IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC., Defendant.	Civil Action No. 15-cv-839-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

On September 18, 2015, Amgen, Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") sued Hospira, Inc. for infringement of U.S. Patent No. 5,856,298 under 35 U.S.C. §§ 271(a) and 271(e)(2)(C) and for infringement of U.S. Pat. No. 5,756,349 under § 271(a). (D.I. 1). The '298 patent and the '349 patent cover erythropoietin ("epoetin" or "EPO") isoforms and aspects of their production. Hospira submitted Biologic License Application ("BLA") No. 125-545 to the FDA in December 2014, seeking FDA approval for Hospira's epoetin biosimilar product. (D.I. 290-1 at 1). Amgen asserts that Hospira's manufacture of drug substance for its epoetin biosimilar drug product infringes claims 24 and 27 of the '298 patent and claims 1-7 of the '349 patent. (D.I. 290 at 1).

I held a jury trial from September 18-22, 2017. (D.I. 328-332 ("Trial Tr.")).[1] The jury found each of the asserted claims not proved invalid, decided that the asserted claims of the '349 patent were not infringed, and returned a verdict of infringement of all asserted claims of the '298 patent. (D.I. 325 at 2). Of Hospira's twenty-one accused drug substance batches, the jury found seven batches entitled to the safe harbor defense. (*Id.* at 3). The jury awarded Amgen $70 million in damages for Hospira's infringement. (*Id.* at 4).

Presently before the Court are Hospira's Rule 50(a) Motion for Judgment as a Matter of Law on the Issues of Safe Harbor, Noninfringement, Invalidity, and Damages and related briefing (D.I. 336, 337, 348, 351), Hospira's Motion for Judgment as a Matter of Law Under Rule 50(b) and, in the Alternative, For Remittitur or New Trial Under Rule 59 and related briefing (D.I. 355, 357, 374, 381), Hospira's Motion to Seal Confidential Exhibits Admitted at Trial and related briefing (D.I. 361, 369, 370), Amgen's Renewed Motion for Judgment as a Matter of Law of

[1] The trial transcript is consecutively paginated. References to the trial transcript will refer to "Trial Tr." in lieu of the docket item reference number.

Infringement of the '349 Patent or, in the Alternative, for a New Trial and related briefing (D.I. 356, 358, 373, 380), and Amgen's Motion for Prejudgment and Post-judgment Interest and related briefing (D.I. 352, 376, 382).

I. LEGAL STANDARDS

A. Judgment as a Matter of Law

Judgment as a matter of law is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. FED. R. CIV. P. 50(a)(1). "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted).

In assessing the sufficiency of the evidence, the Court must give the nonmovant, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor and, in general, view the record in the light most favorable to him." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991). The Court may "not determine the credibility of the witnesses [nor] substitute its choice for that of the jury between conflicting elements in the evidence." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984). Rather, the Court must determine whether the evidence reasonably supports the jury's verdict. *See Gomez v. Allegheny Health Servs. Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995); 9B *Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure* § 2524 (3d ed. 2008) ("The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence

upon which the jury might reasonably find a verdict for that party.").

Where the movant bears the burden of proof, the Third Circuit applies a stricter standard. *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976). To grant judgment as a matter of law in favor of a party that bears the burden of proof on an issue, the Court "must be able to say not only that there is sufficient evidence to support the [movant's proposed] finding, even though other evidence could support as well a contrary finding, but additionally that there is insufficient evidence for permitting any different finding." *Id.*

B. New Trial

Federal Rule of Civil Procedure 59(a)(1)(A) provides, in pertinent part: "The court may, on motion, grant a new trial on all or some of the issues—and to any party— . . . after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court . . . ." Among the most common reasons for granting a new trial are: "(1) when the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) when newly discovered evidence exists that would likely alter the outcome of the trial; (3) when improper conduct by an attorney or the court unfairly influenced the verdict; or (4) when the jury's verdict was facially inconsistent." *See Zarow-Smith v. N.J. Transit Rail Operations, Inc.*, 953 F. Supp. 581, 584-85 (D.N.J. 1997) (citations omitted).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem Corp.*, 9 F.3d 282, 289 (3d Cir. 1993). Although the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law—in that the Court need not view the evidence in the light most favorable to the verdict winner—a new trial should only be granted where "a miscarriage of justice would result if the verdict were to stand" or where the

verdict "cries out to be overturned" or "shocks [the] conscience." *Williamson*, 926 F.2d at 1352-53.

II. HOSPIRA'S 50(a) AND 50(b) MOTIONS

Hospira's Rule 50(a) motion raises the same issues as its Rule 50(b) motion.[2] Having considered and decided the issues in ruling on Hospira's Rule 50(b) motion, I will dismiss Hospira's Rule 50(a) motion as moot.

Hospira seeks judgment as a matter of law on the issues of the applicability of its safe harbor defense, noninfringement and invalidity of the '298 patent, and damages. (D.I. 357, pp. 1-22). Alternatively, Hospira seeks a new trial based on what it characterizes as improper jury instructions on the safe harbor defense and third party liability, improper claim construction, and contradictory infringement and validity verdicts. (*Id.* pp. 22-30). Finally, Hospira argues that it is entitled to a remittitur of the damages award. (*Id.* p. 28).

A. JMOL

1. Safe Harbor

The parties dispute whether any reasonable jury could have found some, but not all, of Hospira's drug substance batches protected by the "safe harbor" defense. (*Id.* p. 1; D.I. 374, p. 2).

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") "create[s] an artificial 'act of infringement,' similar to that of 35 U.S.C. § 271(e)(2)(A), and [allows] infringement suits to begin based on the filing of a biosimilar application prior to FDA approval and prior to marketing of the biological product." *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1321 (Fed. Cir. 2017) (citing 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6)). Section 271(e)(1) carves out an

[2] Hospira's Rule 50(a) motion, filed based on information known at the close of Amgen's case-in-chief, raises the issue of noninfringement of the '349 patent. (D.I. 337 at 10). This issue was mooted when Hospira received a verdict of noninfringement of the '349 patent at trial, and Hospira's Rule 50(b) motion does not raise it. (D.I. 325 at 2).

exception to this rule, creating a "safe harbor" defense for defendants when their otherwise-infringing activities are "solely for uses reasonably related" to obtaining FDA approval. 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997) ("By its terms, this shield from infringement permits use of 'patented invention[s]' to acquire information for regulatory approval of 'drugs or veterinary biological products.'") (brackets in original). "As long as the activity is reasonably related to FDA approval, [a party's] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield." *Abtox*, 122 F.3d at 1030.

Hospira asserts that no reasonable jury could find that the safe harbor defense did not protect each of its twenty-one drug substance batches. (D.I. 357, p. 1). Additionally, Hospira contends that Amgen's arguments improperly limited the applicability of the safe harbor defense to batches required for FDA approval. (*Id.* p. 5). Since each batch was used for one or more of biosimilarity[3] testing, updating product specifications, process validation, stability testing, or continued process verification, Hospira insists that no reasonable jury could have found that each of the batches was not reasonably related to obtaining FDA approval. (*Id.* pp. 4-8). According to Hospira, the jury improperly second-guessed the number of batches that Hospira manufactured,

[3] Hospira cites draft guidance from the FDA, published on September 22, 2017 and distributed for comment purposes only, as further support for its argument that each of the 2013 drug substance batches were reasonably related to FDA approval. (D.I. 357, p. 4). The draft guidance "recommend[s] a minimum of 10 reference product lots be sampled" in order "to establish meaningful similarity acceptance criteria." (D.I. 357-1 at 7).

