

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

MEMORANDUM AND ORDER

November 17, 2017

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 H₂-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 H₂-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 substantially simultaneously with an ANTACID.” Docket # 304-2, at DTX-0005-0014. The parties agreed to notify each other “promptly

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.).

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.

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.

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

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.”)

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, 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 the launch of its Generic Product in 2008 constituted a

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.” 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.

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 standing⁵ 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 out of 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 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,

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.

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 out of 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

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.

asserted claim.” Catalina Marketing Int’l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 812 (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 ANDA⁷ and studies from the New Drug Application (“NDA”) for Pepcid Complete that Brigham contends were incorporated into Perrigo’s label.⁸ Brigham 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

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).

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.”).

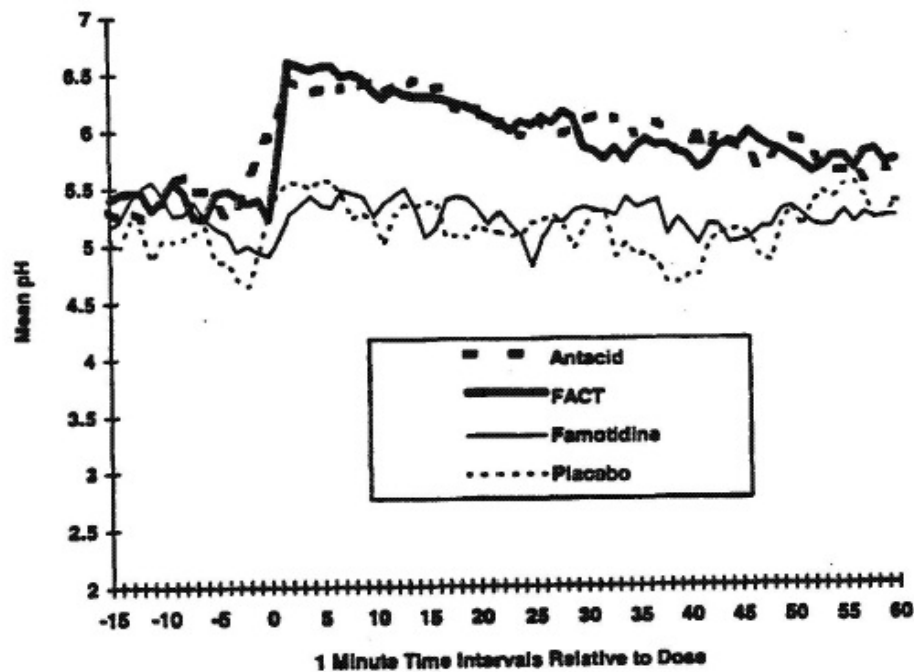
The main dispute hinges on whether Brigham successfully proved that its product meets the “immediate and sustained relief” limitation in claim 1. The court construed that limitation to mean “relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 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 ingredients⁹ 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:

Figure 7

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



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).

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.

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 Procter & 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 co-administration 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).

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, pharmaceuticals, biopharmaceuticals or a doctorate in

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

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 Bringham’s claims for infringement, the jury’s award of damages cannot stand.¹² See CVI/Beta Ventures, Inc.

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

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.

November 17, 2017

DATE

/s/Rya W. Zobel

RYA W. ZOBEL
SENIOR UNITED STATES DISTRICT JUDGE