found in 35 U.S.C. § 284, while exceptional case with attorney fees (governed by *Budinich*) is found in 35 U.S.C. § 285. App. 56a. This logic fails as "interest and costs" are also within § 284 yet both interest and costs are recognized as separate from the accounting and collateral to the merits. Moreover, under the Patent Act, both attorney fees and enhancements fall generally within "Chapter 29-Remedies" along with compensatory damages and injunctive relief.

The Federal Circuit further ruled that judgment on compensatory damages would be "alter[ed] or amend[ed]"

by a later ruling on enhancements. App. 56a. This is incorrect. While the total monetary award ultimately due to the patentee will increase, exactly *as if an attorney fee award had been granted*, the *compensatory* damages for the infringement injury on the merits in the judgment is unchanged. *Halo*, 136 S. Ct. at 1932 (enhancement is "designed as a 'punitive' or 'vindictive' sanction"). Collateral post-judgment monetary awards—costs, interests, attorney fees and enhancements—do not alter the merit rulings that form the final judgment.

Compensatory damages and enhancements in patent law are not inextricably intertwined. Each addresses a very distinct statutory objective and is proven with very different evidence. Compensatory patent infringement damage – such as a reasonable royalty – is a jury issue that involves a classic accounting analysis to compensate for the injury resulting from the infringement tort. It is fundamentally different from the evidence of willful, egregious misconduct required to support an enhancements award by the judge. *Compare Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1239 n.3 (Fed. Cir. 2011) (citing *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970)) *with Read Corp.*, 970 F.2d at 827-28.

The more critical comparison is between *enhancements and attorney fees.* These issues often involve the *same evidence and analysis* and as such are often inextricably intertwined – with both resolved by the district court at the same time. Indeed, the *PODS* case on enhancements relied on by the Federal Circuit (App. 56a) – *itself* relies on, two "attorney fee" cases for authority: *Majorette Toys* and

Budinich[2]. *Budinich*'s clear determination that attorney fees are collateral to the merits would logically govern enhancements because of these overlapping assessments.

2. The Federal Circuit's 2013 *Bosch* en banc decision and its underlying analysis cannot support a claim that enhancement is part of "accounting" under § 1292(c)(2)

The error that plagues the decision below stems from the Federal Circuit's 2013 en banc decision in *Bosch*. It is time for this Court to correct the Federal Circuit's decision in *Bosch*.

The en banc *Bosch* majority construed "accounting" to embrace not only patent compensatory damages, but also the determination of whether defendant's infringement was willful. The en banc decision in *Bosch* – in which the Federal Circuit was split 7 to 5 – fails to recognize that exceptions to the final judgment rule should be narrowly construed. The *Bosch* Court's expansion of "accounting" in § 1292 beyond compensatory damages greatly increases the risk of piecemeal appeals, undermines judicial efficiency and compounds the delay in our courts. Moreover, Congress never intended that an "accounting" would or could include a district court's post-judgment determination of enhancements. S. Rep. No. 69-1319, at 1 (1927). This Court should set aside both *Bosch* and the erroneous decision below.

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2. *Majorette Toys (U.S.) Inc. v. Darda, Inc. U.S.A.*, 798 F.2d 1390, 1392 (Fed. Cir. 1986); *see also PODS, Inc. v. Porta Stor*, 484 F.3d 1359, 1365 n.4 (Fed. Cir. 2007). *PODS* is the sole cited Federal Circuit authority that discusses enhancements in the context of "accounting" viz. § 1292.

3. The Federal Circuit Treatment of "Accounting" Under § 1292(c)(2) Is Ripe for Clarification by this Court

This case provides the ideal vehicle to bring clarity to an important jurisdictional issue that has been clouded by several Federal Circuit decisions including *Bosch*. For example, in *Majorette Toys*, the panel found attorney fees "part of the accounting" in § 1292. *Majorette Toys*, 798 F.2d at 1392. Later, the Federal Circuit ruled that the resolution of attorney fees was not part of § 1292 accounting. *Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1343 n.2 (Fed. Cir. 2001).

The need for intervention by this Court is particularly acute given that § 1292 is specific to patent infringement and therefore does not arise in other circuit courts. The Federal Circuit's en banc decision in *Bosch* and its continued adherence to that decision demonstrate that the Federal Circuit's error will continue to be perpetuated until this Court addresses this important issue.

B. The Federal Circuit's Treatment of Post-Judgment Monetary Awards Has a Number of Problematic Policy Implications.

The Federal Circuit's current interpretation allows the mere possibility of an enhancement motion to disrupt the conclusion of patent disputes. There is no authority to support the mere possibility that a motion seeking an enhancement, following a full jury trial on liability and damages, automatically tolls the matter and indefinitely prevents a judgment from being final. Because there is no statutory framework or deadline for enhancement

motion practice under § 284, it should have no bearing on the appeal timing.

1. The Federal Circuit's Treatment of "Accounting" Under § 1292(c)(2) Risks Piecemeal Appeals of a Single Dispute

The Federal Circuit's interpretation of § 1292 accounting covers multiple discrete court determinations, including "damages," "profits," "willful infringement," and now "enhancements." Under the current framework, each unresolved accounting issue will permit interlocutory appeal of previously resolved non-accounting issues. For example, if patent liability is resolved for the patentee, the case can be appealed; if affirmed, a decision on damages (but not willful infringement) would trigger a second appeal; if affirmed, a third appeal would be allowed on the decision on willful infringement; if affirmed, a fourth appeal would follow on the issue of enhancement. And so on. This lack of certainty and finality was not the intent of Congress and cannot be justified in the face of longstanding policies against piecemeal appeals.

The far better rule is to limit accounting to damages – with enhancements, fees, costs, and interest all considered collateral and appealed together after any merits appeal.

2. The Current Treatment of the Enhancement Determination Undermines the District Court and Parties' Intention on "Finality" for Purposes of Appeal

The district court's and parties' intent as to the finality of a judgment is dispositive. *See Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1362-1363

(Fed. Cir. 2003). "The intention of the judge is crucial in determining finality." *Vaughn v. Mobil Oil Exploration & Producing Southeast, Inc.*, 891 F.2d 1195, 1197 (5th Cir. 1990); *see also Bankers Trust Co. v. Mallis*, 435 U.S. 381, 387-88 (1978) ("Here, the District Court clearly evidenced its intent that the opinion and order from which an appeal was taken would represent the final decision in the case."); *Honeywell Int'l , Inc. v. Hamilton Sundstrand Corp.,* 370 F.3d 1131, 1139 n.6 (Fed. Cir. 2004); *Pandrol*, 320 F.3d at 1362-63; *Alloyd Gen. Corp. v. Bldg. Leasing Corp.*, 361 F.2d 359, 362-63 (1st Cir. 1966).

Perrigo requested a final judgment and the district court's determination to mark this case as "closed" is a strong indication of its intent that the judgment is final, and the parties should treat the judgment as such. *Guggenheim Capital, LLC v. Birnbaum*, 722 F.3d 444, 449 (2d Cir. 2013) ("[A] decision is final when 'the court clearly intends to close the case...'") (quoting *Ellender v. Schweiker*, 781 F.2d 314, 318 (2d Cir. 1986)); *Vona v. Cty. of Niagara*, 119 F.3d 201, 205-06 (2d Cir. 1997).

The Federal Circuit's current treatment of "accounting" and enhancement, however, opens the door for precisely the mischief that has occurred here. It enabled Perrigo's belated objections to finality as a "sword to reopen a case" that all parties agreed was subject to a "final, separate judgment." *Casey v. Albertson's Inc.*, 362 F.3d 1254, 1259 (9th Cir. 2004) (citing the filing of a Rule 60 post-trial motion as an indication of party's belief that a final judgment was entered).

The law should not permit the option of reopening a final judgment when it suits a parties' subsequent needs – as currently allowed under the decision below.

THIS COURT SHOULD EXERCISE ITS SUPERVISORY POWERS TO STOP THE ALARMING TREND IN THE FEDERAL CIRCUIT OF SETTING ASIDE JURY VERDICTS BASED ON THAT CIRCUIT'S VIEW OF HOW THE JURY SHOULD WEIGH CONFLICTING EVIDENCE

A circuit court's erroneous application of the standard for a renewed motion for judgment as a matter of law under Fed. R. Civ. P. 50(b) would not typically merit review by this Court. Here, however, the Federal Circuit's error is egregious and reflects an alarming trend of judges within the Federal Circuit setting aside jury verdicts based on credibility determinations and the weighing of evidence. This Court should exercise its supervisory power over the Federal Circuit to bring this practice into check. S. Ct. R. 10(a).

Ample evidence supported the jury verdict in this case. In this patent infringement action, the issue for the jury was whether Perrigo's drug produced immediate and sustained relief from episodic heartburn (which Brigham's patent defines as "start[ing] within about 5-10 minutes following ingestion"). App. 5a (emphasis added). Because Perrigo was seeking FDA approval of a generic drug, Perrigo's FDA approval of its drug (marketed as Famotidine Complete) was based on the clinical data in support of Brigham's FDA New Drug Application for Pepcid Complete. One study supporting that application showed a rapid rise in pH levels (i.e., decrease in acidity) in patients within two minutes of taking the combination of famotidine and antacid. App. 6a (citing Fed. Cir. J.A. 7044). The average pH level increased by a value of 1.5 during the first two minutes – making the gastric fluids in the patients' esophagus 32 times less acidic within

120 seconds.[3] Another study supporting the New Drug Application showed that 33.7% of patients in the study received adequate relief within 15 minutes. App. 8a (citing Fed. Cir. J.A. 6999). Faced with evidence that one-third of the patients found their pain to be adequately addressed within 15 minutes, the jury could reasonably draw an inference that the onset of immediate relief (i.e., a noticeable decrease in pain) was experienced by patients within about 10 minutes. *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of the word 'about,' avoids a strict numerical boundary to the specified parameter.").

To confirm his trial opinions, Brigham's expert (the patent inventor) personally tested Perrigo's product and experienced relief from heartburn within 10 minutes. Fed. Cir. J.A. 7760. Most importantly, Perrigo's own expert confirmed the immediate onset of relief provided by antacids. Fed. J.A. 8194, 8196. This is the precise combination of active ingredients in both Brigham's and Perrigo's products. At trial, Perrigo did not assert that its product fails to provide immediate relief.

This Court has reiterated that Rule 50(b) motions require a lower court to "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence."

3. Noting that the average of pH levels for the entire study group did not fall below the pH level that the study defined as "acid reflux," the Federal Circuit discounted this study and the expert testimony relating to this study. All of the study participants, however, had a protracted history of food induced heartburn and were fed hamburgers, french fries and milkshakes in order to induce heartburn prior to dosing. Fed. Cir. J.A. 7042.

Reeves v. Sanderson Plumbing Prods., 530 U.S. 133, 150 (2000). Here, the Federal Circuit blatantly made a credibility determination, concluding that the inventor's testimony was insufficient to sustain the jury's verdict, in part, because he was an "interested" party. App. 21a. Similarly, its characterization of the inventor's testimony as "uncorroborated" stands as weighing of the testimony. *Id.* As other circuits have expressly recognized, a single witness' testimony is sufficient to defeat a Rule 50(b) motion even if there is no corroboration. *See DePascale v. Sylvania Elec. Prods.*, 510 Fed. App'x 77, 80-81 (2d Cir. 2013); *Portis v. First Nat'l Bank*, 34 F.3d 325, 329 n.10 (5th Cir. 1994). Neither Rule 50(b) nor this Court's precedent impose a requirement that a witness's testimony must be corroborated. The Federal Circuit's very statement that the persuasive value of this testimony would have been enhanced by corroboration admits to a weighing of the evidence. App. 21a. Finally, the Federal Circuit's characterization of the inventor's testimony as "conclusory" is simply a façade to hide its weighing of his testimony. The inventor explained in detail the studies relied upon by both Brigham and Perrigo to obtain FDA approval and how those studies amply support his conclusions.

The Federal Circuit's willingness to wholly disregard the testimony of Perrigo's own expert that the two active ingredients in the products of Brigham and Perrigo (which are identical for both companies) provides "immediate and sustained relief" demonstrates that it was second-guessing the jury's weighing of the evidence. The admissions of Perrigo's experts – alone – are sufficient support for the verdict. *Reeves*, 530 U.S. at 150-151.

The recent cases in which the Federal Circuit has disregarded this Court's precedent and set aside valid jury verdicts are a disturbing development.[4] As one Federal

4. As a result, the Federal Circuit has been "criticized for weakening the jury function and causing dysfunction in the system in the process." Hon. Kathleen O'Malley, *Trial by Jury: Why It Works and Why It Matters*, 68 Am. U. L. Rev. 1095, 1106 (2019). Examples of the Federal Circuit using Rule 50 to weaken the historic role of juries as the finders of fact are abundant. *See, e.g., Devona v. Zeitels*, 766 F. App'x 946, 961 (Fed. Cir. 2019) (Clevenger, J., dissenting) (disagreeing with affirmance of JMOL in dispute involving ownership of invention between partners given that opposing testimony created classic "credibility contest" that must be resolved by the jury) (unpublished); *see generally Imperium IP Holdings (Cayman), Ltd. v. Samsung Elecs. Co.*, 757 Fed. App'x 974 (Fed. Cir. 2019) (reversing district court's denial of JMOL; district court concluded that patent should not be invalidated based on patent claims being anticipated by a prior published patent given conflicting testimony of experts as to applicability and adequacy of information in prior patent) (unpublished), *petition for cert. filed*, No. 19-101; *Wisconsin Alumni Research Found. v. Apple Inc.*, 905 F.3d 1341, 1345 (Fed. Cir. 2018), *petition for cert. filed*, No. 18-1508; *Trs. of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1362 (Fed. Cir. 2018) (in reversing district court's denial of JMOL, Federal Circuit concluded jury verdict was not supported by substantial evidence because circuit court believed contentions of plaintiff's expert were "difficult to credit"); *Smith v. Garlock Equip. Co.*, 658 Fed. App'x 1017, 1026 (Fed. Cir.2016) (reversing district court's denial of JMOL, Federal Circuit concluded that testimony of plaintiff's expert "was not credible") (unpublished); *see generally ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350 (Fed. Cir. 2015) (reversing district court's denial of JMOL despite trial court's conclusion that legally sufficient evidence supported jury's conclusion that specified process of cycling home air-conditioning units on and off while not heating or cooling in order to prevent air stagnation was not obvious based on prior art); *see generally ACCO Brands, Inc. v. ABA Locks Mfr. Co.*,

Circuit judge has observed, when appellate courts fail to give adequate deference to the jury's factual findings, the "effect is devastating" and incentivizes trial judges "to take questions *away* from juries whenever possible." Hon. Kathleen O'Malley, *Trial by Jury: Why It Works and Why It Matters*, 68 Am. U. L. Rev. 1095, 1105 (2019) (emphasis in original). The Federal Circuit should be brought back in line by this Court. The patent verdicts appealed to the Federal Circuit involve tens to hundreds of millions of dollars. When a valid jury verdict is struck down simply because a judge takes a different view of the weight to be given to competing evidence, the property rights and protections that Congress intended for patents to provide are diminished. The end result is that companies are less willing to invest in research, development and product innovation, and our economy suffers as a result.