Hospira seeks to rely on the draft guidance to support its argument that no reasonable jury could have concluded that the safe harbor did not protect each drug substance batch that Hospira used for biosimilarity testing. The draft guidance was not publicly available at the time of trial, let alone at the time Hospira manufactured the drug substance batches at issue. The draft guidance was not presented to the jury. I thus find Hospira's reliance on the draft guidance misplaced.

when "the subjective reason why any batch was made is not relevant" to whether the safe harbor applies. (D.I. 381, pp. 3-4). Essentially, Hospira argues that since Hospira generated test data for each batch prior to FDA approval, each batch could conceivably have been used to respond to inquiries from the FDA, and each batch was reasonably related to FDA approval.

Amgen disagrees and maintains that substantial evidence supports the jury's reasonable conclusion that Hospira failed to prove that the safe harbor defense applies to each of Hospira's drug substance batches. (D.I. 374, p. 2). According to Amgen, the evidence presented at trial gave the jury ample reason to reject Hospira's arguments about biosimilarity, product specifications, process validation, stability, and continued process verification; credit Amgen's witnesses; and conclude that the safe harbor applied to only seven of Hospira's twenty-one drug substance batches. (*Id.* pp. 2-4).

Regarding biosimilarity, even accepting as true that ten reference product lots are required to establish biosimilarity, Amgen points out that Hospira performed biosimilarity testing on drug product batches, not drug substance batches, and that Hospira had previously manufactured twenty-six drug product batches from four drug substance batches. (*Id.* p. 12 (citing Trial Tr. 811:24-812:8; DTX-266 at 3-4)). Therefore, Amgen argues, though Hospira performed biosimilarity testing on nine drug substance batches, "the jury reasonably concluded that the final two of those batches were not made for uses reasonably related to seeking FDA approval where Hospira had made 26 drug product batches from just 4 of those drug substance batches for biosimilarity testing." (*Id.* pp. 12-13).

Amgen also argues, "Hospira's witnesses admitted, and its submissions to the FDA confirmed, that the FDA never required Hospira to manufacture any additional batches of its drug substance to support its narrowed release specifications." (*Id.* p. 10 (citing Trial Tr. 823:4-824:1)).

Regardless, Hospira would be required to perform release testing on all batches manufactured before or after FDA approval to ensure that the batches complied with the release specifications in place at the time of manufacture. (Trial Tr. 819:11-22). Each of the batches at issue in this case "were released against specifications that were in place at the time of manufacture, not against revised specifications," and they remain available to Hospira for future use, since they comply with the release specifications at the time of their manufacture (D.I. 374, p. 10 (citing Trial Tr. 820:24-822:1)). Therefore, Amgen asserts, Hospira's revised product specifications do not justify the conclusion that product specification testing on each of the batches at issue was reasonably related to obtaining FDA approval.

Regarding process validation, Amgen submits that the "Process Validation and/or Evaluation" section of Hospira's BLA does not refer to batches other than those admitted by Amgen or found by the jury to fall within the safe harbor. (*Id.* p. 11 (citing DTX-250)). Amgen points out that even Hospira's updated BLA does not list any of the fourteen batches that the jury found to fall outside the safe harbor defense. (*Id.*). Additionally, Amgen notes, cleaning validation is "the only specific process validation that Hospira raises in its motion," and "Hospira's FDA expert, Dr. Levine, admitted that cleaning validation need not be completed before FDA approval."[4] (*Id.* (citing Trial Tr. 1102:14-24, 1153:16-18); *see also* Trial Tr. 878:5-18 (Dr. Billingham acknowledging same)).

Stability testing would not have required a reasonable jury to conclude that each of Hospira's batches was protected by the safe harbor, Amgen argues, because FDA guidance

[4] Amgen maintains that Hospira relied on a cleaning validation document authored by GSK for Hospira (DTX-252), in lieu of presenting any cleaning validation data submitted to the FDA. (D.I. 374, p. 12). In reply, Hospira responds, "Dr. Billingham clearly testified that all of the 2013, 2014, and some 2015 batches were used in several cleaning validation studies to be completed before FDA inspection," and that the FDA requires that such cleaning validation studies be performed. (D.I. 381, p. 7).

requires only three batches to demonstrate stability before obtaining FDA approval. (D.I. 374, p. 9 (citing PTX-492, p. 3)). Amgen argues that the jury was therefore free to credit Dr. Martin-Moe's testimony that Hospira's five batches from 2009 to 2012 would have provided sufficient stability data. (*Id.* (citing Trial Tr. 1329:6-1331:9)). Additionally, stability testing was required each time a new drug substance batch was made, regardless of the future uses for the batch. (Trial Tr. 1338:2-1339:5). As further support, Amgen cites an internal Hospira Risk Authorization document confirming Hospira's belief that material from drug substance batches manufactured in 2009 and 2012 was sufficient to "support [the drug substance] 'shelf life and commercial saleability of material produced in subsequent campaigns.'" (D.I. 374, pp. 9-10 (quoting PTX-342 at 1)). The Risk Authorization further states, "The balance of the material from the 2013 campaign (approximately 50%) and most of the material from the 2014 and 2015 campaigns will serve as commercial inventory to support single dose vial launch stock."[5] (PTX-342 at 1).

Like stability testing, Amgen's witnesses testified that continued process verification is "an ongoing program . . . during routine commercial production" that sometimes "can take many years to complete." (D.I. 374, p. 8 (citing Trial Tr. 1336:21-1337:9)). Though the FDA requires that applicants have committed to a continued process verification program before approval, completing continued process verification is not required to obtain FDA approval. (Trial Tr. 1337:10-13; *see also* PTX-435, p. 14). Hospira's witnesses confirmed that continued process verification need not be completed before FDA approval, and Hospira made no commitment to manufacture the thirty batches tested for continued process verification prior to FDA approval. (Trial Tr. 752:7-11 (Ms. Dianis), 747:17-748:3 (Ms. Dianis), 883:3-6 (Dr. Billingham), 1095:8-24 (Dr. Levine)).

[5] The remaining 50% of the 2013 drug substance material was to be "allocated to continuing CMC and Clinical development work." (PTX-342 at 1).

Amgen further argues that the jury was free to credit Amgen's witnesses over Hospira's witnesses given the evidence presented. (D.I. 374, pp. 4-5). First, though Hospira argues that it manufactured each of the 2013, 2014, and 2015 drug substance batches for use in obtaining FDA approval, Amgen notes that Ms. Dianis, the regulatory lead for Hospira's EPO product, "admitted that she did not know why Hospira made its 2015 batches, or why Hospira made as many batches as it did, and that she assumed Hospira's supply team (not the regulatory team) made those decisions." (*Id.* (citing Trial Tr. 738:22-740:2)). Second, though Hospira informed the FDA in 2014 that its 2013 and 2014 batches were for "commercial inventory," Hospira's 2015 resubmission (after litigation began) designated these batches for use for continued process verification. (*Id.* at 5 (citing PTX-250 at 4-6; DTX-255 at 5-8); *see also* Trial Tr. 748:9-751:23). Third, Dr. Levine admitted that he did not consider whether Hospira made any batches for commercial inventory, and that "simply submitting data [to the FDA] isn't a justification" for manufacturing a batch of drug substance. (Trial Tr. 1075:18-1076:1, 1098:1-10).

I agree with Amgen and conclude that substantial evidence supports the jury's verdict that not all of Hospira's drug substance batches are protected by the safe harbor. To demonstrate entitlement to judgment as a matter of law on its safe harbor defense, Hospira must demonstrate that "there is insufficient evidence for permitting any other finding." *Fireman's Fund Ins. Co.*, 540F.2d at 1177. Hospira has not met that burden.

A reasonable jury could have concluded that fewer than all of the batches were protected by the safe harbor defense. Testimony by Ms. Dianis and Dr. Levine either called into question or contradicted Hospira's argument that each of the batches at issue fell within the safe harbor defense. Amgen's presentation of FDA guidance documents, admissions in Hospira's internal documents, and post-litigation changes to Hospira's representations to the FDA also challenged

Hospira's assertion that each batch at issue was covered by the safe harbor. Finally, Hospira's argument that the jury impermissibly focused on Hospira's intent in manufacturing the batches does not stand up to further scrutiny. Though all of the 2015 batches were designated for use as "commercial inventory" in Hospira's Risk Authorization, the jury nonetheless found that some of those batches were protected by the safe harbor. (D.I. 325 at 3). This suggests that the jury did not improperly base its verdict on Hospira's intent. I therefore conclude that substantial evidence supports the jury's verdict that only some batches at issue are covered by the safe harbor defense. I will deny Hospira's motion for JMOL on this ground.

2. *Noninfringement of the '298 Patent*

Hospira submits that I should grant its motion for JMOL that it does not infringe claims 24 or 27 of the '298 patent.

Hospira contends that it is entitled to JMOL of noninfringement of claim 24 of the 298 patent because "Amgen failed to prove that Hospira's process 'selectively elutes' isoforms as required by claim 24 and as construed by the Court." (D.I. 357, p. 12). According to Hospira, elution of all biologically active isoforms does not qualify as selective elution. (*Id.*). Specifically, "Hospira's process does not achieve a precise set of isoforms;" instead, it "results in a variable number of different isoforms [i.e., five to eight], and a variable amount of each isoform in the drug substance." (*Id.* (citing Trial Tr. 984:5-989:17 (Dr. Levine))). Dr. Levine opined that such variability is not consistent with selective elution, because one would expect consistent levels of each isoform across batches in a selective elution process. (Trial Tr. 989:3-9, 1580:4-23). Finally, Hospira argues that Amgen failed to prove infringement of the '298 patent because it did not provide any analysis of the starting material that Hospira puts into the chromatography column. (D.I. 381, p. 9).

Amgen maintains that substantial evidence supports the jury's conclusion that Hospira's process "selectively elutes" isoforms as required by claim 24 of the '298 patent. Dr. Cummings testified that Hospira's process "selectively elutes" isoforms because it "first elute[s] more basic isoforms from the chromatography column, then elute[s] the remaining desired isoforms." (D.I. 374, p. 13 (citing Trial Tr. 468:11-469:4)). During trial, Amgen argued that Dr. Levine ignored the first step in the elution process, and that Dr. Levine admitted that he "was intentionally not showing those [more basic isoform elution] steps because [he] had already discussed this" the day before. (Trial Tr. 1156:22-1157:13). Amgen also notes that contrary to Hospira's argument, the Court's claim construction for claim 24 does not "require a 'precise set of predetermined isoforms.'" (D.I. 374, p. 14; *see also* D.I. 180 at 2). Further, Dr. Strickland, the inventor on the '298 patent, testified that the process he invented "select[s] isoforms by—well, specific mixtures of isoforms[,] by selective elution of an ion exchange chromatography column." (Trial Tr. 373:14-20). As further evidence that Hospira's process met the "selectively elute" limitation, Amgen offered Hospira's lot release specifications, which specified five isoforms that must be present, and three additional isoforms that may be present, with specific ranges for each isoform. (DTX-141, p. 7; Trial Tr. 470:13-472:19). Finally, Amgen asserts that Hospira's "starting material" argument is frivolous because "Hospira admitted in its BLA that its ion-exchange chromatography process first removed the 'more basic' isoforms . . . from the column (DTX-116 at 58), a step that would not be necessary if the starting material did not contain isoforms that were 'more basic' than the isoforms required by Hospira's release specification." (D.I. 374, p. 15). Similarly, Hospira's BLA test results reveal that the only isoforms present in the material leaving the column in Hospira's process are the same isoforms present in Hospira's drug substance. (*Id.* (citing DTX-139, p. 102; DTX-141, p. 7; Trial Tr. 474:19-476:11)).

I agree with Amgen that substantial evidence supports the jury's verdict that Hospira infringes claim 24 of the '298 patent. Dr. Strickland's testimony, Hospira's release specifications, and Dr. Cummings' testimony provided the jury substantial evidence to conclude that Hospira's process met the "selectively elute" limitation and infringed claim 24 of the '298 patent. Additionally, I think Dr. Levine's admission that he did not include all steps of the process in his demonstratives for the jury provided a basis for the jury to question the reliability of his conclusions and discount his testimony.

Claim 27 of the '298 patent requires "preparing a mixture of two or more erythropoietin isoforms of claim 1." Though I construed claim 27 as an independent claim, Hospira argues that it is entitled to JMOL because Amgen did not mention claim 1 during trial, nor did it present evidence that "isoforms are isolated during Hospira's manufacturing process." (D.I. 357, p. 13). Amgen responds that since claim 27 is an independent claim, Amgen was not required to present evidence that each of the limitations of claim 1 was met in order to prove infringement of claim 27. (*Id.* p. 15). As to the isolation of isoforms, Amgen notes that the Court's construction of claim 27 "does not require the isoforms of Claim 1 to be separately prepared prior to making the mixture." (D.I. 374, p. 15 (citing D.I. 308 at 2)). Regardless, Amgen urges, "the evidence at trial showed that the limitations of claim 1 were satisfied, that is, that Hospira's product contains 'biologically active' EPO." (*Id.* (citing DTX-270, p. 17; Trial Tr. 394:1-4 (admission by Dr. Strickland that "all EPO isoforms have biological activity.")).

I agree with Amgen. Though Hospira may be correct that Amgen never explicitly mentioned claim 1 at trial, Hospira does not discuss substantively how Amgen failed to prove that the limitations of claim 1 were met. Amgen has also offered citations to Hospira's BLA and to the trial transcript to support the conclusion that the limitations of claim 1 were satisfied.

Claim 27 also has a limitation requiring the creation of an EPO composition with a "predetermined in vivo specific activity." Hospira argues that Amgen failed to prove that Hospira infringed this limitation because "Dr. Cummings did not provide any evidence of the actual in vivo specific activity of Hospira's product," and Hospira's product targets a range of in vivo specific activities, rather than targeting a specific activity. (D.I. 357, p. 14). Hospira also contends, "Dr. Strickland testified that in order to achieve a predetermined specific in vivo activity, one selects individual isoforms and prepares them in such a way to know what biological activity they are going to get."[6] (D.I. 381, pp. 9-10 (citing Trial Tr. 375:12-376:2)). Since there is no evidence that Hospira separates and selects individual isoforms, Hospira argues, there was insufficient evidence for the jury to conclude that Hospira infringed claim 27. (*Id.* p. 10). Amgen responds that Dr. Cummings relied on Hospira's BLA, which stated that 100% of lots fell within an in vivo specific activity of 93-147 U/ μg.[7] (D.I. 374, p. 16 (citing DTX-270, p. 17)).

I agree with Amgen. I do not find Dr. Strickland's testimony, cited by Hospira, inconsistent with Hospira's BLA, which identifies a predetermined in vivo specific activity—93-147 U/μg. (DTX-270, p. 17; *see* Trial Tr. 375:12-376:2). Hospira's BLA provided the jury with substantial evidence to conclude that Hospira's process achieved an EPO composition having a predetermined in vivo specific activity.