The constitutional right to a "trial by jury in civil cases [stands as] an important bulwark against tyranny and corruption, a safeguard too precious to be left to the whim of the sovereign, or, it might be added, to that of the judiciary." *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 343 (1979) (Rehnquist, J., dissenting); *see Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 501 (1959) ("Maintenance of the jury as a fact-finding body is of such importance and occupies so firm a place in our history and jurisprudence

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501 F.3d 1307 (Fed. Cir. 2007) (reversing district court's denial of JMOL relating to computer key lock system that incorporated both infringing and non-infringing locking mechanism; jury weighed testimony of plaintiff's expert that the most natural and intuitive way to use the lock was through the infringing locking mechanism versus defendant's testimony that customers were instructed to use the non-infringing locking mechanism).

that any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care." (internal quotations, citation omitted)). Taking a case away from the jury based on how it has weighed circumstantial evidence circumvents the Seventh Amendment's right to trial by jury. U.S. Const. Amend. VII; *Tennant v. Peoria & Pekin Union Ry. Co.*, 321 U.S. 29, 35 (1944). As other circuits have recognized, the Seventh Amendment prohibits a re-examination of a jury's determination of the facts if there is substantial evidence to support the verdict. *Johansen v. Combustion Eng'g, Inc.*, 170 F.3d 1320, 1330 (11th Cir. 1999). This Court's review is warranted to protect the right to trial by jury and to send a clear message to the Federal Circuit that credibility determinations and the weighing of evidence have no role in the consideration of a motion for judgment as a matter of law.

CONCLUSION

For the reasons stated above, the Petition should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DECIDED FEBRUARY 28, 2019

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIGHAM AND WOMEN'S HOSPITAL, INC.,
INVESTORS BIO-TECH, L.P.,

Plaintiffs-Cross-Appellants

v.

PERRIGO COMPANY, L. PERRIGO COMPANY,

Defendants-Appellants

Decided: February 28, 2019

2017-1950, 2017-2021, 2017-2555, 2018-1243

Appeals from the United States District Court for the District of Massachusetts in No. 1:13-cv-11640-RWZ, Judge Rya W. Zobel.

Before LOURIE, O'MALLEY, and STOLL, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Appendix A

Perrigo Company and L. Perrigo Company (collectively, "Perrigo") appeal from the order of the U.S. District Court for the District of Massachusetts denying judgment of invalidity as a matter of law of U.S. Patent 5,229,137 (the "'137 patent") on the basis of anticipation and obviousness. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, 280 F. Supp. 3d 192, 205-06 (D. Mass. 2017) ("*Decision*"). Brigham and Women's Hospital, Inc. and Investors BioTech, L.P. (collectively, "Brigham") cross-appeal from the same order granting judgment of noninfringement as a matter of law. *Id.* at 205. Because the district court did not err in its judgment of noninfringement, we *affirm* and do not reach the remaining issues.

I. Background

Brigham's '137 patent is directed to a method for treating episodic heartburn by coadministering two known types of heartburn medications, H_2-receptor antagonists (known as H_2-blockers) and antacids. Antacids were known to provide fast but momentary relief from heartburn; in contrast, H_2-blockers were known to provide slower but longer-lasting relief. Critically, the method of treatment as claimed requires that coadministering an antacid and H_2-blocker achieves a certain clinical result: "*immediate and sustained relief* from pain, discomfort and/or symptoms associated with episodic heartburn." '137 patent col. 7 ll. 23-25 (emphasis added). The dispositive issue on appeal is whether Perrigo's product meets the "immediate and sustained relief" limitation.

Appendix A

A.

Claim 1 of the '137 patent is the sole independent claim asserted by Brigham and reads as follows:

> 1. A method of providing *immediate and sustained relief* from pain, discomfort and/or symptoms associated with episodic heartburn in a human, said method comprising:
>
> orally administering to a human together or substantially together an antacid in an amount effective to substantially neutralize gastric acid and a histamine H_2-receptor antagonist in an amount effective to substantially inhibit or block gastric acid secretion for providing the human with immediate and sustained relief from pain, discomfort and/or symptoms associated with episodic heartburn, the immediate and sustained relief provided lasting longer in duration than when the human is orally treated with only the antacid and the immediate and sustained relief provided being faster than and lasting at least about as long in duration as when the human is orally treated with only the histamine H_2-receptor antagonist.

Id. col. 7 ll. 23-42 (emphasis added). The specification defines "immediate and sustained relief," disclosing:

> It should therefore be appreciated that by the term "immediate and sustained relief,"

> *it means herein immediate, temporary and sustained relief which starts within about 5-10 minutes following ingestion of the active ingredients and continues and remains constant for at least about 4-6 hours after ingestion of the active ingredients*; the actual ingredients being an antacid and a histamine H_2-receptor antagonist.

Id. col. 3 ll. 22-29 (emphasis added).

B.

The '137 patent was filed on May 6, 1992, issued in 1993, and expired on May 6, 2012. Brigham exclusively licensed the patent in 1996 to Johnson & Johnson Merck Consumer Pharmaceuticals ("J&J"), also giving J&J the right to pursue any infringement claims. In December 2004, Perrigo sent Brigham a Paragraph IV notice letter informing Brigham that it had submitted an Abbreviated New Drug Application ("ANDA") to market a combination H_2-blocker/antacid tablet prior to the expiration of the '137 patent, and Brigham relayed this information to J&J soon thereafter. J&J declined to assert the '137 patent against Perrigo but did sue on a different patent. Perrigo prevailed and then launched its generic product in 2008. Several years later, in 2013, Brigham brought the present suit accusing Perrigo's generic product of infringing the '137 patent's independent claim 1 and dependent claims 4, 5, 6, 7, and 12. Perrigo counterclaimed, asserting that the '137 patent was invalid as anticipated and obvious.

Appendix A

At claim construction, the district court construed the term "immediate and sustained relief" to mean "relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 5-10 minutes following ingestion of the active ingredients and continues for at least about 4-6 hours." J.A. 1380-82; *Decision*, 280 F. Supp. 3d at 200.

The parties proceeded to trial. A key dispute was whether Perrigo's generic product provided immediate relief as defined by the '137 patent. The main evidence regarding this limitation came from clinical data underpinning J&J's branded H_2-blocker/antacid product, Pepcid Complete®. Brigham argued that the clinical data demonstrated that Pepcid Complete® provides immediate relief, and since Perrigo's generic product has the same active ingredients and dosages as Pepcid Complete®, Perrigo's generic product must also provide immediate relief.

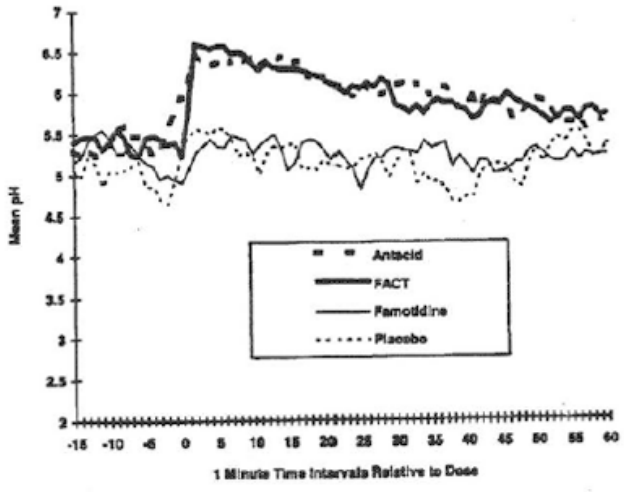
The clinical data came from three studies presented in the New Drug Application ("NDA") for Pepcid Complete®. The first, Study 98, measured 23 qualifying patients' esophageal and stomach pH levels after administering Pepcid Complete® and compared changes in these pH values to controls (an antacid or H_2-blocker alone, or a placebo). Undisputedly, lower (more acidic) esophageal pH may correspond to episodic heartburn, which results from reflux of stomach acid into the esophagus that can cause pain associated with episodic heartburn. In the study, "[a]n episode of acidic reflux was counted as a drop from pH 5 or more to 4 or below . . . ." J.A. 7044. The

study was designed to show that Pepcid Complete® would raise esophageal pH faster than an H_2-blocker alone and comparably fast to an antacid alone.

Although the NDA's description of Study 98 does not directly state whether Pepcid Complete® provided symptomatic relief from episodic heartburn starting within about 5-10 minutes, as required by claim 1, the NDA does include a figure of the patients' mean esophageal pH measured over one minute intervals before and after administration of an antacid, Pepcid Complete® ("FACT"), an H_2-blocker ("famotidine"), or a placebo. We reproduce this figure—Figure 7—below:

Figure 7

Esophageal pH Means at 1-Minute Time Intervals Relative to Dose: 0 to 60 Minutes Postdose (n=23) (Protocol 098)



J.A. 7044.

At trial, Brigham's fact and expert witness and the inventor of the '137 patent, Dr. M. Michael Wolfe, testified concerning Figure 7. He opined that "the antacid, whether it was in the combination or by itself, the pH rapidly rose in the esophagus, and it persisted." J.A. 7721. With respect to the claimed immediate relief from episodic heartburn, Dr. Wolfe further attested that "the increase in pH is what we're aiming for. It's mopping up of the acid that's present there. If you mop it up, it's going to relieve symptom; it's going to start to relieve symptoms fairly quickly." *Id.*

In addition to the data from Figure 7, Study 98 also reported the number and duration of esophageal reflux episodes that occurred in the hour after administration of the drugs. On average, patients experienced between 2 and 5 esophageal reflux episodes over the measurement period.

In addition to the pH study, the NDA included two symptom relief studies, Studies 110 and 127. Study 110 measured "adequate relief for *onset* of effect within 2 hours, and for *duration* of effect the number of episodes of heartburn adequately relieved for at least 7 hours." J.A. 7067. Adequate relief from heartburn, as determined by a patient's own assessment, was first measured fifteen minutes after administration of one of the drugs listed above. Results are shown in the table reproduced below:

Appendix A

NUMBER AND (CUMULATIVE %) EPISODES ADEQUATELY RELIEVED IN 1231 PARTICIPANTS TREATED

	FACT	FCT	antacid	Placebo
adequate relief	n = 305	n = 311	n = 308	n = 307
at (minutes)	*-1205 episodes*	*1229 episodes*	*1212 episodes*	*1217 episodes*
15	322 (27.0%)	249 (20.3%)	301 (25.1%)	191 (15.7%)
30	222 (45.3%)	215 (37.8%)	190 (40.9%)	210 (33.0%)
45	234 (64.6%)	257 (58.6%)	200 (57.4%)	203 (54.4%)
60	172 (78.8%)	190 (73.9%)	159 (70.5%)	203 (71.2%)
120	77 (85.3%)	94 (81.5%)	102 (78.8%)	(77 (77.5%)

J.A. 7068.

Study 127 was similar to Study 110. It also measured "adequate relief" beginning fifteen minutes after administration. Table 8, reproduced below, displays the results:

Table 8
Study MRL Protocol 127
Onset Data
NUMBER AND CUMULATIVE % EPISODES ADEQUATELY RELIEVED
ALL-PATIENTS TREATED APPROACH (N=1618)

Adequate Relief At:	FACT n=406 Tot Eps†=1585		FAMOTIDINE 10-mg FCT n=406 Tot Eps=1598		ANTACID 21 mEQ n=407 Tot Eps=1565		PLACEBO n=399 Tot Eps=1533	
	n	cum %†	n	cum %	n	cum %	n	cum %
15 mins	540	33.7	430	27.3	508	32.4	386	25.4
30 mins	291	52.4	304	46.6	259	48.8	265	42.7
45 mins	284	70.5	279	63.8	281	66.9	291	61.7
60 mins	188	82.2	170	74.3	188	78.7	187	73.7
120 mins	72	86.8	91	79.9	81	84.0	74	78.5
>120 mins	210	100.0	324	100.0	248	100.0	330	100.0

† Eps = episodes
‡ Cumulative percentages are "patient-based."
Based on sponsor's table 13

J.A. 6999.

At trial, Dr. Wolfe testified that the parameter measured in Studies 110 and 127—adequate relief at 15 minutes—would "correlate to immediate relief" within

5-10 minutes, but he admitted that the two parameters were different. J.A. 7847-48.

The jury returned a verdict finding that the asserted claims of the '137 patent were not invalid, that Perrigo's generic product infringed each asserted claim, and that Perrigo's infringement was willful. The jury awarded Brigham damages of about $10 million. The district court entered judgment consistent with the verdict on December 19, 2016, but without specifying damages or resolving Brigham's claim for enhanced damages. J.A. 8739.

C.

Several days after the judgment, on December 23, 2016, both parties jointly requested the district court to extend various deadlines for filing post-trial motions. The joint request suggested a deadline for Perrigo's motions for judgment as a matter of law ("JMOL") of January 24, 2017. The court granted the extensions in full.

Perrigo then moved for JMOL of noninfringement and invalidity on the date of the revised deadline. Brigham also then moved for enhanced damages. Additionally, in Brigham's opposition to Perrigo's JMOL motions, Brigham contended that Perrigo's motions were untimely under Rule 50(b). Soon afterwards, in February 2017, Perrigo noticed an appeal from the district court's December 19 judgment.

Several months later, the district court resolved the parties' pending motions. *Brigham & Women's Hosp., Inc.*

v. Perrigo Co., 251 F. Supp. 3d 285 (D. Mass. 2017) ("*April Decision*"). The court ruled that its December 19, 2016, judgment was final except for an accounting and therefore triggered the 28-day mandatory deadline set forth in Rule 50(b) for renewed motions for JMOL. *Id.* at 289-90. The 28-day deadline fell on January 17, 2017, a week earlier than the agreed-upon day on which Perrigo renewed its JMOL motions. While the court recognized that it had blessed the January 24 deadline, the court concluded that it had lacked authority under the Federal Rules to do so. *Id.* at 290-91 (citing Fed. R. Civ. P. 6(b)(2)). The court thus denied Perrigo's motions for JMOL and its notice of appeal as untimely. *Id.* at 292. Finally, the district court denied Brigham's motion for enhanced damages because it found that Perrigo's conduct was not egregious. *Id.* at 293-94.

Perrigo again moved for JMOL and noticed a second appeal on May 19 and May 11, 2017, respectively, this time from the district court's April decision. Brigham then moved to dismiss for lack of jurisdiction, arguing that Perrigo failed to timely file its JMOL motions and notice of appeal. In a single-judge order, we denied the motion. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, No. 2017-1950, -2021, slip op. at 4 (Fed. Cir. June 21, 2017), ECF No. 33 ("*Jurisdiction Decision I*"). We concluded that the district court's December 19 judgment was not final because it did not resolve Brigham's claim for enhanced damages. *Id.* at 3. Although we observed that Perrigo could have appealed from the December 19 judgment under 28 U.S.C. § 1292(c), we held that Perrigo was not obliged to do so because such an appeal from a non-final judgment "is permissive, not mandatory." *Id.* (quoting

DNIC Brokerage Co. v. Morrison & Dempsey Comm'cns Inc., No. 90-1389, 1991 U.S. App. LEXIS 33748, 1991 WL 335745, at *1 (Fed. Cir. Apr. 25, 1991)). We held that "[w]hat matters is that [Perrigo] filed a timely appeal once all the issues were resolved by the April 24, 2017 decision." *Id.* We thus consolidated both of Perrigo's appeals and deactivated them pending the district court's consideration of certain unresolved motions. *Id.* at 4.

Brigham moved for panel reconsideration. A three-judge panel reaffirmed our original decision. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, No. 2017-1950, -2021, slip op. at 8-9 (Fed. Cir. Aug. 2, 2017), ECF No. 38 ("*Jurisdiction Decision II*").

D.

The district court then considered the pending motions and granted JMOL of noninfringement because it concluded that Brigham failed to present sufficient evidence of direct infringement. *Decision*, 280 F. Supp. 3d at 199. Specifically, the court determined that the clinical evidence did not demonstrate that Pepcid Complete® provided immediate relief from episodic heartburn. *Id.* at 202.