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[6] I do not think Dr. Strickland's testimony is as clear as Hospira makes it out to be. The transcript reflects that Dr. Strickand testified as follows:

> Q. And how does that experiment relate to the inventions in claim 24 and 27?
>
> A. Well, it's directly related to both of them in that in claim 24, it's selective elution of isoforms on an ion exchange column, which is what this is an ion exchange column, and it's related to claim 27 in that if we – we can select the fractions from that column to give us a mixture of predetermined biological activity if it was desired since in the background experiments, we determined what the biological activity was of each isoform. Now, since this method separates the isoforms, then we can recombine them and know what biological activity we're going to get.

(Trial Tr. 375:12-376:2 (discussing the '298 patent at 4:12-22)).

[7] EPO is measured in "activity units or international units," represented by "U." (Trial Tr. 208:8-10).

I therefore conclude that substantial evidence supports the jury's verdict that Hospira infringes claims 24 and 27 of the '298 patent. I will deny Hospira's JMOL on this ground.

3. *Invalidity of the '298 Patent*

Hospira argues that it is entitled to JMOL that the '298 patent is invalid because no reasonable jury could have found that claims 24 and 27 were not anticipated or obvious over U.S. Pat. No. 4,667,016 ("Lai"). (D.I. 357, p. 14). Since it was Hospira's burden to prove invalidity, to prevail on its JMOL, Hospira must demonstrate that "there is insufficient evidence for permitting any different finding" than that the disclosures in Lai render invalid claims 24 and 27 of the '298 patent. *See Fireman's Fund Ins. Co.*, 540F.2d at 1177.

The parties dispute whether Hospira adequately proved that the Lai process inherently anticipates claim 24 of the '298 patent. Specifically, they dispute whether Hospira proved that Lai meets the "selectively eluting" and "predetermined number of sialic acids" limitations of claim 24.

Hospira asserts that Dr. Levine's testimony, Dr. Strickland's testimony, and Dr. Cummings' testimony conclusively established that Lai includes a "selective elution" step. (*Id.* pp. 15-16). Dr. Levine did not dispute that Lai does not refer to the removal of biologically active EPO in ion exchange chromatography. (Trial Tr. 1010:10-16). Based on "the fundamental principles on which ion exchange chromatography works, and the difference in pKa[8] between high sialic and low sialic acid containing isoforms," however, Dr. Levine opined that Lai's step 2 example 2 "low pH, low salt wash will remove proteins that have a pKa greater than the biologically active EPO . . . [which] will include the isoforms of EPO that have a small number of sialic acid[s] and are therefore not biologically active, or less biologically active." (*Id.* 1010:1-16). As further support, Hospira points to Dr. Levine's and Dr. Strickland's discussions of the

[8] pKa is "related to the isoelectric point" of a substance. If a substance "has a low pKa, it's more basic." (Trial Tr. 422:6-22).

'298 patent's disclosure that the starting material for the fourth isoform of EPO is the material removed from the column in Example 2 of Lai, which contains EPO isoforms with less than or equal to nine sialic acids. (*Id.* 1034:5-14, 393:14-21). Dr. Cummings confirmed that when Dr. Strickland replicated the experiment reported in Example 2 of Lai, the result was that EPO isoforms containing nine to fourteen sialic acids were retained on the chromatography column after the first acid wash step. (*Id.* 1508:15-1509:9). Therefore, Hospira argues, Lai inherently discloses selective elution of EPO with less than nine sialic acids. (D.I. 357, p. 16).

Amgen responds that the jury declined to credit Hospira's argument that "practicing Example 2 of Lai 'necessarily and inevitably' resulted in 'selectively eluting' EPO molecules with a 'predetermined' number of sialic acids." (D.I. 374, pp. 16-17). Amgen points to Dr. Cummings, who testified that, contrary to Dr. Levine's assertion, "all EPO is biologically active," and the purpose of Lai was to purify EPO, not to separate EPO isoforms. (Trial Tr. 1494:12-1495:4). Amgen maintains that despite testimony that "some isoforms may be removed in Example 2 of Lai, none of the witnesses "testified that Example 2 in Lai 'necessarily and inevitably' results in" selectively eluting EPO isoforms with a predetermined number of sialic acids, as would be required to prove inherent anticipation. (D.I. 374, p. 18). Amgen argues that Dr. Levine's admission that several factors could affect which isoforms are present in the starting material (including cell culture conditions and the components of the cell culture medium) further supports that the Lai process does not "necessarily and inevitably" meet the limitations of claim 24. (Trial Tr. 1128:19-1130:1). Finally, Amgen notes, Dr. Levine agreed that, "Lai couldn't have selectively eluted isoforms having a predetermined number of sialic acids because Lai eluted all bound isoforms at the same time." (*Id.* 1127:4-9).

Despite the '298 patent disclosures, I think that Dr. Levine's admission that Lai could not

have eluted isoforms having a predetermined number of sialic acids, combined with the absence of testimony from other witnesses that Lai process "necessarily and inevitably" met each of the limitations of claim 24, adequately supports the jury's conclusion that Hospira had failed to prove by clear and convincing evidence that Lai anticipated claim 24.

The issue underlying the parties' dispute over whether Hospira adequately proved that the Lai process inherently anticipates claim 27 of the '298 patent is whether Hospira proved that the Lai process necessarily resulted in an EPO composition "having a predetermined in vivo specific activity." Hospira alleges that testimony by Dr. Levine established that "Lai discloses a composition having a predetermined in vivo specific activity" because Lai "disclosed how to create compositions of the high sialic acid, biologically active EPO." (D.I. 357, p. 18 (citing Trial Tr. 1039:2-1040:16)). Additionally, Hospira asserts that Amgen's witness, Dr. Cummings, essentially conceded that Lai anticipated claim 27 because he opined in the context of infringement that claim 27 may be satisfied by a process that results in a variable amount of the most biologically active isoforms, thus achieving a broad range of in vivo specific activity. (D.I. 381, p. 11). Amgen responds that Dr. Cummings opined that Lai does not disclose a "predetermined in vivo specific activity" because Lai provides no indication of any "finding ahead of time for select mixtures of isoforms." (Trial Tr. 1496:16-1497:16). Amgen also maintains that Lai's disclosure that "biologically active" EPO was eluted does not mean that Lai disclosed an EPO composition with predetermined in vivo specific activity, because all EPO isoforms have some biological activity, and "Lai never refers to a composition with a predetermined in vivo activity." (D.I. 374, p. 19).

The evidence at trial regarding anticipation of claim 27 by Lai consisted primarily of expert testimony. The jury was free to assess the credibility of the experts and weigh their testimony accordingly. Hospira's argument about Dr. Cummings' concession ignores the "predetermined"

portion of the limitation, and does not account for the role of Hospira's BLA to establish an in vivo specific activity in the infringement analysis. It seems to me that a reasonable jury could have credited Dr. Cummings' testimony over that of Dr. Levine, and decided that Lai did not disclose a "predetermined in vivo specific activity," particularly since Hospira was required to prove anticipation by clear and convincing evidence.

Hospira also argues that no reasonable jury could have found that claims 24 and 27 of the '298 patent were non-obvious over Lai in view of Lukowsky. During trial, Dr. Levine offered his opinion that claim 24 would have been obvious because (1) it was known that more sialylated forms of EPO were more biologically active (Trial Tr. 1047:16-23); (2) it was known that sialic acid "add[ed] negative charge to the" EPO molecules to which it was attached (*Id.* 957:3-8); (3) ion exchange chromatography was a well-known method for separating protein molecules by their net charge (*Id.* 967:4-10); and (4) the Beeley reference taught that glycoproteins could be separated by charge using ion exchange chromatography (*Id.* 1052:24-1054:23). Therefore, Hospira argues, a POSA would have been motivated to separate isoforms and create a preparation of EPO with a predetermined in vivo specific activity, and have a reasonable expectation of success in doing so. (D.I. 357, p. 19).

Amgen submits that the Patent Office considered both Lai and Lukowsky during prosecution, and the "PTO examiner acknowledged that the '298 patent taught the unexpected advantage of combinations of isoforms, and the ability to prepare EPO compositions with predetermined EPO isoforms." (D.I. 374, p. 20 (citing PTX-4B, pp. 11-12; Trial Tr. 1500:22-1502:23)). Amgen further points to Dr. Cummings' explanation that Lukowsky does not supply the limitations missing from Lai, because Lukowsky does not disclose EPO "isoforms," a "predetermined mixture of [EPO] isoforms," or "predetermined specific activity" of any EPO

isoforms. (*Id.* (citing Trial Tr. 1489:14-1490:2)).

I think that substantial evidence supports the jury's conclusion that neither claim 24 nor claim 27 of the '298 patent is obvious over Lai in view of Lukowsky and Beeley. Hospira bore the burden by clear and convincing evidence to prove that the asserted claims of the '298 patent were invalid. Since neither Lukowsky nor Lai discloses EPO isoforms, or predetermined mixtures or in vivo specific activities of EPO isoforms, and the PTO acknowledged unexpected results produced by the '298 patent, I cannot say that the jury was unreasonable in deciding that Hospira had not met its burden to prove obviousness. I also note that in the relevant briefing, Hospira's statements of a POSA's motivation to combine these references lack explanation. (D.I. 357, p. 19 ("[A] person of ordinary skill in the art would have been motivated to create a preparation of EPO with a predetermined specific activity, and would have had a reasonable expectation of success in doing so.")).

I therefore conclude that substantial evidence supports the jury's verdict that claims 24 and 27 of the '298 patent are not anticipated by or rendered obvious by Lai. I will deny Hospira's motion for JMOL on this ground.

4. Damages

Hospira also moves for JMOL on the ground that the jury's damages award is not reasonable, challenging both the amount and the lump sum nature of the award. (D.I. 357, p. 20). Based on Dr. Bell's analysis, Hospira asserts, "Dr. Bell's proposed royalty of $1.5 million per batch, when the batch is sold, is the only damages methodology that properly accounts for the expectations of the hypothetical negotiators at the time concerning FDA approval, and the reality of what occurred afterwards." (*Id.* p. 22).

Relying on Dr. Bell's trial testimony, Hospira contends, "Hospira, as a willing licensee,

would not have been willing to pay more than the replacement cost of the batches, which was from $4.1 to $4.6 million per batch." (*Id.* p. 20 (citing Trial Tr. 1241:1-1243:13)). Considering the *Georgia-Pacific* factors, Dr. Bell adjusted this downward to 35% of the replacement cost. (Trial Tr. 1246:12-1248:21). Dr. Bell further opined that due to the uncertainties associated with FDA approval, Hospira would not willingly pay an up-front lump sum royalty. (*Id.* 1252:13-19). According to Dr. Bell, if the FDA never approves Hospira's biosimilar, then Hospira has no opportunity to sell the product and realizes no gain, and Amgen has no losses. (*Id.* 1252:1-9). Hospira further criticizes Amgen's damages theory because it "requires Hospira to bear all the 'risk' of the license," and it reflects an award "more than the twenty-year net present value of the entire EPO project." (D.I. 357, pp. 20-21). According to Hospira, this is inconsistent with a willing licensor and a willing licensee. (*Id.*). Hospira also criticizes Amgen's damages theory as "based entirely on the cost to Hospira of the supposed delay that would have occurred if it had to wait until after patent expiration to manufacture its EPO substance for launch," when "no such delay ever occurred." (D.I. 381, p. 13). Finally, Hospira argues that the Vifor Agreement cited by Amgen "is a non-comparable marketing and distribution agreement with an upfront payment that can be refunded if Hospira does not obtain FDA approval." (D.I. 357, pp. 21-22).

Amgen responds, "Dr. Bell's testimony provides the lowest reasonable royalty that may be supported by the evidence," not the only reasonable royalty. (D.I. 374, p. 21). The jury's award was supported by the evidence, Amgen argues, because "[t]he jury [i]s entitled to choose a damages award within the amounts advocated by the opposing parties."[9] (*Id.* (quoting *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1347 (Fed. Cir. 2011), *abrogated on other grounds by Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016)) (brackets in original)).

[9] Here, the difference between the parties' positions is $116 million, as Hospira proposed $21 million and Amgen proposed $137 million. (D.I. 374, p. 24).

Amgen presented the Vifor Agreement as an example of a lump sum agreement involving Hospira, asserting that Amgen would not agree to a refund in this case because Amgen and Hospira are competitors. (*Id.* p. 23 (citing Trial Tr. 665:4-666:1)). Additionally, Amgen argues, "Hospira cites no legal support for its contention that economic harm is required for a jury to award a royalty as a lump sum." (*Id.*). "The reasonable royalty determined in a hypothetical negotiation does not compensate for lost sales but rather the lost opportunity of a reasonable royalty before infringement." (*Id.* (citing *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1334 (Fed Cir. 2015))).

Amgen maintains that Dr. Heeb "provided numerous bases in addition to the Vifor agreement " to support his damages theory. (*Id.*). Dr. Heeb opined that since Amgen and Hospira are competitors, Amgen would not agree to a running royalty that required Amgen to share any risk associated with Hospira's manufacture of EPO. (Trial Tr. 640:12-641:15). Additionally, Dr. Heeb cited administrative advantages of a lump sum royalty, such as there being no need to track sales. (*Id.* 641:16-23).

Regarding Hospira's arguments that the award does not reflect events occurring after the hypothetical negotiation (i.e., the lack of FDA approval), Amgen notes that the jury was instructed that it could consider such events. (D.I. 374, p. 22). Amgen argues, "It is not error that the jury did not agree with Hospira" about the effect of such events on the reasonable royalty rate. (*Id.*). Contrary to Hospira's argument that Dr. Bell's theory is the only one under which the jury could have found a per-batch royalty (D.I. 357, p. 29), Amgen notes that Dr. Heeb offered testimony on the value of the license if the jury found only some batches to infringe. (D.I. 374, p. 22). For example, if fourteen batches were found to infringe, the value to Hospira of a license would have been $137 million. (*Id.* (citing Trial Tr. 645:22-646:6)). Amgen would have valued a license at

$170 million. (Trial Tr. 636:2-11). Regarding Hospira's criticism that Dr. Heeb's analysis resulted in an award that exceeded the net present value of Hospira's EPO project, Amgen points to testimony by Dr. Bell acknowledging Hospira documents that stated the net present value of its EPO project as up to $297 million. (*Id.* 1273:10-1274:5).

I conclude that substantial evidence supports the jury's $70 million damages award. Regarding the lump sum payment, both parties' experts provided testimony to support their positions on whether a lump sum would be appropriate, and the jury was free to determine the experts' credibility and weigh their testimony accordingly. I decline to substitute my judgment for that of the jury.

Hospira essentially argues that Dr. Heeb's methodology was not supported by substantial evidence because no launch delay ever materialized. Indeed, Hospira's expert Dr. Bell testified that he considered only the hypothetical negotiation scenario in which Hospira does not launch a product prior to mid-2017, "because it's the one that we happen to be in." (Trial Tr. 1293:16-1294:15). In other words, Dr. Bell's analysis focuses solely on a hypothetical negotiation in which the parties have knowledge of all subsequent events. Amgen's analysis appears to amount to a hypothetical negotiation in which the parties do not have the benefit of subsequent knowledge that Hospira did not receive FDA approval.