The district court first assessed Study 98 and Dr. Wolfe's related testimony concerning Figure 7, including his contention that Figure 7 showed immediate relief through its rapid rise in esophageal pH after administering Pepcid Complete®. However, the court observed that Study 98 defined an episode of acid reflux

as requiring esophageal pH to go to 4 or below, but the average pH values in Figure 7 never did so. *Id.* at 202. And, as the study did not otherwise purport to correlate pH recordings to heartburn severity or other symptoms, the court concluded that Figure 7 did not prove that patients in the study were provided with immediate relief. *Id.*

The district court next considered the symptom relief studies. Because these studies indisputably measured a parameter different from the claimed immediate relief—"adequate relief" at 15 minutes, not the start of relief within 5-10 minutes—the court determined that the symptom relief studies also did not support the infringement verdict. *Id.*

Given Brigham's proffered evidence of infringement, the district court concluded that "no reasonable jury could have found direct infringement and Perrigo is entitled to judgment as a matter of law" of noninfringement with respect to claim 1. *Id.* It similarly followed that Brigham could not prove direct infringement of the dependent claims. *Id.* Consequently, the court vacated the jury's award of damages. *Id.* at 205. The court denied Perrigo's motions for JMOL of invalidity. *Id.* at 204-05.

Perrigo appealed from the district court's denial of JMOL of invalidity and its denial of Perrigo's evidentiary motion. Brigham cross-appealed from the court's grant of JMOL of noninfringement, its denial of enhanced damages, attorney fees, and pre-judgment interest, and its conclusion with respect to a disputed invention date.

Appendix A

II. Discussion

A. Jurisdiction

Notwithstanding that this court has twice decided that we have jurisdiction over Perrigo's appeal, Brigham maintains that "[t]here is a serious question regarding this Court's jurisdiction to hear Perrigo's appeal." Cross-Appellant Br. 1-2. Brigham points to no error, however, in our decision, and simply requests that we "assure [ourselves] that [we have] jurisdiction to hear the appeals as presented." *Id.* at 2. Presumably, Brigham refers to the timeliness issue. But our prior decisions are law of the case, and we do not disturb them.

Under the law of the case doctrine, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816, 108 S. Ct. 2166, 100 L. Ed. 2d 811 (1988) (quoting *Arizona v. California*, 460 U.S. 605, 618, 103 S. Ct. 1382, 75 L. Ed. 2d 318 (1983)). The underlying principle of the doctrine is self-consistency. *See* Charles Alan Wright et al., 18B Federal Practice & Procedure Jurisdiction § 4478 (2d ed. 2002). "Without something like it, an adverse judicial decision would become little more than an invitation to take a mulligan, encouraging lawyers and litigants alike to believe that if at first you don't succeed, just try again." *Entek GRB, LLC v. Stull Ranches, LLC*, 840 F.3d 1239, 1240 (10th Cir. 2016) (Gorsuch, J.). As the doctrine is directed at the integrity of the judicial process, we may address the law of the case

sua sponte. *See United States v. Wallace*, 573 F.3d 82, 90 n.6 (1st Cir. 2009).

In two decisions, the latter by a three-judge panel, we decided that Perrigo's appeal in this case was timely but deactivated it to allow the district court to resolve Perrigo's pending JMOL motions. *Jurisdiction Decision I*, slip op. at 3; *Jurisdiction Decision II*, slip op. at 8-9. In accordance with those decisions, the district court resolved those motions, resulting in the judgment now before us. Brigham now invites us to disregard the law of the case and our prior decisions, without articulating any reasons why we should do so.

We decline. We depart from the law of the case only in "extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice.'" *Christianson*, 486 U.S. at 817 (quoting *Arizona*, 460 U.S. at 618 n.8). No such circumstances are evident here. The prior panel concluded that the district court's December 19 judgment was not a final judgment because it did not resolve the issue of enhanced damages, and that Perrigo's appeal from that judgment was therefore interlocutory. *Jurisdiction Decision II*, slip op. at 4-5. While an aggrieved party may appeal under 28 U.S.C. § 1292(c)(2) from a district court's judgment that does not fully resolve damages, *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1309 (Fed. Cir. 2013) (en banc), the panel held that an appeal from such a judgment was permissive, not mandatory. *Jurisdiction Decision II*, slip op. at 8 (citing *DNIC*, 1991 U.S. App. LEXIS 33748, 1991 WL 335745, at *1); *see Jurisdiction Decision I*, slip op. at

3. In *DNIC*, we encountered a situation similar to the one here—an untimely appeal from a judgment not specifying damages, but a timely appeal from a later judgment that did specify damages. 1991 U.S. App. LEXIS 33748, 1991 WL 335745, at *1. There, we permitted the appeal as to issues from both the earlier and later judgments. 1991 U.S. App. LEXIS 33748, [WL] at *2. We see no clear error or manifest injustice in the prior panel's consistent holding here.

As Brigham has alleged no extraordinary circumstances warranting departure from the law of the case, we conclude that we have jurisdiction over these appeals under 28 U.S.C. § 1295(a)(1). We therefore proceed to the merits. We decide only the question regarding infringement.[1]

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1. Under *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 113 S. Ct. 1967, 124 L. Ed. 2d 1 (1993), a judgment of noninfringement does not moot a counterclaim of invalidity. However, "we retain the discretion to limit the grounds upon which appeals are decided." *Meds. Co. v. Mylan, Inc.*, 853 F.3d 1296, 1302 n.1 (Fed. Cir. 2017) (affirming judgment of noninfringement and not reaching issues of validity). Given the facts here, we decline to reach the issues of validity. Perrigo agrees that affirming noninfringement would make it unnecessary to review the patent's validity. Reply Br. 3. And while we recognize the "strong public interest" in resolving questions of patent validity, *Cardinal Chem.*, 508 U.S. at 100, that interest here is minimal because the '137 patent has expired and cannot be asserted against others, there are no pending suits involving the patent, and there are no related patents in examination at the U.S. Patent and Trademark Office.

B. Infringement

We review the district court's grant of JMOL of noninfringement under First Circuit law. "In assessing the sufficiency of the evidence, we consider whether, viewing the evidence in the light most favorable to the verdict, a rational jury could find in favor of the party who prevailed." *Soto-Lebron v. Fed. Express Corp.*, 538 F.3d 45, 56 (1st Cir. 2008). JMOL is warranted when the prevailing party's case contained no legally sufficient evidentiary basis for a reasonable jury to find for that party. *Id.*; Fed. R. Civ. P. 50(a)(1). We review the court's grant of JMOL *de novo. Soto-Lebron*, 538 F.3d at 56.

At trial, Brigham alleged only literal infringement. Literal infringement is a question of fact and requires every limitation in the claim to be found in the accused product. *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1339, 1341 (Fed. Cir. 2016). "If even one limitation is missing or not met as claimed, there is no literal infringement." *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). The patentee has the burden of proving literal infringement by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998).

Brigham argues that the district court erred in overturning the jury verdict and granting JMOL of noninfringement. According to Brigham, the court misinterpreted Figure 7 and improperly dismissed the other studies. Based on the totality of the evidence presented, Brigham asserts that a reasonable jury could have found infringement.

Perrigo responds that the district court properly granted JMOL of noninfringement because none of the evidence presented to the jury demonstrated immediate and sustained relief as claimed in the '137 patent.

We agree with Perrigo that the district court's JMOL of noninfringement was proper. The parties' dispute centers on whether the evidence at trial was sufficient to show that Pepcid Complete®, and by implication Perrigo's generic product, provides "immediate . . . relief from pain, discomfort and/or symptoms associated with episodic heartburn." '137 patent col. 7 ll. 23-25. The district court's construction of this term is undisputed: immediate relief means "relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 5-10 minutes following ingestion of the active ingredients." J.A. 1380-82; *Decision*, 280 F. Supp. 3d at 200. As we discuss, Brigham's evidence was insufficient to show immediate relief as claimed, and no reasonable jury could have found otherwise.

Brigham's infringement case relied primarily on the clinical studies 98, 110, and 127 reported in the NDA for Pepcid Complete®. Like the district court, we begin with Figure 7 of Study 98, reproduced earlier. Figure 7 depicts mean esophageal pH before and after Pepcid Complete® or a control drug is administered to a set of patients. The sole heartburn symptom related to esophageal pH measured in the study was acidic reflux, and "[a]n episode of acidic reflux was counted as a drop from pH 5 or more to 4 or below." J.A. 7044. None of the curves at any point in Figure 7 depict a mean pH below 4. Nor does the study disclose individual esophageal pH data.

Because Study 98 defined an episode of acidic reflux as requiring a drop in pH to below 4, but the pH curves in Figure 7 never drop below 4, the district court concluded that Figure 7 could not prove that the patients in Study 98 taking Pepcid Complete® were provided with immediate relief from episodic heartburn within 5-10 minutes. *Decision*, 280 F. Supp. 3d at 202. We agree. While Figure 7 does show a rapid rise in esophageal pH after administering Pepcid Complete®, that rise is untethered to any symptomatic relief. It cannot support the jury verdict that Pepcid Complete® provides immediate relief from episodic heartburn within 5-10 minutes. At most, the study suggests that Pepcid Complete® *might* provide immediate and sustained relief; such speculative data, however, cannot sustain Brigham's burden of proof.

Brigham argues that Study 98's definition of an episode of acidic reflux only applies to a prior table showing the number and duration of esophageal reflux episodes, not to Figure 7. Implicit in Brigham's argument is the notion that the investigators defined an episode of acidic reflux in different ways within the same study. Brigham cites no evidence in support of that reading. Moreover, the general definition of an episode of acidic reflux offered in Study 98 does not refer to any particular data or figure, and the study contains no alternative definition. Thus, no reasonable jury could have interpreted the study according to Brigham's newly presented reading.

Brigham also emphasizes that Figure 7 involved patients who generally experienced heartburn. This may be true but it is irrelevant to whether Figure 7

demonstrated immediate relief from heartburn symptoms within 5-10 minutes. The fact that the patients in Study 98 experienced heartburn at some time does not support a finding that the rise in esophageal pH shown in Figure 7 demonstrated the claimed immediate relief.

We next consider Studies 110 and 127, which did report symptomatic relief from heartburn. However, the district court concluded that these studies could not support the infringement verdict because they each measured "adequate relief" beginning at 15 minutes, not immediate relief starting within 5-10 minutes as claimed. *Decision*, 280 F. Supp. 3d at 202. There is no dispute that adequate relief first measured at 15 minutes after administration is a parameter different from relief starting 5-10 minutes after administration. Dr. Wolfe testified as such. J.A. 7846 ("[I]t's onset versus — this is adequate relief. Different parameters."). As Studies 110 and 127 did not measure the result that Brigham claimed in the '137 patent, we agree with the district court that they do not support the jury verdict.

On appeal, Brigham argues that the evidence of adequate relief at 15 minutes necessarily showed onset of relief within 5-10 minutes. But at most, Dr. Wolfe's testimony only indicated that the measured parameter would "correlate to" the claimed result. J.A. 7847 ("'15 minutes would be in the five or ten, around that time.' So that would correlate to immediate relief."). Data merely correlating to the claimed limitation does not suffice to prove literal infringement. As Dr. Wolfe testified regarding the data on adequate relief at 30 minutes, "[w]e have no

idea" how many patients in Studies 110 and 127 were provided relief starting within 5-10 minutes because that result was not measured or even estimated in either study. J.A. 7791. "Although a jury is entitled to draw reasonable inferences from circumstantial evidence, reasonable inferences themselves must be more than speculation and conjecture." *Phillip M. Adams & Assocs., LLC v. Dell Comput. Corp.*, 519 F. App'x 998, 1004 n.10 (Fed. Cir. 2013) (quoting *Sunward Corp. v. Dun & Bradstreet, Inc.*, 811 F.2d 511, 521 (10th Cir. 1987)); *see Welch v. Ciampa*, 542 F.3d 927, 935 (1st Cir. 2008) ("Although we give the nonmoving party the benefit of all reasonable inferences, a party cannot rest on 'conclusory allegations, improbable inferences, [or] unsupported speculation' to defeat a motion for summary judgment." (alteration in original) (quoting *McCarthy v. Northwest Airlines, Inc.*, 56 F.3d 313, 315 (1st Cir. 1995))). Because only speculation supports Brigham's contention that data showing adequate relief at 15 minutes implies that relief started within 5-10 minutes, it cannot sustain the jury verdict.

Brigham also points to other evidence purportedly showing that Pepcid Complete® provided the claimed immediate relief—that antacids were conventionally known to act quickly, and that the NDA stated that Pepcid Complete® worked as quickly as an antacid. However, none of this evidence indicates that Pepcid Complete® provides immediate relief within 5-10 minutes as claimed. It therefore cannot support the infringement verdict.

Last, we consider the bare assertion by Dr. Wolfe, the inventor of the '137 patent, that he ingested Perrigo's

product after litigation began, and that it provided immediate relief as claimed. J.A. 7760 ("Q. And you have no direct evidence that Perrigo's generic product provides immediate relief within five to ten minutes, correct? A. Well, yeah. I took it myself, and it does."); J.A. 7758. Considering the absence of any clinical data demonstrating the claimed immediate relief, we conclude that this uncorroborated, conclusory, and interested testimony is insufficient to carry Brigham's burden of proof and to sustain the jury verdict. *See Medtronic Inc. v. Boston Sci. Corp.*, 558 F. App'x 998, 1000 (Fed. Cir. 2014) ("The district court correctly noted that conclusory statements are insufficient to support a verdict finding infringement under the doctrine of equivalents . . . ."); *cf. McKeown v. Bayshore Concrete Prods. Corp.*, 34 F. App'x 741, 743 (Fed. Cir. 2002) ("[U]nsupported, conclusory statements on the ultimate issue of infringement are wholly insufficient to raise a genuine evidentiary dispute for trial.").

Having considered the totality of the evidence, we agree with the district court that Brigham failed as a matter of law to prove that Perrigo's product meets the claimed limitation of providing immediate relief from episodic heartburn within 5-10 minutes. Because each asserted claim contains this limitation, the court did not err in concluding that the infringement verdict and damages award could not stand.

Appendix A

CONCLUSION

We have considered Brigham's remaining arguments but find them unpersuasive. For the foregoing reasons, we *affirm* the judgment of the district court.

AFFIRMED

APPENDIX B — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS FILED NOVEMBER 17, 2017

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 13-11640-RWZ

BRIGHAM AND WOMEN'S HOSPITAL, INC.
AND INVESTORS BIO-TECH, L.P.,

v.

PERRIGO COMPANY
AND L. PERRIGO COMPANY.

November 17, 2017

MEMORANDUM AND ORDER

ZOBEL, S.D.J.

On June 21, 2017, the United States Court of Appeals for the Federal Circuit, by Judge Wallach, deactivated the appeals filed by defendants Perrigo Company and L. Perrigo Company (collectively, "Perrigo"). *See* Docket # 319. Accordingly, before me now are Perrigo's renewed motions for judgment as a matter of law and, in the alternative, motions for a new trial. *See* Docket ## 298, 300, 303, 306. Plaintiffs Brigham and Women's Hospital, Inc., and Investors Bio-Tech, L.P. (collectively, "Brigham")

oppose all these motions and separately move to amend the August 9, 2017, final judgment (Docket # 344).