I cannot say that it was unreasonable for the jury to find neither expert struck the proper balance in considering how post-negotiation events would have affected the reasonable royalty.

> The [reasonable royalty] methodology encompasses fantasy and flexibility; fantasy because it requires [the jury] to imagine what warring parties would have agreed to as willing negotiators; flexibility because it speaks of negotiations as of the time infringement began, yet permits and often requires [the jury] to look to events and facts that occurred thereafter and that could not have been known to or predicted by the hypothesized negotiators.

Fromson v. W. Litho Plate & Supply Co., 853 F.2d 1568, 1575 (Fed. Cir. 1988), *overruled on other*

grounds by Knorr–Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337 (Fed.Cir.2004) (en banc); *see also Sinclair Ref. Co. v. Jenkins Petroleum Process Co.*, 289 U.S. 689, 698 (1933) ("[A] different situation is presented if years have gone by before the evidence is offered. Experience is then available to correct uncertain prophecy. Here is a book of wisdom that courts may not neglect."). Though the parties would have recognized the possibility, as of the time of the hypothetical negotiation, that Hospira may not receive FDA approval before the expiration of the patents, Hospira did not expect such a result.[10] In essence, Hospira wants me to do what the Federal Circuit has expressly held was error, to "replace[] the hypothetical inquiry into what the parties would have anticipated, looking forward when negotiating, with a backward-looking inquiry into what turned out to have happened." *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 772 (fed. Cir. 2014). I therefore cannot say that the consideration in Dr. Heeb's analysis of the value to Hospira of avoiding launch delay was not supported by substantial evidence. The parties' experts each provided an endpoint for the range of potential hypothetical reasonable royalties, and as Amgen points out, the jury was free to choose a damages award within the amounts advocated by the opposing parties. Therefore, I will deny Hospira's motion for JMOL on this ground.

B. New Trial

1. Safe Harbor Instruction

Hospira asserts that it is entitled to a new trial because the safe harbor jury instruction was "legally erroneous and prejudicial." (D.I. 357, p. 22).[11] Specifically, Hospira argues that the instructions "confused the 'manufacture' and 'use' of the batches in a way that misrepresents the

[10] Hospira projected that it would obtain FDA approval in the fourth quarter of 2015. (PTX-342, p. 1).

[11] Citing its JMOL arguments, Hospira also argues that the jury's verdict that fourteen batches were not protected by the safe harbor defense is against the clear weight of the evidence. Having already addressed these arguments in Hospira's JMOL, I will not address them again in considering Hospira's motion for a new trial.

statute," and Hospira challenges the instructions' "fail[ure] to instruct the jury that ulterior motives and intent are irrelevant to the Safe Harbor." (*Id.*). Amgen submits that the instructions were adequate, and that any instructional error was "at most harmless error." (D.I. 374, p. 24).

Hospira contends that the verdict form and jury instructions were erroneous because they did not use the terms "make" and "use" consistently with the statute, thus failing to "clarify the difference between 'manufacture' and 'use' under the Safe Harbor." (D.I. 357, pp. 23-24; *see also* Trial Tr. 1404:11-1405:15 (Hospira objecting to the safe harbor jury instruction and stating, "We would urge the broader standard for uses, but focus on the instruction should be on the uses and not the motives or purposes in making [a] batch. The statutory exemption is premised on the use aspect."); Trial Tr. 1445:12-1449:18, 1452:8-23 (Hospira's continuing objections)). The instructions initially refer to Hospira's burden to prove "uses reasonably related to obtaining FDA approval," and Hospira's burden to prove "that the safe harbor defense applies to Hospira's use of Amgen's patented invention," but they subsequently "ask[] the jury to determine whether the manufacture is covered." (D.I. 357 p. 24). According to Hospira, the verdict form "compounded this error[] by asking the jury to find whether the 'Safe Harbor Defense applied to the manufacture of the following batches.'" (*Id.*). Amgen responds that the jury instructions and verdict form track the statute because, "The Court correctly instructed the jury that the alleged infringing activity was Hospira's making of its drug substance, which needed to be 'for uses reasonably related' to seeking FDA approval." (D.I. 374, p. 25 (citing Trial Tr. 1522:5-20, 1553:3-1554:13)).

I agree with Amgen. The safe harbor defense provides,

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) . . .) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

35 U.S.C. § 271(e)(1). The safe harbor exempts activity that would ordinarily constitute an act of infringement if that activity is undertaken "solely for uses reasonably related" to obtaining FDA approval. Asserted claims 24 and 27 of the '298 patent are method claims. Hospira is correct in pointing out that the instructions and the safe harbor statute refer to "use" of a patented invention. Here, Hospira's potentially infringing "use" of Amgen's patented invention is Hospira's manufacture of the EPO drug substance referred to in its BLA (i.e., Hospira's performance of the steps of Amgen's method claims), not Hospira's subsequent use of the EPO drug substance (i.e., Hospira's subsequent use of the product obtained by practicing Amgen's method claims). *See Joy Techs, Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is directly infringed only by one practicing the patented method." (emphasis omitted)); *Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (Ct. Cl. 1976) ("It is well established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized."). Therefore, the safe harbor defense applies in this case only if Hospira's manufacture of its EPO drug substance is reasonably related to obtaining FDA approval. Though Hospira's subsequent uses of its EPO drug substance are probative in determining whether Hospira's manufacture of its EPO drug substance was reasonably related to obtaining FDA approval, it is the manufacture itself (not Hospira's subsequent uses of EPO drug substance) that is the potentially infringing act which must be evaluated for safe harbor protection. I thus think the jury instructions and the verdict form were proper in asking the jury to determine whether Hospira's potentially infringing act, i.e., its manufacture of the EPO drug substance, was covered by the safe harbor defense.

According to Hospira, "the Court's Safe Harbor instructions were erroneous for a second reason—they omitted any discussion of how intent related to the Safe Harbor analysis." (D.I. 357, p. 23; Trial Tr. 1404:11-1405:15 (Hospira's charge conference objection to the safe harbor jury

instruction); D.I. 318, pp. 30-31 (Hospira's objection to the Court's proposed jury instruction on safe harbor); Trial Tr. 1445:12-1449:18). Though the instructions stated that "Hospira's additional underlying purposes for the manufacture and use of that batch do not remove that batch from the safe harbor defense" (D.I. 323, p. 19), Hospira contends that "this language was ambiguous and did not explicitly state that intent does not matter." (D.I. 357, p. 23). Per Hospira, "This error, coupled with the Court's denial of Hospira's motion *in limine* to preclude Amgen[] from introducing the Risk Authorizations allowed the jury to hear evidence of alleged commercial intent based on the highly prejudicial Risk Authorizations." (*Id.* (citation omitted)). To support its assertion that its internal Risk Authorizations are unduly prejudicial and should not have been admitted into evidence, Hospira repeats its argument that intent is irrelevant to evaluating safe harbor protection. (*Id.*). Essentially, Hospira asserts that I should have used its proposed jury instructions on the safe harbor defense. (*Id.*). Amgen responds, "Hospira's proposed instruction [] also omitted any discussion of 'intent'; it did not even contain that word." (D.I. 374, p. 24 (citing D.I. 304, pp. 3-4). Regardless, Amgen submits that the instructions adequately addressed intent because the court "instruct[ed] the jury that 'Hospira's additional underlying purposes for the manufacture and use of [a] batch do not remove that batch from the safe harbor defense.'" (*Id.* pp. 24-25).