I. Procedural Background

The court held an eight-day jury trial which concluded on December 14, 2016, with a jury verdict in favor of plaintiffs. *See* Docket # 222. Specifically, the jury found (1) direct, induced, contributory, and willful infringement by Perrigo of all asserted claims of U.S. Patent No. 5,229,137 ("the '137 patent"); (2) an effective priority date of March 1990; and (3) all asserted claims valid. It declined to award pre-judgment interest but awarded Brigham $10,210,071 in damages and rejected Perrigo's laches defense, finding that Brigham knew or should have known of their infringement claim against Perrigo as of August 11, 2008. Judgment was entered on December 19, 2016, without specifying the amount of damages owed to Brigham. On January 24, 2017, Perrigo filed several motions for judgment as a matter of law or a new trial under Federal Rules of Civil Procedure 50(d) and 59(d). Brigham opposed these motions on the ground that they had not been timely filed, and further argued that Perrigo failed to timely appeal from the December 2016 judgment. In a memorandum and order issued on April 24, 2017, I denied Perrigo's post-trial motions. The Federal Circuit, however, ruled that the December 2016 judgment was not final because "the issue of enhanced damages had not been resolved," Docket # 319, at 3, and therefore denied Brigham's motion to dismiss the appeals. Subsequently, this court entered a final judgment in accordance with the December 14, 2016, jury verdict and the court's April

24, 2017, memorandum and order. *See* Docket # 342. The Federal Circuit deactivated the appeals and instructed the court to consider the pending post-judgment motions.

II. Factual Background

A. '137 Patent

The '137 patent discloses Dr. M. Michael Wolfe's invention of pharmaceutical medications and methods for providing humans with instant and sustained relief from the pain, discomfort, and other symptoms associated with episodic heartburn.[1] Claim 1, the only independent claim asserted, of the '137 patent claims:

> A method of providing immediate and sustained relief from pain, discomfort and/or symptoms associated with episodic heartburn in a human, said method comprising:
>
> > orally administering to a human together or substantially together an antacid in an amount effective to substantially neutralize gastric acid and a histamine H^2-receptor antagonist in an amount effective to substantially inhibit or block

1. Dr. Wolfe assigned his rights to the '137 patent to Brigham and Women's Hospital, Inc., which subsequently entered into an exclusive license with Investors Bio-Tech, L.P. because "the Brigham is not in the business of licensing drugs," Docket # 231, at 34:1–13 (Jury Trial Day 2 Tr.).

> gastric acid secretion for providing the human with immediate and sustained relief from pain, discomfort and/or symptoms associated with episodic heartburn, the immediate and sustained relief provided lasting longer in duration than when the human is orally treated with only the antacid and the immediate and sustained relief provided being faster than and lasting at least about as long in duration as when the human is orally treated with only the histamine H^2-receptor antagonist.

Docket # 299-2 (JTX-001), Col. 7:23-42. Brigham also asserts that Perrigo infringed dependent claims 4, 5, 6, 7 and 12.[2]

B. The License Agreement

In 1996, Brigham and Johnson & Johnson Merck Consumer Pharmaceuticals ("JJMCP") entered into an exclusive license agreement (the "License Agreement") that gave JJMCP the first right, but not obligation, "to prosecute . . . any infringement of the ['137 patent] that involves products or methods in which FAMOTIDINE is combined or used in combination simultaneously or

2. Perrigo's main argument in its post-judgment motion, however, is that its Generic Product did not infringe claim 1, and therefore, did not infringe the dependent claims. Thus, my analysis focuses only on claim 1 of the '137 patent.

substantially simultaneously with an ANTACID." Docket # 304-2, at DTX-0005-0014. The parties agreed to notify each other "promptly of each such infringement of which [Brigham] or JJMCP is or becomes aware." *Id.* Section 8.6 of the License Agreement further provides:

> If, after the expiration of one hundred and twenty (120) days from a request to do so, JJMCP has not demonstrated that in fact no infringement has occurred, obtained a discontinuance of infringement, or brought suit against the third party infringer, then [Brigham] shall have the right after such one hundred twenty (120) day notice period, but not the obligation, to bring suit against such infringer and at its option to join JJMCP as a party plaintiff, provided that [Brigham] shall bear all the expenses of such suit.

Id. at DTX-0005-0016.

> Section 11.6, under "Termination," states:
>
> The termination of this Agreement for any reason shall not relieve any party of any obligation relating to activities occurring prior to the effective date of such termination, nor shall any party be deemed to waive any right to seek damages, equitable relief or other remedies following any termination of the Agreement.

Id. at DTX-0005-0022.

Appendix B

1. Perrigo's ANDA and Launch of Its Generic Product

On December 23, 2004, Perrigo sent Brigham its Paragraph IV notice letter informing Brigham that it had submitted an Abbreviated New Drug Application ("ANDA") to the FDA for permission to market famotidine/antacid chewable tablets prior to the expiration of the '137 patent, and its certification of invalidity and non-infringement. Docket # 333-3. On January 4, 2005, Brigham in turn notified JJMCP. Citing to paragraph 8.1 of the License Agreement, Brigham sought a response from JJMCP whether it would elect to pursue Perrigo. *See* Docket # 307-4, at DTX-0071-0002. On January 31, 2005, JJMCP informed Brigham that it would "refrain from exercising its rights under Article 8.1 of [the License Agreement] at this time," and that "[t]his election applies to Perrigo's activities and actions associated with the filing of an [ANDA] . . . for permission to market famotidine/antacid chewable tablets prior to expiration of [the '137 patent]." Docket # 333-5, at PTX-016.0001. JJMCP elected instead to sue Perrigo under its own separate patent, which triggered the thirty-month statutory stay on approval of Perrigo's ANDA. *See* Docket # 225, at 64:11–18 (Jury Trial Day 3 Tr.). Consequently, Brigham declined to file suit in 2005 because "[it] had no reason to file a lawsuit. There's not going to be a product launch [for another 30 months due to JJMCP's litigation], but, more importantly, if Johnson & Johnson succeeded, then Perrigo could never launch a product. So, in 2005, [Brigham] had absolutely no reason to do anything other than to see what happens." *Id.* at 64:19–24.

Perrigo launched Famotidine Complete (the "Generic Product") in 2008.[3] Brigham declined to file suit at that time because it decided not "to engage in protracted and expensive litigation with a generic company that may never sell much of their product," *id.* at 68:3–7. In 2013, Brigham eventually brought suit against Perrigo for direct infringement because the '137 patent was soon expiring and Perrigo was "sell[ing] tens of million of dollars worth of product," *id.* at 69:21–22.

III. Standard

"The standard for granting a Rule 50 motion is stringent. 'Courts may only grant a judgment contravening a jury's determination when the evidence points so strongly and overwhelmingly in favor of the moving party that no reasonable jury could have returned a verdict adverse to that party.'" *Malone v. Lockheed Martin Corp.*, 610 F.3d 16, 20 (1st Cir. 2010) (quoting *Rivera Castillo v. Autokirey, Inc.*, 379 F.3d 4, 9 (1st Cir. 2004)). In making its determination, the court may not weigh the evidence, determine the credibility of the witnesses presented, or attempt to resolve conflicting testimony. *MacQuarrie v. Howard Johnson Co.*, 877 F.2d 126, 128 (1st Cir. 1989).

Under Federal Rule of Civil Procedure 59(a), a court may order a new trial "only if the verdict is against the law,

3. The lawsuit between JJMCP and Perrigo, in which Perrigo prevailed, concluded in 2008. *See* Docket # 225, at 67:16–18 (Jury Trial Day 3 Tr.) ("By 2008 that lawsuit had ended and Perrigo won. So, Perrigo apparently now had the opportunity and decided to launch Famotidine Complete.")

against the weight of the credible evidence, or tantamount to a miscarriage of justice." *Crowe v. Marchand*, 506 F.3d 13, 19 (1st Cir. 2007) (quoting *Casillas-Diaz v. Palau*, 463 F.3d 77, 81 (1st Cir. 2006)).

IV. Discussion

Perrigo seeks judgment as a matter of law on standing, infringement, invalidity, and damages, or in the alternative, moves for a new trial on these issues. I address first the threshold issue of standing.

A. Standing

Perrigo renews its motion for judgment as a matter of law on the issue of standing.[4] Perrigo contends that

4. In my pretrial order, I allowed defendants to file supplemental briefing on the issue of standing because "[t]he existing record [was] insufficient to resolve this question." Docket # 183, at 3. Perrigo subsequently filed its motion to dismiss for lack of standing a week prior to trial. At the outset of trial, the same day that Brigham's opposition was due, I heard argument from the parties. I denied Perrigo's motion because I found "that the [License Agreement] is sufficiently ambiguous" to decide the issue of standing, Docket # 336-1, at 7. Brigham contends that because Perrigo's motion to dismiss was denied, and Perrigo failed to file a motion for reconsideration, it cannot move for judgment as a matter of law on this issue. As Perrigo correctly notes, however, it continued to preserve its right to judgment as a matter of law and I reserved judgment on that issue. *See* Docket # 235, at 164 (Jury Trial Day 8 Tr.); *see* also Docket # 218 (Perrigo's pre-verdict Rule 50(a) motion raising the issue of standing). In any event, to the extent there may have been procedural errors, the issue of standing "can be neither waived nor assumed."

the launch of its Generic Product in 2008 constituted a separate potentially infringing action apart from the filing of its ANDA in 2005 that triggered the notice requirement under section 8.1 of the License Agreement. Accordingly, it argues, because Brigham failed to notify JJMCP about Perrigo's launch of its Generic Product prior to filing suit in 2013, and thereby failed to trigger the 120-day notice period and seek the requisite authority from JJMCP, Brigham lacked prudential standing[5] to bring suit against Perrigo. Brigham maintains that it has standing to sue because: (1) it owned title to the '137 patent at all times; (2) the License Agreement only authorized JJMCP to bring suit during the effective period of its license; and (3) JJMCP's waiver of its right to pursue Perrigo in 2005 "was for any infringement arising of out Perrigo's activities broadly relating to the '137 patent occurring prior to patent expiration," Docket # 333, at 16.

"The typical challenge to prudential standing in a patent infringement case occurs when an alleged infringing party asserts that the plaintiff, a licensee with

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Willis v. Government Accountability Office, 448 F.3d 1341, 1343–44 (Fed. Cir. 2006) (internal citations omitted). Accordingly, Perrigo's renewed motion on standing is properly before me.

5. Perrigo concedes that "Plaintiffs are the owner/exclusive licensee of the '137 patent, so they have Article III standing." Docket # 336, at 4. Accordingly, Perrigo's reliance on *Abraxis Bioscience v. Navinta*, 625 F.3d 1359, 1367 (Fed. Cir. 2010), is misplaced. In *Abraxis*, the issue was whether the plaintiff was able to "'demonstrate that it held enforceable title to the patent,'" *id.* at 1364 (quoting *Paradise Creations Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309–10 (Fed. Cir. 2003)), *i.e.*, Article III standing.

rights to or under the asserted patent, lacked standing to bring the original lawsuit because the patent owner was not a party to the suit." *Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1314 (Fed. Cir. 2005). Instead, "[t]his case presents a converse scenario in which the patent owner seeks to bring suit," *Alfred E. Mann Found. For Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1359 (Fed. Cir. 2010), and defendants dispute the patent owner's prudential standing based on the terms of the License Agreement. The facts of this case are nearly identical to the facts in *Alfred E. Mann*, with one important exception: here, Brigham did not notify JJMCP prior to filing suit in 2013 based on Perrigo's launch of its Generic Product in 2008. *Cf. id.* at 1358 ("After [the] license agreement was entered into, [licensor] notified [licensee] of [defendant's] allegedly infringing activity and sought to determine [licensee's] decision regarding whether to sue [defendant] for infringement"). The Federal Circuit noted, albeit in dicta, that a licensor's "right to choose to sue an infringer *does not vest until* [the exclusive licensee] chooses not to sue that infringer," *id.* at 1362 (emphasis added). Thus, the issue turns on whether Brigham was required, under the License Agreement, to notify JJMCP after Perrigo had launched its Generic Product in order to bring suit against Perrigo under 31 U.S.C. § 271(a).

Brigham argues that it did not need to notify JJMCP again in 2008, or anytime thereafter, about Perrigo's launch of its Generic Product because JJMCP's waiver in 2005 applied to "any infringement arising of out Perrigo's activities broadly relating to the '137 patent occurring prior to patent expiration," Docket # 333, at 16. Brigham

also argues that it was not required to notify JJMCP because it brought suit a year after the License Agreement had terminated in 2012. I reject both arguments. First, the License Agreement explicitly provides that the parties would notify each other "promptly of *each* such infringement of which [Brigham] or JJMCP is or becomes aware." Docket # 304-2, at DTX-0005-0014 (emphasis added). The launch of its generic product was a separate infringing action from the filing of its ANDA. Second, JJMCP explicitly cabined its waiver in 2005 to "refrain from exercising its rights under Article 8.1 of [the License Agreement] *at this time*," and that "[t]his election applies to Perrigo's activities and actions associated with the filing of an [ANDA] . . . for permission to market famotidine/antacid chewable tablets prior to expiration of [the '137 patent]." Docket # 333-5, at PTX-016.0001 (emphasis added). And although Brigham brought suit a year after the License Agreement expired, it seeks damages for alleged infringing activity that occurred while the License Agreement was still in effect. Section 11.6 of the License Agreement provides that "[t]he termination of this Agreement for any reason *shall not relieve any party of any obligation relating to activities occurring prior to the effective date of such termination* . . . ." Docket # 304-2, at DTX-0005-0022 (emphasis added). As a result, Brigham was obligated to abide by the requirements of Section 8 and provide notice to JJMCP prior to initiating suit in 2013.

Nevertheless, I find that Brigham has prudential standing to sue Perrigo. "Prudential standing to sue for patent infringement derives from 35 U.S.C. § 281: 'A

patentee shall have remedy by civil action for infringement of his patent.'" *Int'l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1276 (Fed. Cir. 2007). "The crux of [Federal Circuit] standing caselaw has always been whether a plaintiff has all substantial rights in the patent-at-issue." *Keranos, LLC v. Silicon Storage Tech., Inc.*, 797 F.3d 1025, 1033 (Fed. Cir. 2015). Here, Brigham retained substantial rights in the '137 patent under the License Agreement:

- The right to control JJMCP's ability to settle or dispose of litigation by requiring JJMCP seek written consent from Brigham prior to entering any such disposition. Brigham's consent could not be unreasonably withheld.

- The secondary right to sue to enforce the '137 patent and maintain absolute control over any suit it brought in its own name.

- The right to terminate the License Agreement if JJMCP missed payments to Brigham.

See Docket # 304-2, at DTX-005.0014–19, 21; *see AsymmetRx, Inc v. Biocare Med., LLC*, 582 F.3d 1314, 1321 (Fed. Cir. 2009) (explaining that "even if [licensee] exercises its option to sue for infringement, it is obligated under the [license agreement] to consider [licensor's] views and . . . [licensor's] approval is necessary for any settlement of any suit"); *see also Alfred E. Mann*, 604 F.3d at 1362 ("Such a broad right to decide whether to bring

suit and to control litigation is thoroughly inconsistent with an assignment of the patents-in-suit to [the licensee]"). Further, the grant was for a field-of-use license that was limited to "products and methods in which FAMOTIDINE is combined or used in combination simultaneously or substantially simultaneously with an ANTACID." Docket # 304-2, at DTX-014.0003. Thus, had JJMCP elected to sue Perrigo in 2005 or 2008, it would have had to join Brigham as a necessary party in order to establish prudential standing. *See A123 Sys. Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1217 (Fed. Cir. 2010) ("Under long-standing prudential standing precedent, an exclusive licensee with less than all substantial rights in a patent, such as a field-of-use licensee, lacks standing to sue for infringement without joining the patent owner.").Therefore, prudence does not warrant a determination that Brigham lacked standing to sue in this case.[6]

B. Infringement

In any event, after consideration of the record evidence, I find that Brigham failed to present sufficient evidence to prove direct infringement. "Literal infringement requires the patentee to prove that the accused [product] contains each limitation of the asserted claim." *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 812

6. Perrigo argues that Brigham's "positions on standing and laches are irreconcilable, thus requiring a judgment of no standing and/or laches as a matter of law." Docket # 307, at 10. Perrigo, however, did not brief the issue of laches in its pending post-judgment motions. Therefore, I decline to disturb the jury's finding on this issue.

(Fed. Cir. 2002) (citation omitted). The patentee bears the burden to prove infringement by a preponderance of the evidence. *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011).

Perrigo argues that Brigham failed to meet its burden because it did not present any evidence that Perrigo's product directly reads onto the asserted claim limitations of the '137 patent. Specifically, Perrigo argues that Brigham failed to present evidence of data relating to Perrigo's product. Indeed, Brigham's expert, Dr. Wolfe, conceded that there is no direct evidence that shows a person who took Perrigo's product met the limitations of claim 1—namely, the immediate and sustained relief limitation. Instead, during the trial, Brigham relied on indirect evidence, including bioequivalence data from Perrigo's ANDA[7] and studies from the New Drug Application ("NDA") for Pepcid Complete that Brigham contends were incorporated into Perrigo's label.[8] Brigham

7. *See* Docket # 225, at 21:5–12 (Jury Trial Day 3 Tr.) (Dr. Wolfe testifying that the FDA knew Perrigo's Generic Product would be therapeutically effective because "an antacid is an antacid is an antacid, [the FDA] would look at the effects . . . on absorption and bioavailability of the H2 blocker. That's accomplished by looking at the blood levels, and that's [why] bioequivalence was deemed to be necessary").

8. *See* Docket # 225, at 23:22–23 (Jury Trial Day 3 Tr.) (Dr. Wolfe testifying that the label for Perrigo's Generic Product is the same exact label as that for Pepcid Complete such that the graphs concerning onset and duration of relief on Perrigo's product label incorporates the same onset and relief data in JJMCP's NDA).

thus attempted to circumstantially prove that Perrigo's Generic Product infringed the '137 patent by arguing that Pepcid Complete is a commercial embodiment of the '137 patent and that Perrigo's Generic Product is an exact copy of Pepcid Complete. *See* Docket # 231, at 153:21–24 (Jury Trial Day 2 Tr.) ("Q: And did you have any basis for your opinion that Perrigo's product infringed in 2008? A: Yes . . . . It was basically Pepcid Complete."). Therefore, Brigham could only prevail if it proved that its product meets all of the claim limitations. *See Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. Civ. A. 11-1341-PGS, 2013 WL 211252, at *5 (D.N.J. Jan. 18, 2013), vacated and remanded, 749 F.3d 1349 (Fed. Cir. 2014) (explaining that where a generic product is "exactly the same" as the branded product, infringement is found "if each claim limitation is met by [the branded product]"); *see also Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1289 (Fed. Cir. 2010) ("[W]hen a commercial product meets all of the claim limitations, then a comparison to that product may support a finding of infringement.").

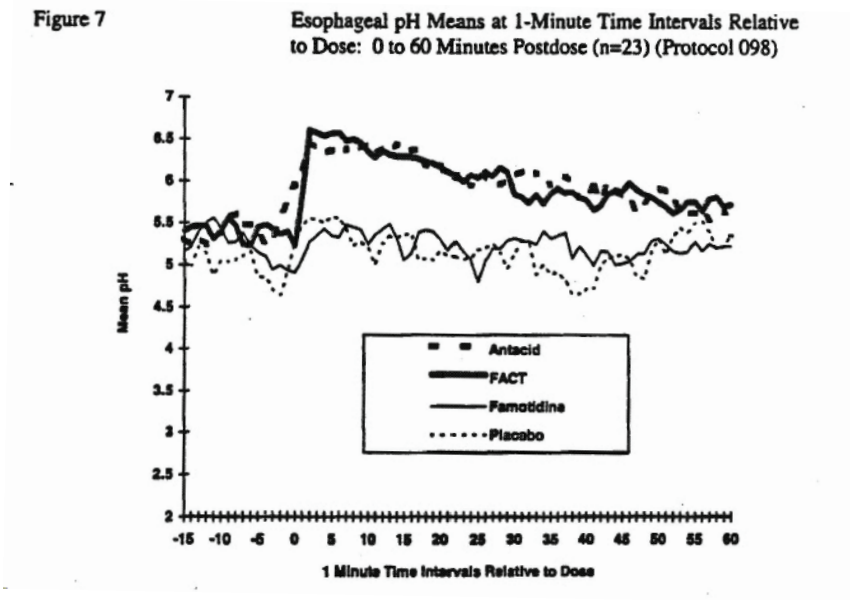
The main dispute hinges on whether Brigham successfully proved that its product meets the "immediate and sustained relief" limitation in claim 1. The court construed that limitation to mean "relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 5–10 minutes following ingestion of the active ingredients and continues for at least about 4–6 hours." Docket # 105, at 6. Claim 1 further requires that: (1) "the immediate and sustained relief provided last[s] longer in duration than when the

human is orally treated with only the antacid;" and (2) "the immediate and sustained relief provided [is] faster than and last[s] at least about as long as in duration as when the human is orally treated with only the histamine H2-receptor antagonist." Docket # 299-2, at 7:34–42.

To prove that Pepcid Complete meets this limitation, and thereby the Generic Product does as well, Brigham relied on clinical studies that were submitted to the FDA as part of JJMCP's NDA for Pepcid Complete. Brigham argues that "these studies demonstrated that the combination of active ingredients[9] present in both parties' products ('famotidine-antacid combination tablet') provided the same therapeutic benefit for episodic heartburn." Docket # 334, at 10. To prove this limitation, Brigham specifically relied on Study 098, which measured "the pharmacodynamic effect on esophageal and intragastric pH of the four preparations that were to be used in the clinical studies." Docket # 299-15, at PTX-044.015. Dr. Wolfe referred to a graph, Figure 7, from Study 098 that measured the esophageal pH means at 1-minute intervals:

9. Brigham provided undisputed evidence that the Generic Product contains the same active ingredients as Pepcid Complete. *See* Docket # 334-2, at 3 (excerpt from Perrigo's ANDA showing that Generic Product contains the same active ingredients, strength, and indications as Pepcid Complete).

Appendix B



Docket # 299-15, at PTX-044.0107.

Dr. Wolfe testified that Figure 7 shows how Pepcid Complete meets the "immediate" part of the claim limitation because it shows that the mean pH in the esophagus rose rapidly within the first five minutes for participants who took the famotidine-antacid combination (*i.e.*, the bold solid line). *See* Docket # 225, at 26-27 (Jury Trial Day 3 Tr.). Accordingly, Brigham argues that Figure 7 establishes "that the active ingredients in the tested famotidine-antacid combination [FACT] provided increased esophageal pH (*i.e.*, lower acidity) within 5–10 minutes of dosing—faster than when famotidine is used alone." Docket # 334, at 10.

Dr. Wolfe further testified that the label for Perrigo's Generic Product, which states that its product was "Proven Effective In Clinical Studies," Docket # 299-6, at DTX-0493-0014, is based on "the same exact data [as Pepcid Complete]," Docket # 225, at 23:23 (Jury Trial Day 3 Tr.). Thus, it argues, because Pepcid Complete provides the relief as described in the '137 patent, so, too, does Perrigo's Generic Product. This was in essence Brigham's bioequivalence argument. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (citations omitted) ("Generic drug companies are not required to conduct their own independent clinical trials to prove safety and efficacy, but can instead rely on the research of the pioneer pharmaceutical companies. However, in order to rely on the research of the pioneer pharmaceutical companies, an ANDA applicant is required to show bioequivalence of its generic drug to the NDA drug.").

However, the NDA explains that in Study 098 "[a]n episode of acidic reflux was counted as a drop from pH 5 or more to 4 or below," Docket # 299-15, at PTX- 044.0107. This is consistent with testimony from Perrigo's expert witness, Dr. Annunziata, who testified that esophageal pH of 4 or less indicates "symptoms from episodic heartburn." Docket # 229, at 61–62 (Jury Trial Day 6 Tr.). In Figure 7, the line representative of participants who took FACT—the bold line—shows that none of those participants ever had esophageal pH of 4 or less. Moreover, "neither the occurrence nor severity of heartburn or other symptoms . . . were recorded on the case reports forms [in Study 098] and no analyses were done to correlate those observations

with the pH recordings." Docket # 299-15, at PTX-044.109. Thus, this graph did not prove that participants were provided immediate relief "from pain, discomfort and/or symptoms associated with episodic heartburn" as required by claim 1 of the '137 patent.

Although Brigham did present data involving symptom relief studies, *see e.g.*, Docket # 299-17, at PTX-044.0138, those studies compared "time to adequate relief" measured at 15-minute intervals, which Brigham's expert testified encompasses relief obtained within 5–10 minutes. *See* Docket # 225, at 15–16 (Jury Trial Day 3 Tr.). Dr. Wolfe agreed that the symptom relief studies, however, involved "different parameters" from the patent. *Id.* at 16. Thus, Figure 7 was the only evidence Brigham presented in support of its argument that Pepcid Complete—and therefore the Generic Product—meets the "immediate" limitation of claim 1. Because Brigham cannot prove that its product, Pepcid Complete, reads on all the claim limitations of the '137 patent, it cannot, as a matter of law, establish that Perrigo's Generic Product infringes. Accordingly, no reasonable jury could have found direct infringement and Perrigo is entitled to judgment as a matter of law on direct infringement.

Further, because Brigham failed to prove direct infringement of claim 1, it necessarily follows that Brigham cannot prove direct infringement of the remaining dependent claims 4, 5, 6, and 12 of the '137 patent. Without proof of direct infringement, Perrigo is also entitled to judgment as a matter of law of on indirect

or willful infringement.[10] *See Molinaro v. Fannon/Courier Corp.*, 745 F.2d 651, 654 (Fed. Cir. 1984) ("Where there is no direct infringement, there is nothing to which the accused products could 'contribute.'"); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014) ("[I]nducement liability may arise "if, but only if, [there is] . . . direct infringement." (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961)); *SynQor, Inc. v. Artesyn Technologies, Inc.*, 635 F. App'x 891, 894–95 (Fed. Cir. 2015) (finding that it was appropriate for district court to decline to find willful infringement when the district court was correct to determine that defendant did not directly infringe).

C. Invalidity

As an initial matter, Perrigo contends that the jury erred in its finding that the priority date was March 1990, which, it argues, ultimately "tainted the verdict by preventing the jury from considering WO 92/00102 to Davis ("Davis"), which clearly and convincingly shows the '137 patent is anticipated." Docket # 301, at 7. In support, Perrigo argues that Brigham failed to corroborate the earlier priority date, and instead, relied merely on the inventor's testimony and his unwitnessed laboratory notebooks.

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10. Accordingly, in the event that the grant of judgment as a matter of law on infringement is overruled on appeal, Perrigo's motion for a new trial on infringement is warranted because "the jury's verdict is against the clear weight of the evidence." *Newell Puerto Rico, Ltd. v. Rubbermaid Inc.*, 20 F.3d 15, 22 (1st Cir. 1994) (citing *Kearns v. Keystone Shipping Co.*, 863 F.2d 177, 181 (1st Cir. 1988)).

Corroboration is required when a patentee tries to prove that the conception date was earlier than the filing date of his patent application. *See Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009) ("The inventor 'must provide independent corroborating evidence in addition to his own statements and documents.'" (quoting *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989)). Brigham emphasizes that the laboratory notebooks were admitted into evidence and as such, a reasonable jury could find that they were reliable to corroborate Dr. Wolfe's testimony and to sufficiently establish the earlier priority date. Although Dr. Wolfe's laboratory notebooks were admitted into evidence, they were unwitnessed. Accordingly, as a matter of law, Brigham is not entitled to the earlier priority date. *See Proctor & Gamble Co.*, 566 F.3d at 998–99 (finding that inventor's unwitnessed notebook was not adequate corroborating evidence of an earlier invention date).

1. Anticipation

Nevertheless, Perrigo is not entitled to judgment as a matter of law on invalidity because it has failed to show by clear and convincing evidence that Davis anticipates the '137 patent. *See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). "A patent claim is anticipated if a single prior art reference expressly or inherently discloses every limitation of the claim." *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1252 (Fed. Cir. 2014).

Davis is a patent that discloses the "[c]o-administration of a histamine H2-receptor antagonist and antacid for

the treatment of gastric disorders." Docket # 301-9, at 1. Perrigo, however, does not point to any evidence from its affirmative case to support its burden of showing that Davis discloses the limitation of "immediate and sustained relief" as defined in the '137 patent. *See Novo Nordisk A/S v. Caraco Pharm. Labs, Ltd.*, 719 F.3d 1346, 1353 (Fed. Cir. 2013) ("[T]he burden of persuasion [as to invalidity] remains with the challenger during litigation because every issued patent is entitled to a presumption of validity."). Dr. Tornay, defendants' expert, testified that Davis meets this limitation because it discusses "the rationale [] for the coadministration being rapid relief and the combination with the H2-receptor antagonist independently, so that by combining the effects of the two drugs, the immediate and the sustained relief, that that meets that claim." Docket # 232, at 87:12–16 (Jury Trial Day 5 Tr.). But this is not enough. Dr. Tornay failed to point to any portion of the Davis reference that specifically discloses that co-administration of an H2-receptor antagonist and antacid would provide relief within about 5–10 minutes following ingestion of the active ingredients and continues for at least about 4–6 hours. Nor does he explain how Davis discloses the limitation that the combined administration provides relief that lasts longer in duration than when a human is orally treated with the antacid alone. Thus, although Davis may have disclosed generally the oral co-administration of H2-receptor antagonists and antacids with high acid-neutralizing capacity, there is insufficient evidence to clearly and convincingly find that Davis discloses the "immediate and sustained relief" limitation in claim 1. Because there is substantial evidence to support a finding that Davis fails

to anticipate claim 1, there is also substantial evidence to support the jury's finding that Davis does not anticipate any of the asserted dependent claims.[11]

2. Obviousness

An invention cannot be patented if the subject matter would have been obvious at the time of the invention. Perrigo bears the burden to show by clear and convincing evidence that a person skilled in the art would have (1) been motivated to combine the teachings of the prior art references to achieve the claimed invention; and (2) had a reasonable expectation of success in doing so. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). "The obviousness determination turns on underlying factual inquiries involving: (1) the scope and content of prior art, (2) differences between claims and prior art, (3) the level of ordinary skill in pertinent art, and (4) secondary considerations such as commercial success and satisfaction of a long-felt need." *Procter & Gamble Co.*, 566 F.3d at 994 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). Here, "both parties submitted proposed jury verdict forms that did not include interrogatories or otherwise request specific factual findings [on the obviousness analysis]. Accordingly, the verdict form submitted to the jury asked for a verdict on the ultimate issue of obviousness with respect to each claim at issue, without requiring specific factual findings." *Abbott GmbH & Co., KG v. Centocor Ortho Biotech, Inc.*, 971 F. Supp. 2d 171, 182 (D. Mass. 2013).

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11. For the same reason, Perrigo's motion for a new trial as to invalidity is unwarranted.

Appendix B

The parties agreed that a person of ordinary skill in the art at the time of the filing of the application that led to the '137 patent "would include someone with a graduate degree in pharmacy, pharmaceutics, biopharmaceutics or a doctorate in medicine or osteopathic medicine, and at least two years academic, industry, or clinical experience in such fields." Docket # 299-3, at 3. The jury was instructed on this definition. Thus, there is no factual dispute as to the level of ordinary skill in the art.