Hospira appears to argue that intent is entirely irrelevant to the safe harbor analysis, but I do not think the cases Hospira cites in its brief stand for such a broad proposition. In *Abtox*, the court found a competitor's limited testing during development of a device "consistent with the collection of data necessary for filing an application with the [FDA]," despite allegations that that the actual purpose of the tests was "to promote the [device] and other equipment to potential customers." 122 F.3d at 1027. Accordingly, the *Abtox* court concluded that the safe harbor defense

"allows [a party] to use its data from the tests for more than FDA approval" and "does not look to the underlying purposes or attendant consequences of the activity (*e.g.*, tests led to the sale of the patent), as long as the use is reasonably related to FDA approval." *Id.* at 1030. Notably, the *Abtox* court did not state that intent was irrelevant in determining whether an activity is reasonably related to obtaining FDA approval.

Hospira's citations to other cases quote language clarifying that the mere existence of some intent, "ulterior motives," or "alternate purposes" to commercialize does not preclude a party from successfully invoking the safe harbor defense. (D.I. 357, pp. 22-23 (citing *Intermedics, Inc. v. Ventritex Co.*, 1993 WL 87405, at *5 (Fed. Cir. Feb. 22, 1993) ("Reliance on section 271(e)(1) is not precluded by manifestation of an intent to commercialize upon FDA approval."); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 108 (D. Mass. 1998) ("[U]lterior motives or alternate purposes do not preclude application of the section 271(e)(1) exemption."); *Intermedics, Inc. v. Ventritext Co.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991), *aff'd* 991 F.2d 808 (Fed. Cir. 1993) ("[I]f a party were to lose the exemption every time a business purpose was detectable in its otherwise infringing activities, the exemption would virtually never be available and thus would fail to achieve Congress' objective.")). I think that evidence of intent can be a relevant factor in determining whether an activity is reasonably related to obtaining FDA approval, and that these cases stand for the proposition that evidence of commercial intent is not determinative of the safe harbor inquiry. In my view, they do not support Hospira's assertions that intent is irrelevant to determining whether an activity is reasonably related to obtaining FDA approval and that intent may not be considered at all. But once it is determined that "the activity is reasonably related to obtaining FDA approval, [] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e) shield." *See Abtox*, 122 F.3d at 1030.

Additionally, adopting Hospira's interpretation of the safe harbor defense would expand the defense beyond recognition and create a loophole that would make it virtually impossible to prove infringement in cases involving products regulated by the FDA. Since Hospira's interpretation requires ignoring intent in deciding whether the safe harbor applies, a party could manufacture 200 drug substance batches and earmark them for future use as commercial inventory without infringing, so long as the party used each of those batches for at least one test to generate data of the type used by the FDA in determining whether to approve the drug. In that scenario, each batch would be tested to generate data that could conceivably be used to respond to inquiries from the FDA, making each batch reasonably related to obtaining FDA approval. Essentially, Hospira's interpretation allows a single "token" submission of information derived from a potential infringing act to exempt that act from infringement, without regard to the realities surrounding the potentially infringing act. It seems to me that Hospira's interpretation reads the words "solely" and "reasonably" out of the statute, and that a party's stated intent may be considered as part of whether the manufacture or use of a patented drug was "solely for uses reasonably related to" obtaining FDA approval. I think that the jury instructions properly recited the role of intent in the safe harbor analysis.

Hospira also argues that FDA draft guidance on statistical approaches to evaluate analytical similarity, published on September 22, 2017, constitutes new evidence that "proves the uncertainty of the regulatory landscape" and warrants a new trial. (D.I. 357, p. 24; *see also* D.I. 357-1). Amgen responds that the draft guidance is cumulative of Hospira's other evidence of regulatory uncertainty that would not have changed the outcome at trial. (D.I. 374, p. 26). Setting aside the fact that the draft guidance was distributed for comment purposes only, Amgen points out that the guidance "recommend[s] a minimum of 10 reference product lots be sampled" to "establish

meaningful acceptance similarity criteria." (*Id.* (citing D.I. 357-1 at 2, 7)). The guidance would not have changed the outcome, Amgen maintains, because, "Here, Hospira tested 26 drug product batches to demonstrate biosimilarity, all made using material from 4 drug substance batches on which the jury did not award damages." (*Id.* (citing DTX-266, pp. 3-4)). Finally, Amgen notes that Hospira did not present evidence that the FDA required Hospira to manufacture a certain number of batches to demonstrate biosimilarity. (*Id.*).

I agree with Amgen that the FDA draft guidance does not constitute new evidence that would justify a new trial. Since Hospira submitted test data from twenty-six drug product batches manufactured from four drug substance batches that the jury found not to infringe, the jury could have found the remaining drug substance batches to infringe even if the draft guidelines had constituted a final regulation requiring Hospira to submit data from at least ten drug product batches to prove biosimilarity. Hospira has not shown that the FDA draft guidance would likely alter the outcome of the trial.

Having concluded that neither the safe harbor instructions nor the FDA draft guidance warrants a new trial, I will deny Hospira's motion for a new trial on safe harbor grounds.

2. *Contradictory Verdicts*

Hospira argues that it is entitled to a new trial because the jury's verdicts on infringement of the '298 patent and validity of the '298 patent are inherently contradictory. (D.I. 357, p. 24). Having found each of the jury's infringement and validity verdicts supported by substantial evidence, and having found that Hospira failed to meet its burden of proof that the '298 patent is invalid, I will deny Hospira's motion for a new trial based on contradictory infringement and validity verdicts.

3. *Claim Construction*

Hospira also argues that "the jury received a claim construction order with errors that warrant a new trial." (*Id.* p. 26). Specifically, Hospira argues, "For the reasons advanced by Hospira during claim construction," the Court's construction of claims 24 and 27 of the '298 patent were incorrect. (*Id.*). Amgen responds that Hospira's assertion amounts to an improper request for reconsideration of the Court's claim constructions, since "Hospira raises no new arguments" to support its contention that the Court's claim constructions were improper. (D.I. 374, pp. 27-28).

Hospira frames its claim construction arguments as repetitions of the arguments it made during claim construction. I decline at this late stage to reconsider my constructions based on the same arguments considered and addressed in my previous claim construction opinions. (*See* D.I. 162, 177). Therefore, I will deny Hospira's motion for a new trial based on claim construction.

4. Third Party Liability Instruction

Hospira further submits that it is entitled to a new trial because the jury was erroneously instructed that "Hospira is responsible for the manufacturing activities of GlaxoSmithKline, or GSK, as they relate to Hospira's epoetin drug substance." (D.I. 357, p. 27 (citing Trial Tr. 1552:23-1553:2)). The third party liability jury instruction challenge is proper, Hospira submits, because Hospira "vigorously disputed the jury instruction on third party liability and confirmed that its objections to the jury instructions were preserved." (D.I. 381, p. 15 (citing Trial Tr. 1389:15-1390:11, 1524:11-19)). According to Hospira, the erroneous instruction "allowed Amgen to circumvent the requirements to show induced infringement under 35 U.S.C. § 271(b)[, when] Amgen never pled induced infringement of the '298 patent nor amended its pleadings to do so." (D.I. 357, p. 27).

Amgen asserts that Hospira's motion for a new trial represents an improper vehicle to

challenge the Court's JMOL decision during trial that "Hospira was responsible for GSK's manufacture of Hospira's EPO drug substance for purposes of direct infringement." (D.I. 374, p. 28; *see* Trial Tr. 1391:18-1392:6). According to Amgen, since "Hospira has not sought reconsideration of that ruling and did not object to the jury instruction," Hospira's motion "cannot overturn the Court's decision to grant JMOL on Hospira's responsibility for GSK's activities." (D.I. 374, p. 28).