In addition to Davis, the prior art references submitted into evidence at trial include: French '933 patent (DTX-140, Docket # 299-4); French '103 patent (DTX-52, Docket # 301-6); Donn Article (DTX-51, Docket # 301-5); Desager Article (DTX-88, Docket # 301-7); 1990 PDR including Zantac (DTX-466, Docket # 301-10); 1990 PDR referencing Pepcid Complete (DTX-470, Docket # 301-11); and the Mihaly Article (DTX-7, Docket # 301-4). "The scope and content of the prior art are factual questions to be determined by the jury." *Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1019 (Fed. Cir. 2009) (citing *Graham*, 383 U.S. at 17).

Similar to the shortcoming of Davis, none of the prior art references disclosed the key limitation found in claim 1, namely, the "immediate and sustained relief" limitation. Again, Dr. Tornay testified that these prior art references meet the "immediate and sustained relief" limitation because each reference generally teaches that co-administration of antacid with an H2-receptor antagonist will provide rapid and sustained relief. *See* Docket # 232, at 71, 83, 87, 92, 95–97, 101–03 (Jury Trial

Day 5 Tr.). But defendants' expert witness failed to point out where specifically the limitation of "immediate and sustained relief" as defined under the '137 patent—that is, "relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 5–10 minutes following ingestion of the active ingredients and continues for at least about 4–6 hours" is disclosed in these prior art references, or explain how the prior art in combination would make this claim limitation obvious to a person of skill in the art at the relevant time when none of the prior art references contained symptom relief data. "[G]eneral and conclusory testimony 'does not suffice as substantial evidence of invalidity.'" *NewRiver, Inc. v. Newkirk Products, Inc.*, 674 F. Supp. 2d 320, 330 (quoting *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1152 (Fed. Cir. 2004)). Accordingly, the jury's verdict of nonobviousness for claim 1 (and thereby all dependent claims 4, 5, 6, 7, and 12) is supported by substantial evidence.

D. Damages

Since Perrigo is entitled to judgment as a matter of law on Brigham's claims for infringement, the jury's award of damages cannot stand.[12] *See CVI/Beta Ventures,*

12. In the event that the grant of judgment as a matter of law on infringement is overruled on appeal, Perrigo's motion for a new trial on damages is unwarranted. "[T]he jury's damages award 'must be upheld unless the amount is grossly excessive or monstrous, clearly not supported by the evidence, or based only on speculation or guesswork.'" *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1383 (Fed. Cir. 2004) (quoting *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1580 (Fed. Cir.1992)). Here, Perrigo argues that Brigham

Inc. v. Tura LP, 112 F.3d 1146, 1149 (Fed. Cir. 1997). Relatedly, Brigham's motion to alter judgment to award pre-judgment interest is moot.

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failed to present substantial evidence in support of a 3.5 cents per-tablet royalty (or 18% royalty rate) because "all actual licenses to the '137 patent have been structured as a percent of net sales, not per tablet," Docket # 340, at 17. During the trial, Brigham's expert, Philip Green, testified that a hypothetical negotiation to determine patent damages assumes validity and infringement. Docket # 226, at 59:18–22 (Jury Trial Day 6 Tr.). He reasoned that "a per-unit royalty would be appropriate because . . . the use of the patent technology is when somebody actually takes the pill. That's when the infringement occurs. So, for the use made struck [him] as being on a per-pill basis," *id.* at 27:17–23. He explained that the date of the hypothetical negotiation would have occurred in 2008, when Perrigo first launched its Generic Product. Green agreed that the royalty rates in the four other licenses to the '137 patent were between one to three percent, *id.* at 71:23–72:1, but testified that Perrigo would have paid a higher royalty rate because at the time of the hypothetical negotiation Pepcid Complete had already been developed and on the market, and thus Perrigo bore less risk in developing a generic product. *id.* at 59:15–60:10. He further testified that he reviewed two sets of projections prepared by Perrigo in 2005/2006 and 2008 to determine "how much money would Perrigo be able to pay and still earn its normal rates of return based on these models," *id.* at 51:25–52:2. Based on these projections, he opined that Perrigo would have gone into the hypothetical negotiation in 2008 knowing that "it could afford to pay somewhere between . . . 2.9 cents and 10.7 cents [per tablet] . . . as a royalty to be able to have rights to the '137 patent." *id.* at 55:1–4. Ultimately, "[he] concluded that their royalty rate of 3 ½ cents made sense in all of all [sic] these data points," *id.* at 59:4–6. Perrigo did not object or cross-examine Green on this portion of his testimony, and thus waived its argument that Perrigo's projections were not in evidence. *See Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009). Thus, the evidence supports a per-tablet royalty of $10,210,071.

V. Conclusion

Brigham's Motion for Leave to File Sur-Reply (Docket # 343) is ALLOWED.

Perrigo's Renewed Motion for Judgment as a Matter of Law of No Direct, No Indirect, and No Willful Infringement and Motion for a New Trial (Docket # 298) is ALLOWED in its entirety.

Perrigo's Renewed Motions for

(a) Judgment of Invalidity as a Matter of Law or New Trial and Motion for Judgment of Invalidity Over the Prior Art (Docket # 300); and

(b) Judgment as a Matter of Law on Lack of Standing (Docket # 306) are DENIED.

Brigham's Motion to Alter Judgment to Award Prejudgment Interest (Docket # 344) and Perrigo's Renewed Motion for Judgment as a Matter of Law on Damages, and Motion for Remittitur or New Trial (Docket # 303) are DENIED AS MOOT.

Final judgment consistent with this opinion shall enter. Counsel shall jointly submit a proposed form of judgment on or before December 4, 2017.

Appendix B

November 17, 2017
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
SENIOR UNITED STATES
DISTRICT JUDGE

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED AUGUST 2, 2017

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1950, -2021

BRIGHAM AND WOMEN'S HOSPITAL, INC.
AND INVESTORS BIO-TECH, L.P.,

Plaintiffs-Appellees,

v.

PERRIGO COMPANY, L. PERRIGO COMPANY,

Defendants-Appellants.

August 2, 2017, Decided

Appeals from the United States District Court for the District of Massachusetts in No. 1:13-cv-11640-RWZ, Judge Rya W. Zobel.

ON MOTION

Before NEWMAN, WALLACH, and STOLL, Circuit Judges. WALLACH, *Circuit Judge*.

ORDER

The appellees move for panel reconsideration of this court's June 21, 2017 order denying the appellees' motion

to dismiss, consolidating the above-captioned appeals, and deactivating the appeals because of pending post-judgment motions. The appellants oppose the motion.

I. Background

Although the June 2017 order detailed the procedural history of these appeals, we repeat the facts essential to resolving this motion for ease of the panel and the reader.

This is a patent infringement case in which the appellees' complaint included a claim for enhanced damages pursuant to 35 U.S.C. § 284. On December 14, 2016, the jury returned a verdict in favor of the appellees on infringement and invalidity. On December 19, 2016, judgment was entered without specifying the amount of damages that was owed by the appellants.

On January 24, 2017, the appellants moved for judgment as a matter of law (JMOL) or a new trial under Rules 50(d) and 59(d) of the Federal Rules of Civil Procedure. The appellees moved for enhanced damages and attorneys' fees and opposed the appellants' motions on the ground that they had not been timely filed. In response, on February 17, 2017, the appellants moved for an extension of time to file an appeal and noticed an appeal, which was subsequently docketed as Appeal No. 2017-1950.

On April 24, 2017, the district court resolved the parties' post-trial motions, including the appellees' motion for enhanced damages. As to the appellants' motions, the district court agreed with the appellees that the motions

had not been timely filed because they were filed more than 28 days after the judgment. The district court also denied the appellants' motion to extend time to file an appeal from the December 2016 judgment. On May 11, 2017, the appellants filed an amended notice of appeal, which was docketed as Appeal No. 2017-2021.

The appellees moved to dismiss Appeal No. 1950 and to limit the issues in Appeal No. 2017-2021, arguing that the appellants could not seek review of the underlying infringement and invalidity determinations. They contended that the appellants failed to file a timely appeal from the December 2016 judgment and also failed to file timely motions that would toll the time to appeal.

On June 21, 2017, this court issued a single-judge order denying that motion. The order explained that the December 2016 judgment was not a final judgment because the enhanced damages claim remained unresolved. The order further explained that while the appellants could have appealed the judgment as an interlocutory appeal because it was final "except for an accounting," the appellants' failure to do so did not preclude review of the liability issues after entry of final judgment.

Because there were pending motions that challenged the judgment on appeal, the court deactivated the case until the district court resolved those motions.

II. This Court's June 21, 2017 Order Was Not Procedurally Improper as a Single-Judge Decision

Rule 27(c) of the Federal Rules of Appellate Procedure provides that a single judge "may not dismiss or otherwise determine an appeal." An order denying a motion to dismiss and allowing an appeal to ultimately proceed to the merits panel clearly does not fall into one of those categories. *See, e.g., Fieldturf, Inc. v. Sw. Recreational Indus., Inc.*, 357 F.3d 1266, 1268 (Fed. Cir. 2004) (citing Fed. R. App. P. 27(c) and *Nilssen v. Motorola, Inc.*, 203 F.3d 782, 785 n.2 (Fed. Cir. 2000)); *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1345-46 (Fed. Cir. 2005). The Advisory Committee Notes do not suggest otherwise. They state that a single judge may "entertain and act upon any motion other than a motion to dismiss or otherwise determine an appeal or other proceeding." Here, the June 21, 2017 did not "act upon" the motion in the relevant sense in that it did not dismiss the appeal.

III. The December 2016 Judgment Was Not a Final Judgment Ending the Litigation on the Merits

While "the court may review the action of a single judge," Fed. R. App. P. 27(c), the appellees also fail to provide any basis to question the prior order's conclusion.

The appellees argue that the December judgment "end[ed] the litigation on the merits," Mot. at 7, and thus the appellants are entirely precluded from seeking review of the liability issues because they failed to file a notice of appeal within 30 days from the entry of that judgment

and failed to file a timely motion that would toll the clock from running. They contend that "the District Court and the parties intended the December Judgment to be a final judgment" and that "[g]iven the District Court's clear intent, finality would not be affected even if the District Court failed to expressly rule on all of [the appellees'] claims." *Id.* The appellees further argue that "the fact that [the appellees] could bring a post-verdict request to 'enhance' the damages award does not impact the finality of a judgment that resolves liability and damages." *Id.*

Section 1295(a)(1) of the title 28 authorizes this court to review "final decisions" of the district courts," those that "end[] the litigation on the merits and leave[] nothing for the court to do but execute judgment." *Catlin v. United States*, 324 U.S. 229, 233, 65 S. Ct. 631, 89 L. Ed. 911 (1945) (citation omitted). A "final decision" within the meaning of section 1295(a)(1) is one where the district court has resolved all damages issues. *See Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1581 (Fed. Cir. 1994) ("A judgment on an appeal under § 1292(c)(2) allowing interlocutory appeals of liability judgments in patent cases does not end the litigation."); *see also Calderon v. GEICO Gen. Ins. Co.*, 754 F.3d 201, 204-06 (4th Cir. 2014) (holding no final judgment where damages were not fixed because the assessment of damages is part of the merits of the claim); *Ariz. State Carpenters Pension Tr. Fund v. Miller*, 938 F.2d 1038, 1040 (9th Cir. 1991) (noting that there was no final judgment where punitive damages count was unresolved because the "punitive damages count and [the] compensatory damage counts are 'inextricably intertwined'").

Contrary to the appellees' arguments, enhanced damages are not collateral to the judgment akin to attorney fees. The source of authority to award damages is the same source of authority that authorizes enhanced damages. *See* 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement . . . . When the damages are not found by a jury, the court shall assess them. In either event, the court may increase the damages up to three times the amount found or assessed."). Moreover, the resolution of a claim for enhanced damages in favor of the patentee, unlike a pending matter of attorney fees, has the effect of altering or amending the judgment. We have accordingly treated enhancement as part of the accounting of damages. *See PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1365 n.4 (Fed. Cir. 2007).

The appellees cite *Pyle Nat. Co. v. Lewin*, 92 F.2d 628, 629 (7th Cir. 1937) in support of a "long-standing" contrary rule. If anything, however, that case confirms, rather than undermines, the conclusion that enhancements are part of the merits of the case. In *Pyle*, the defendants appealed from the trial court's order determining that the patents were valid and that treble damages should be awarded before conducting accounting of the profits and damages. In other words, the defendants were appealing from an interlocutory decision that was "final except for an accounting," § 1292(c)(2), not one that "end[ed] the litigation." *Mendenhall*, 26 F.3d at 1580.

In *Pyle*, the Seventh Circuit merely held that the appropriate procedure was for the trial court to

determine the issue of enhancement "in connection with the accounting [of damages] and not before." 92 F.2d at 632; *see also id.* at 631-32 ("We are of the opinion that such increase should not be allowed until after an accounting has been had. This evidently is what this Court had in mind in *Pollock v. Martin Gauge Co.*, 261 F. 201, on page 202, where it is said: 'But whether damages in excess of the compensatory damages shall be awarded, as well as the amount thereof, must be determined by the District Court upon the accounting.'"). It does not suggest, let alone hold, that enhancements are collateral to the judgment.

The appellees contend that the district court and the parties' intentions with respect to finality should be treated as "controlling" even if the enhancement claim remained pending. Mot. at. 7. According to the appellees, "[i]f a district court intends to enter a final judgment but overlooks or fails to address all issues in the action, the finality of the judgment is not affected. Rather, it is the obligation of the parties to file a timely post-trial motion or Notice of Appeal to correct that error." Mot. at. 9-10 (emphasis omitted). In support of their contention that the district court and the parties all intended for the December judgment to resolve all merits in the case, the appellees note the district court initially closed the case and the parties referred to the judgment as final. *Id.* at. 11.

The appellees' argument fundamentally misunderstands the final judgment rule and this court's own "special obligation" to ensure that it has jurisdiction over a case. *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541, 106 S. Ct. 1326, 89 L. Ed. 2d 501 (1986);

cf. Workman v. Bredesen, 486 F.3d 896, 904 (6th Cir. 2007) ("While we generally do not have jurisdiction to review temporary restraining orders, our jurisdiction is not controlled by the name that a claimant attaches to a motion or the name that a district court attaches to an order. Rather than looking to the label attached by the trial court, we look[ ] to the nature of the order and the substance of the proceeding below to determine whether the rationale for denying appeal applies." (citation and internal quotation marks omitted)).

In any event, the record belies the notion that the district court and the parties treated the December judgment as anything other than "final except for an accounting." The district court characterized the order in those terms. *See* District Court's April 24, 2017 Order at 5 ("Therefore, the only matter that remains outstanding is the issue of enhanced damages. [ ] The Federal Circuit, however, has exclusive jurisdiction over an appeal "of an appeal from a judgment in a civil action for patent infringement which would otherwise be appealable to the [Federal Circuit] and is otherwise final except for an accounting."). Moreover, the appellees themselves did not treat the case as if the litigation had ended on the merits, as they soon thereafter asked the court to award enhanced damages.

The appellees cite in support *Moreau v. Harris County*, 158 F.3d 241 (5th Cir. 1998), *Cox v. United States*, 783 F.3d 145 (2d Cir. 2015), and *Pandrol USA, LP v. Airboss Railway Products, Inc.*, 320 F.3d 1354 (Fed. Cir. 2003); these cases are easily distinguishable. In each case,

the district court actually disposed of all claims in the case. In *Moreau*, the appellant had abandoned the only claim that was not expressly addressed by the district court. 158 F.3d at 244. In *Cox*, the district court expressly dismissed all claims although its reasoning was incorrect as to some of the claims. 783 F.3d at 147-48. And in *Pandrol*, the district court found that the defendants had effectively waived their counterclaims. 320 F.3d at 1362. This case clearly differs from *Cox*, *Moreau*, and *Pandrol*. Unlike in *Moreau* and *Pandrol*, the appellees here did not abandon or waive their enhanced damages claims. To the contrary, they pressed their claims before and after the December 2016 judgment. And unlike *Moreau*, *Cox*, and *Pandrol*, the district court here did not express any indication that it had finally resolved all damages issues.

IV. Failure to Timely File an Interlocutory Appeal Does Not Preclude Review of Liability Issues after Entry of a Final Judgment

The confusion here appears to stem from the fact that the appellants initially tried but failed to file a timely interlocutory appeal under § 1292(c)(2). That, however, does not alter the fact that the appellants still are allowed to seek review of such determinations once a final judgment in the case has been entered.

It is well established as a general rule that parties are allowed to wait for a final judgment to raise all claims of error in a single appeal even though interlocutory appeal was permitted. *See Brownlee v. DynCorp.*, 349 F.3d 1343, 1348-49 (Fed. Cir. 2003) (citing 16 Charles Alan Wright

et al., *Federal Practice and Procedure* § 3921, at 20 n.27 (2d ed. 1996) and cases from other courts).

That rule applies with equal force to situations where a party could have appealed under § 1292(c)(2). *See DNIC Brokerage Co. v. Morrison & Dempsey Comm'cns Inc.*, No. 90-1389, 1991 U.S. App. LEXIS 33748, 1991 WL 335745, at *1 (Fed. Cir. Apr. 25, 1991); *see also Bingham Pump Co. v. Edwards*, 118 F.2d 338, 339 (9th Cir. 1941) (rejecting "suggestion that the question as to the validity of the patent is not open because of a failure to appeal from the interlocutory decree as permitted by" the predecessor statute of § 1292(c)(2)).

We see no reason to treat an appellant who initially tried but failed to file a timely permissive interlocutory appeal differently than one who simply waited until final judgment to raise all claims of error in one appeal.

V. The Appeals are Deactivated, Not Remanded

The appellees mischaracterize this court's June 21, 2017 order as having remanded the case back to the district court; the order did no such thing. The appellants informed this court that at the district court they had filed motions listed under Rule 4(a)(4) of the Federal Rules of Appellate Procedure within 28 days from the date the district court issued its April 24, 2017 order, and currently the motion remains pending. Per the court's usual practice, these appeals were deactivated, as such motions ordinarily render an appeal from a final judgment premature until the motions are acted upon. The court rendered no judgment on the merits of the arguments raised in that motion.

Accordingly,

IT IS ORDERED THAT:

The motion is denied.

For the Court

/s/ Peter R. Markstein
Peter R. Marksteiner
Clerk of Court

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED JUNE 21, 2017

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1950, 2017-2021

BRIGHAM AND WOMEN'S HOSPITAL, INC.,
INVESTORS BIO-TECH, L.P.,

Plaintiffs-Appellees,

v.

PERRIGO COMPANY, L. PERRIGO COMPANY,

Defendants-Appellants.

June 21, 2017, Decided

Appeals from the United States District Court for the District of Massachusetts in No. 1:13-cv-11640-RWZ, Judge Rya W. Zobel.

ON MOTION

Before WALLACH, *Circuit Judge.*

ORDER

The appellees move to dismiss Appeal No. 2017-1950 for lack of jurisdiction and to "limit the issues for review

on appeal" in Appeal No. 2017-2021. The appellants oppose and move to consolidate the above-captioned appeals. The appellees oppose consolidation. The appellants also inform the court of post-judgment motions pending at the district court. The court denies the motion to dismiss and to limit the issues, grants the motion to consolidate, and deactivates these appeals.

This is a patent infringement case in which the appellees' complaint included a claim for enhanced damages pursuant to 35 U.S.C. § 284. On December 14, 2016, the jury returned a verdict in favor of the appellees on infringement and invalidity. On December 19, 2016, judgment was entered without specifying the amount of damages that was owed by the appellants.

On January 24, 2017, the appellants moved for judgment as a matter of law (JMOL) or a new trial under Rules 50(d) and 59(d) of the Federal Rules of Civil Procedure. The appellees moved for enhanced damages and attorneys' fees and opposed the appellants' motions on the ground that they had not been timely filed. In response, on February 17, 2017, the appellants moved for an extension of time to file a notice of appeal and also filed a notice of appeal, which was subsequently docketed as Appeal No. 2017-1950.

On April 24, 2017, the district court resolved the parties' post-trial motions, including the appellees' motion for enhanced damages. As to the appellants' motions, the district court agreed with the appellees that the motions had not been timely filed because they were filed more

than 28 days after the judgment. The district court also denied the appellants' motion to extend time to file an appeal from the December 2016 judgment. On May 11, 2017, the appellants filed a second notice of appeal, which was docketed as Appeal No. 2017-2021.

The appellees argue that the appellants cannot seek this court's review of the underlying infringement and invalidity determinations. They contend that the appellants failed to file a timely appeal from the December 2016 judgment and also failed to file timely Rule 50 and Rule 59 motions that would toll the time to appeal.

There was, however, no final judgment in December 2016; a full accounting of the damages remained outstanding because the issue of enhanced damages had not been resolved. *See PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1365 n.4 (Fed. Cir. 2007); *see also Calderon v. GEICO Gen. Ins. Co.*, 754 F.3d 201, 204 (4th Cir. 2014) ("[A] judgment on liability that does not fix damages is not a final judgment because the assessment of damages is part of the merits of the claim that must be determined." (citation and quotation marks omitted)); *Pause Tech. LLC v. TiVo, Inc.*, 401 F.3d 1290, 1292 (Fed. Cir. 2005) (stating that a "final judgment" is a decision that "'ends the litigation on the merits and leaves nothing for the court to do but execute the judgment.'"(quoting *Catlin v. United States*, 324 U.S. 229, 233, 65 S. Ct. 631, 89 L. Ed. 911 (1945))).

The district court's denomination of the December 2016 judgment as a "final judgment" in the April 24,

2017 order is not controlling. *See Calderon*, 754 F.3d at 204 (citation omitted). Nor is it dispositive that the appellants could have appealed under 28 U.S.C. § 1292(c) but failed to timely do so. While § 1292(c) permits appeals of patent infringement judgments that are "final except for an accounting," such an appeal "is permissive, not mandatory." *DNIC Brokerage Co. v. Morrison & Dempsey Comm'cns Inc.*, No. 90-1389, 1991 U.S. App. LEXIS 33748, 1991 WL 335745, at *1 (Fed. Cir. Apr. 25, 1991) (citing *Adamian v. Jacobsen*, 523 F.2d 929 (9th Cir. 1975)). What matters is that they filed a timely appeal once all the issues were resolved by the April 24, 2017 decision.

The appellees have not shown that dismissal is warranted. The appellants inform this court that they have filed additional Rule 50 and 59 motions, in addition to motions pursuant to Rule 60 of the Federal Rules of Civil Procedure, directed at the April 24, 2017 decision. The court deems it the proper course to deactivate these appeals pending the district court's consideration of the motions. *See* Practice Notes to Federal Circuit Rule 4.

Accordingly,

IT IS ORDERED THAT:

(1) The motions to dismiss and limit the issues are denied.

(2) The motion to consolidate is granted. The revised official caption is reflected above.

(3) The appeals are deactivated. Within seven days from the district court's decision on appellants' now pending post-judgment motions, the parties are directed to inform this court how they believe these appeals should proceed.

FOR THE COURT

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX E — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS FILED APRIL 24, 2017

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 13-11640-RWZ

BRIGHAM AND WOMEN'S HOSPITAL, INC.
AND INVESTORS BIO-TECH, L.P.,

v.

PERRIGO COMPANY AND L PERRIGO COMPANY.

APRIL 24, 2017

MEMORANDUM AND ORDER

ZOBEL, S.D.J.

All parties have filed a series of post-judgment motions. Defendants Perrigo Company and L. Perrigo Company (collectively, "Perrigo") renew their motions for judgment as a matter of law on all issues that were tried to a jury in late December 2016 and, in the alternative, move for a new trial. *See* Dockets ## 247, 249, 252, 255. Perrigo also moves for an extension of time to file a notice of appeal to the Federal Circuit. *See* Docket # 268. Plaintiffs Brigham and Women's Hospital, Inc., and Investors Bio-Tech, LP. (collectively, "Brigham") oppose

all these motions and also move for attorney's fees (Docket # 239) and enhanced damages (Docket # 244).

I. Procedural History

The court held an eight-day jury trial which concluded on December 14, 2016, with a jury verdict in favor of plaintiffs. *See* Docket # 222. Specifically, the jury found (1) direct, induced, contributory, and willful infringement by Perrigo of all asserted claims of U.S. Patent No. 5,229,137 ("the '137 patent"); (2) an effective priority date of March 1990; and (3) all asserted claims valid. It awarded Brigham $10,210,071 in damages[1] and rejected Perrigo's laches defense, finding that Brigham knew or should have known of their infringement claim against Perrigo as of August 11, 2008.

On December 19, 2016, judgment was entered that simply stated that "[t]his action came before the court for a trial by jury. The issues have been tried and the jury has rendered its verdict. . . . Judgment entered for Plaintiffs." *See* Docket # 227.[2] The amount of damages was not included. Shortly after judgment entered, the

1. The jury declined to award pre-judgment interest, and accordingly, the judgment does not reflect any such award. Therefore, I reject Perrigo's perplexing argument that the "12/19 Entry [should be vacated under Rule 60(b)(1) because it] incorrectly awarded pre-judgment interest to the Plaintiffs." Docket # 2781 at 6.

2. That same day, the docket has an entry that the "Civil Case Terminated" on December 19, 2016. *See* Docket # 228. Neither party objected to either of these docket entries.

parties filed a joint motion for extension of time for post-trial motions, seeking to extend the deadlines to file motions for judgment as a matter of law and/or new trial and motion for attorney's fees to January 24, 2017, which the court granted by endorsement. Docket ## 237 and 238. It was only after Brigham filed their oppositions to Perrigo's renewed motions for judgment as a matter of law, however, that the parties raised a potential conflict with the Federal Rules of Civil and Appellate Procedures regarding the timeliness of Perrigo's post-trial motions and notice of appeal.

II. Discussion

After the parties submitted their post-trial briefing regarding the timeliness issue, the court raised initial concerns about the judgment entered on December 19, 2016, specifically, whether it constituted a final judgment that would trigger the clock on the relevant procedural rules because it failed to include any damages, as well as the jury's special verdict on the several claims and defenses. It also failed to address the issue of enhanced damages that had yet to be decided. Accordingly, I requested the parties to submit supplemental briefing regarding these questions and, if necessary, the remedy. *See* Dockets ## 278 and 279. Thus, before addressing the post-trial motions, the threshold question to be resolved is whether a proper judgment was entered in this case.

A. Final Judgment

A "judgment" under the Federal Rule of Civil Procedure is "a decree and any order from which an

appeal lies." Fed. R. Civ. P. 54(a). The Supreme Court has explained that "there is no statute or rule that specifies the essential elements of a final judgment, and [the] Court has held that '[n]o form of words and no peculiar formal act is necessary to evince [the] rendition [of a judgment.]" *United States v. F. & M. Schaefer Brewing Co.*, 356 U.S. 227, 233 (1958) (quoting *United States v. Hark*, 320 U.S. 531, 534 (1944)); *see also Alloyd Gen. Corp. v. Bldg. Leasing Corp.*, 361 F.2d 359, 362 (1st Cir. 1966) (explaining that a final judgment is one that does not leave the suit pending for further proceedings and "clearly evidence[s] the district court's intention that it shall be its final act in the case").

Perrigo contends that the December 19, 2016, entry is not a final and appealable judgment because it "did not expressly dispose of Perrigo's counterclaims of invalidity, non-infringement, and laches." Docket # 278, at 3. Perrigo also argues that the December 19 entry does not satisfy Federal Rule of Civil Procedure 58 because it is "incomplete" as it does not "identify which claims of the asserted patent were found infringed and not invalid and, as the Court pointed out, is silent on damages." *Id.* at 5-6.

Although the judgment lacks the details found on the jury's special verdict form, Perrigo's assertion that the issues of non-infringement[3] obviousness, and laches

3. Although Perrigo asserts that "the 12/19 Entry did not expressly dispose of Perrigo's counterclaims of . . . non-infringement," it provides argument only regarding its defenses of obviousness and laches. *See* Docket # 278, at 3. In any event, I find the jury's verdict was complete in addressing non-infringement by finding infringement on a claim-by-claim basis.

remain outstanding and were not disposed of by the jury's verdict is incorrect. Here, the court instructed the jury to decide all three issues by answering the questions on the verdict form with no objections from Perrigo. Indeed, during Perrigo's closing argument to the jury, it re-iterated the court's instruction and explained that "if [Brigham's] delay [was] unreasonable and Perrigo was harmed because of that delay, then there can be no monetary damages and that's Perrigo's equitable defense of laches." Docket # 235, at 81:12-15. Perrigo explicitly acknowledged that the jury would have to decide whether "plaintiff's delay [was] unreasonable and was Perrigo harmed as a result of it." *Id.* at 81:24-82:1. Accordingly, "[t]he instruction [on laches] was not given to seek a merely advisory verdict on the issue. The jury rejected the defense." *Simon Prop. Grp., L.P. v. mySimon. Inc.*, No. IP 99-1195-C H/G, 2001 WL 66408, at *16 (S.D. Ind. Jan. 24, 2001). Likewise, Perrigo never objected to having the jury decide the question of obviousness. Here too, the jury found that Perrigo had failed to prove invalidity of any of the asserted claims of the '137 patent for both obviousness and anticipation, and thus rejected Perrigo's counterclaim. *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1547 (Fed. Cir. 1983) ("We hold that it is not error to submit the question of obviousness to the jury."); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1248 (Fed. Cir. 2010).

Therefore, the only matter that remains outstanding is the issue of enhanced damages. Docket # 275, at 9:15. The Federal Circuit, however, has exclusive jurisdiction of "an appeal from a judgment in a civil action for patent infringement which would otherwise be appealable to the

[Federal Circuit] and is final *except for an accounting.*" 28 U.S.C. § 1292(c)(2) (emphasis added). "The Federal Circuit has ruled that, as a result [of the § 1292 exception], claims for enhancement of damages do not have to be addressed in order to have a final judgment." *Open Text S.A. v. Box. Inc.*, No. 13-cv-04910-JD, 2015 WL 4940798, at *10 (N.D. Cal. Aug. 19, 2015) (citing *PODS. Inc. v. Porta Star. Inc.*, 484 F.3d 1359, 1365 n. 4 (Fed. Cir. 2007), *appeal dismissed* (Apr. 4, 2016)). Although Perrigo asserts that the December 19 entry does not qualify for the exception to the final judgment rule under 28 U.S.C. § 1292(c)(2), it fails to provide any support for this argument other than re-asserting that the entry "did not dispose of Perrigo's counterclaims of invalidity, non-infringement, and laches, and thus the § 1292 exception does not apply." Docket # 278, at 5.

Moreover, it is difficult to accept in earnest Perrigo's argument that the "12/19 Entry [did not] constitute[] **a *final and appealable judgment*** such that it would trigger the deadlines for filing Perrigo's post-trial motions and Notice of Appeal," Docket # 278, at 2, based on its actions. In particular, shortly after the jury returned its verdict, Perrigo sought entry of judgment from the court in order to "determine deadlines for post-trial motions," Docket # 280-2, at 2, and then proceeded to act in accordance with an understanding that the judgment was final by submitting post-trial briefing. *E.g.* Docket # 268, at 1 (explaining in its motion for extension of time to file notice of appeal that "[t]he Court entered Final Judgment in favor of Plaintiffs on December 19, 2016."); *cf F. & M. Schaefer Brewing Co.*, 356 U.S. at 235-36 (looking at

"[t]he actions of all concerned" when determining whether the parties "understood the opinion to be the judge's. . . final judgment in the case").

B. Post-Trial Briefing and Defendants' Motion to Extend Time to File Notice of Appeal

Because the December 19, 2016, judgment was final, Perrigo had to adhere to the federal procedural rules regarding the deadlines for filing post-trial motions. Specifically, Perrigo had twenty-eight days after the entry of judgment to file a renewed motion for judgment as a matter of law or joint request for a new trial. *See* Fed. R. Civ. P. 50(b) and 59(b). This deadline is mandatory; "[a] court must not extend the time to act under Rules 50(b). . . 59(b), (d), and (e), and 60(b)." Fed. R. Civ. P. 6(b)(2).

Perrigo argues that the time limitations in Rules 50(b) and 59(e) are "claim-processing" rules and not jurisdictional time limitations, and thus, Brigham "waived their objection to the timeliness of Perrigo's post-trial motions when they expressly agreed to and filed a joint motion to extend the post-trial motion deadlines." Docket # 273, at 2. It further contends that the court should apply the unique circumstances doctrine to excuse Perrigo's delay because it acted in reliance on the court's ruling.

First, whether Brigham waived its objection is irrelevant because the court did not have the authority under Rule 6(b)(2) in the first instance to allow the joint motion extending the Rule 50(b) and 59(e) deadlines. Second, the court's granting of the parties' joint motion

by endorsement was not an affirmative "assurance" from the court that the parties were in compliance with the Federal Rules, which prohibits the court from extending the post-trial briefing deadline. *See Garcia-Velazquez v. Frito Lay Snacks Caribbean*, 358 F.3d 6, 10 (1st Cir. 2004) (explaining that "[t]o the extent [the unique circumstances doctrine] remains viable, the doctrine 'applies only where a party has performed an act which, if properly done, would postpone the deadline for filing [the] appeal and has received specific assurance by a judicial officer that this act has been properly done'") (quoting *Osterneck v. Ernst & Whitney*, 489 U.S. 169, 179 (1989)). Thus, although the parties jointly moved to extend the deadline to file post-trial motions, and although the court granted by endorsement such a motion, neither the parties nor the court had the authority to do so per Federal Rule of Civil Procedure 6(b)(2).[4] *See Scola v. Beaulieu Wielsbeke, N.V.*, 131 F.3d 1073, 1074 (1st Cir. 1997) (finding that the unique

4. The court recognizes that difficulty in reaching this decision because on its face the rules are divorced from one another; Rules 50(b) and 59(e) make no cross-reference to Rule 6(b)(2). Nevertheless, it is the duty of counsel to review the Federal Rules in their entirety. *See Dill v. Gen. Am. Life Ins. Co.*, 525 F.3d 612, 620 (8th Cir. 2008) (noting that "[a]lthough this is a harsh and unfortunate result for [defendant], as it relied on the extension granted by the district court, [defendant] is not without fault—a simple scan of Rule 6(b)(2) would have provided [defendant] notice that the district court lacked authority to grant an extension of time to file the Rule 50(b) motion") (citation omitted); *but see S.O.I.TEC Silicon On Insulator Tech., S.A. v. MEMC Elect. Materials, Inc.*, No. 08-cv-292-SLR. 2011 WL 2748725, at *8 (D. Del. July 13, 2011) (applying the unique circumstances doctrine and allowing a day late-filed Rule 50(b) motion).

circumstances doctrine did not apply where the court improperly granted by endorsement an extension of the Rule 59(e) motion filing deadline). As a result, Perrigo had until January 17, 2017, to file its renewed motions for judgment as a matter of law, but filed such motions, instead, on January 24, 2017.

Similarly, under Federal Rule of Appellate Procedure 4(a)(1)(A), Perrigo had thirty days after the entry of judgment to file a notice of appeal with the district clerk. In other words, it had until January 19, 2017, to file its notice of appeal. Perrigo, however, did not file a notice of appeal until February 17, 2017. Perrigo now moves to extend the time to file a notice of appeal for good cause. *See* Fed. R. App. P. 4(a)(5). It argues that good cause exists for the court to grant its extension because "it relied on the Court's order setting a post-trial briefing schedule and Plaintiffs' agreement with that schedule." Docket # 268, at 1.

Setting aside the fact that neither the parties nor the court had the authority to extend the post-trial briefing schedule, an extension of post-trial briefing has no effect on the time to file a notice of appeal. The Federal Rules of Appellate Procedure require a party to file a notice of appeal within thirty days after entry of the judgment. Fed. R. App. P. 4(a)(1)(A). And the rules toll the time to appeal when a party seeks to file renewed motions for judgment as a matter of law. The rules state that "[i]f a party timely files in the district court [a motion for judgment under Rule 50(b) or a motion for a new trial under Rule 59], the time to file an appeal runs for all

parties from the entry of the order disposing of the last such remaining motion." Fed. R. App. P. 4(a)(4)(A). "[T]he notice becomes effective to appeal a judgment or order, in whole or in part, when the order disposing of the last such remaining motion is entered." Fed. R. App. P. 4(a)(4)(B)(i). The 2016 Advisory Committee Notes further explain that "[a] motion made after the time allowed by the Civil Rules will not qualify as a motion that, under Rule 4(a)(4)(A), re-starts the appeal time—and that fact is not altered by, for example, a court order that sets a due date that is later than permitted by the Civil Rules, another party's consent or failure to object to the motion's lateness." Fed. R. App. P. 4(a)(4)(A) advisory committee's note to 2016 amendment. Accordingly, Perrigo was required to file a notice of appeal within thirty days following entry of the judgment—to which Perrigo never objected until the court's inquiry—regardless of the (improper) extension of a post-trial briefing schedule.

Although a court may extend the time to file a notice of appeal if the moving party establishes that either good cause or excusable neglect exists, Perrigo has failed to establish either grounds for extension. Fed. R. App. P. 4(a)(5). Good cause exists if the "tardiness in filing a notice of appeal resulted entirely from external causes." *Mirpuri v. ACT Mfg., Inc.*, 212 F.3d 624, 630 (1st Cir. 2000). Here, there were no external causes. *See id.* (finding that no good cause existed to extend notice to appeal where, even assuming "that the district court's decision was unclear as to its finality, the clerk also entered an unambiguous 'case closed' notation on the docket, and the plaintiffs could have discovered this telltale simply by checking the docket in person or on-line at any time thereafter").

Because Perrigo's post-trial motions and notice of appeal were filed after the mandatory deadlines, which the court has no authority to extend, they are denied as untimely.[5]

C. Brigham's Motion for Attorney's Fees

On January 17, 2017, Brigham filed its motion for attorney's fees, which was also dilatory and filed well after the mandatory deadline.[6] See Fed. R. Civ. P. 54(d)(2)B)(i).The Patent Act allows for the court to award attorney's fees to the prevailing party in "exceptional cases." *See* 35 U.S.C. § 285. Brigham bears the burden to establish by a preponderance of the evidence that this case was "exceptional." *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1758 (2014). "[A]n 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in

5. In the alternative, Perrigo requests that the court vacate judgment under Federal Rule of Civil Procedure 60(b)(6) because "equity strongly favors Perrigo because Plaintiffs initiated and agreed to an extension of post-trial motions and thus waived any argument regarding their alleged untimeliness." Docket # 278, at 6. For the reasons discussed above, the facts of this case do not warrant vacating judgment. *See Ackermann v. United States*, 340 U.S. 193, 199 (1950) (explaining that Rule 60(b)(6) relief is proper only in "extraordinary circumstances").

6. However, unlike Rule 50(b) and 59(e) motions, a court may extend the deadline to file a motion for attorney's fees, which this court did by endorsement of the parties' joint motion for extension of deadlines. *See* Docket # 238.

which the case was litigated." *Id.* at 1756. The court can also consider factors such as frivolousness, motivation, objective unreasonableness, and the need to advance considerations of compensation and deterrence. *Id.* at 1756 n.6. After considering the totality of the circumstances, courts should exercise "equitable discretion" in deciding whether to award attorney's fees. *Id.* at 1756.

Here, under the totality of the circumstances, I find that this is not an exceptional case. Perrigo investigated whether it infringed the '137 patent, and whether the patent was valid, and after concluding that it did not infringe and that the '137 patent was invalid, it sent a Paragraph IV certification to Brigham upon filing an ANDA. While Perrigo's invalidity arguments ultimately failed, its defense of the suit was neither frivolous or vexatious. Brigham's own corporate witness, Harry Barnett, testified that one of the reasons plaintiffs did not bring suit against Perrigo after receiving the Paragraph IV certification was because they feared losing royalties if the '137 patent was found invalid. *See* Docket # 225, at 110:1-9. Brigham also argues that it should be awarded fees due to Perrigo's "obstructionist" conduct throughout trial. Docket # 240, at 24. Both parties vigorously litigated their respective positions—at times acrimoniously so—but Perrigo's behavior did not rise to the level of litigation misconduct. Because this case is not exceptional, attorney's fees are not appropriate.

D. Brigham's Motion for Enhanced Damages

Section 284 of the Patent Act also provides that, in a case of infringement, courts "may increase the damages

up to three times the amount found or assessed." *See* 35 U.S.C. § 284. The Supreme Court has instructed that "[c]onsistent with nearly two centuries of enhanced damages under patent law, however, such punishment should generally be reserved for egregious cases typified by willful misconduct." *Halo Elec. Inc. v. Pulse Elec. Inc.*, 136 S. Ct. 1923, 1934 (2016). In other words, "this is not to say that a jury verdict of willful infringement ought to result in enhanced damages. Whether the conduct is sufficiently egregious as to warrant enhancement and the amount of the enhancement that is appropriate are committed to the sound discretion of the district court." *WBIP, LLC. v. Kohler Co.*, 829 F.3d 1317, 1341 n.13 (Fed. Cir. 2016). Brigham bears the burden of showing by a preponderance of the evidence that Perrigo engaged in such egregious conduct. *Halo*, 136 S. Ct. at 1934.

Here, the jury found that Perrigo willfully infringed the '137 patent. I do not disturb the jury's finding. I do find, however, that Perrigo's conduct did not rise to the level of egregiousness meriting an award of enhanced damages. *See Sociedad Espanola de Electromedicina y Calidad. S.A. v. Blue Ridge X-Ray Co, Inc.*, No. 1:10-cv-00159-MR, 2016 WL 7473422, at *7 (W.D.N.C. Dec. 28, 2016) ("The jury's finding of willful infringement, however, 'does not mandate that damages be enhanced, much less mandate treble damages.'" (quoting *Read Corp. v. Portee. Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992))). Although the various factors set forth in *Read Corp.* may be useful to help determine whether an award of enhanced damages is warranted, the Supreme Court has cautioned that "there is no precise rule or formula for awarding damages under § 284[.]" *Halo*, 136 S. Ct. at 1932 (citation omitted); *see*

also Trustees of Boston Univ. v. Everlight Elec. Co. Ltd., No. 12-cv-12326-PBS, 2016 WL 3976617, at *2 (D. Mass. July 22, 2016) ("[T]he touchstone for awarding enhanced damages after *Halo* is egregiousness."). For the same reasons discussed above regarding Brigham's motion for attorney's fees, I find that Perrigo's conduct was not egregious. Further, the jury's award of $10,210,071 in damages is at the high end of the damages sought. The evidence reflected that prior license agreements to the '137 patent used royalty rates between one to three percent. Brigham's expert opined that a reasonable royalty rate equates to approximately eighteen percent, or nearly six times that in the prior licenses. The jury adopted that expert's method of calculation and awarded the full amount Brigham sought. Under these circumstances, enhanced damages are inappropriate. *Cf. Enplas Display Device Corp. v. Seoul Semiconductor Co. Ltd.*, No. 13-cv-05038 NC, 2016 WL 4208236, at *8 (N.D. Cal. Aug. 10, 2016) (declining to award enhanced damages despite a finding of willful infringement because "[t]he jury awarded the maximum amount that. . . [plaintiff] sought. [Plaintiff] has recovered the full value of its requested relief').

III. Conclusion

Brigham's Motion for Attorney Fees (Docket # 239) and Motion for Enhanced Damages Pursuant to 35 U.S.C. § 284 (Docket # 244) are DENIED.

Perrigo's Renewed Motions for

(a) Judgment as a Matter of Law of No Direct, No Indirect, and No Willful Infringement, and Motion for New Trial (Docket # 247),

(b) Judgment of Invalidity as a Matter of Law or New Trial and Motion for Judgment of Invalidity Over the Prior Art (Docket # 249),

(c) Judgment as a Matter of Law on Damages, and Motion for Remittitur or New Trial (Docket # 252), and

(d) Judgment as a Matter of Law on Lack of Standing[7] and Laches (Docket # 255) are DENIED.

Perrigo's Motion for Extension of Time to 2/17/2017 to File a Notice of Appeal from the Court's Final Judgment (Docket # 268) is DENIED.

Perrigo's Motion for Leave to File *Instanter* A Reply in Support of Their Renewed Motion for Judgment as a Matter of Law of No Direct, No Indirect, and No Willful Infringement, and Motion for New Trial (Docket # 273) is ALLOWED.

April 24, 2017
DATE

/s/ RYA ZOBEL
RYA W. ZOBEL
SENIOR UNITED
STATES DISTRICT JUDGE

7. The issue of standing was not decided by the jury. Rather, prior to commencement of trial, and after hearing the parties' oral arguments, I denied Perrigo's motion to dismiss for lack of standing (Docket # 191) from the bench. *See* Docket # 224, at 72:7-10. Accordingly, the appropriate request for relief was a motion for reconsideration.

APPENDIX F — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS FILED DECEMBER 19, 2016

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 13CV11640-RWZ

BRIGHAM AND WOMEN'S HOSPITAL *et al.*,

Plaintiff(s),

v.

PERRIGO COMPANY *et al.*,

Defendant(s).

JUDGMENT IN A CIVIL CASE

☒ **Jury Verdict.** This action came before the court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

☐ **Decision by the Court.** This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED:

Judgment entered for Plaintiffs.

Dated: 12/19/16

By /s/ Lisa A. Urso
Deputy Clerk

APPENDIX G — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED MAY 2, 2019

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIGHAM AND WOMEN'S HOSPITAL, INC.,
INVESTORS BIO-TECH, L.P.,

Plaintiffs-Cross-Appellants,

v.

PERRIGO COMPANY,
L. PERRIGO COMPANY,

Defendants-Appellants.

2017-1950, 2017-2021, 2017-2555, 2018-1243

Appeals from the United States District Court for the District of Massachusetts in No. 1:13-cv-11640-RWZ, Judge Rya W. Zobel.

ON PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, CHEN, HUGHES, and STOLL, *Circuit Judges.*[*]

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* Circuit Judge Taranto did not participate.

Appendix G

PER CURIAM.

ORDER

Cross-Appellants Brigham and Women's Hospital, Inc. and Investors Bio-Tech, L.P. filed a combined petition for panel rehearing and rehearing *en banc*. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing *en banc* was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing *en banc* is denied.

The mandate of the court will issue on May 9, 2019.

FOR THE COURT

May 2, 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court