I will deny Hospira's motion for a new trial based on the third party liability instruction. Hospira acknowledges that I granted JMOL that Hospira was responsible for the activities of GSK. (D.I. 357, p. 27; *see* Trial Tr. 1392:14-24). Assuming JMOL was properly granted,[12] I think it was proper to instruct the jury that, "Hospira is responsible for the manufacturing activities of GlaxoSmithKline, or GSK, as they relate to Hospira's epoetin drug substance." (Trial Tr. 1553:1-4). Though Hospira reserves its right to appeal the grant of JMOL on this issue (D.I. 357, p. 27 n.1), Hospira does not object to the grant of JMOL in its post-trial briefing. (*See id.* pp. 27-28; D.I. 381, p. 15). Regardless, I do not think Hospira's citations to the trial transcript demonstrate a

[12] As I noted at trial, I think the evidence supports the grant of JMOL that Hospira is responsible for the activities of GSK. (Trial Tr. 1392:17-1393:7). As the Federal Circuit stated in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1023 (Fed. Cir. 2015), it has "held that an actor is liable for infringement under § 271(a) if it acts through an agent (applying traditional agency principles) or contracts with another to perform one or more steps of a claimed method." Under Delaware law, "If the principal assumes the right to control the time, manner and method of executing the work, as distinguished from the right merely to require certain definite results in conformity to the contract, a master/servant type of agency relationship has been created." *Fisher v. Townsends, Inc.*, 695 A.2d 53, 59 (Del. 1997).

Here, Hospira reserves particular time slots with GSK for manufacturing, "sets the overarching specifications for the manufacture of the drug substance" in accordance with Hospira's BLA, and owns the drug substance on completion of manufacturing. (Trial Tr. 296:1-297:12, 554:9-555:14, 886:3-887:6). Additionally, Hospira employees worked with GSK during the manufacturing process and were present at the GSK facility during the FDA's pre-approval inspection. (Trial Tr. 834:3-835:3, 864:3-866:3). I therefore think that Hospira exercises sufficient direction and control over the manufacturing process such that GSK qualifies as Hospira's agent. Accordingly, even if Hospira could not be held liable for direct infringement based on its contract with GSK to perform the steps of the claimed method, Hospira could be held liable for direct infringement based on GSK's actions under an agency theory.

clear objection by Hospira to the third party liability jury instruction. (*See* Trial Tr. 1390:15-1394:24 (discussing third party liability issue, discussing proposed "infringement by agent" instruction ultimately not given, granting JMOL that Hospira is responsible for the activities of GSK, and instructing Amgen to submit a sentence on this issue for the final jury instructions), 1519:9-1524:21 (indicating Hospira's objection to the safe harbor jury instruction; demonstrating no specific objection by Hospira to revised Instruction 5.2, which included a sentence drafted by Amgen stating that Hospira is liable for the activities of GSK; and reflecting both parties' preservation of prior objections)).

5. Remittitur

Finally, Hospira argues that remittitur to $1.5 million per batch, if sold, is appropriate because "the $70 million damages award contradicts the weight of the evidence." (D.I. 357, pp. 28, 30). As support, Hospira restates in part and incorporates by reference its arguments raised in its motion for JMOL regarding damages. (*Id.* pp. 28-30). I will deny Hospira's request for remittitur or a new trial for the same reasons already discussed with respect to Hospira's motion for JMOL regarding damages.

III. HOSPIRA'S MOTION TO SEAL CONFIDENTIAL EXHIBITS

Hospira requests that the Court seal three exhibits admitted at trial which it asserts contain confidential business information. The exhibits are DTX-138 (the Vifor Agreement), DTX-177 (the GlaxoSmithKline ("GSK") Agreement), and DTX-178 (amendments to the GSK Agreement). (D.I. 361 at 2). Amgen opposes Hospira's motion. (D.I. 369).

The Third Circuit recognizes "a strong presumption that material introduced into evidence at trial should be made available for public access." *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (citation omitted). "It is well established that the release of information in open court

is a publication of that information and, if no effort is made to limit its disclosure, operates as a waiver of any rights a party had to restrict its future use." *Id.* at 680 (citation omitted). "The party seeking the closure of a hearing or the sealing of a transcript bears the burden of showing that the material is the kind of information that courts will protect and that there is good cause for the order to issue. Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure." *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1069-70 (3d Cir. 1984) (citations omitted).

According to Hospira, it is appropriate to seal these exhibits because they contain "confidential commercial and technical information" that "would damage the competitive standing of the parties and the third parties named in those agreements." (D.I. 361 at 1). Hospira contends that it "took efforts to keep the contents [of these exhibits] confidential" during trial because only limited portions of the exhibits were discussed or shown. (*Id.* at 3). Specifically, Hospira's witnesses discussed these documents only in general terms, and Amgen's witness Dr. Heeb referenced only one page of DTX-178 in live testimony. (*Id.*). Though "[t]he exhibits were discussed in deposition testimony of Mr. Noffke and Mr. Pinnow," they "were only shown on a split screen as the testimony was played," and Hospira had marked the deposition transcripts and exhibits "confidential." (*Id.*). Finally, Hospira argues, "Redaction of the documents is not practicable, as the information discussed at trial was often intertwined with other sensitive information and because the organization and structure of the documents themselves are confidential." (*Id.*).

Amgen submits that the exhibits should not be sealed because "[d]uring trial, the parties introduced exhibits into evidence without restriction." (D.I. 369 at 1). Since "[t]he Court never sealed the courtroom, and Amgen's corporate representative, members of the press, and other

members of the public were present throughout the trial," Amgen maintains that the exhibits are in the public record. (*Id.*). Additionally, Amgen argues that the exhibits should not be sealed because "several witnesses testified about the three agreements, including about specific details in those agreements." (*Id.* at 2 (citing Mr. Noffke's testimony about GSK's reserve capacity in the GSK Agreement (Trial Tr. 565:8-568:5); Dr. Bell's testimony about cost of manufacture information derived from the GSK Agreement (Trial Tr. 1244:6-1245:14); Mr. Pinnow's and Dr. Bell's testimony about payment terms in the Vifor Agreement (Trial Tr. 306:19-22, 309:3-312:2, 1254:1-15))). Finally, Amgen expresses concern that Hospira seeks to seal portions of the GSK Agreement on which Hospira intends to rely in raising the argument that GSK is not an agent of Hospira. (*Id.* at 3-4).

I agree with Amgen that the exhibits should not be sealed. On the first morning of trial I indicated my preference that the parties "redact out [the] portions that aren't relevant," and suggested that the parties ought to think about limiting disclosures of portions of the exhibits to those that are "critical to the testimony" at trial. (Trial Tr. 18:13-19). Though Hospira may have taken some measures to keep the exhibits confidential, Hospira published portions of the exhibits in open court and relied on information from the exhibits in presenting its case. That portions of the exhibits "were only shown on a split screen" does not change the fact that they were published and admitted into evidence without any request by Hospira to seal them at the time. (*Id.* at 317:5-13, 594:16-595:19). Hospira's broad argument about the impracticality of redaction is not sufficient for me to conclude that it would be impractical to redact the exhibits.

Accordingly, I will not seal the exhibits. Since the exhibits were not published in their entirety in open court and contain sensitive information about ongoing commercial agreements, I will allow Hospira to submit proposed redactions within ten days of the date of the order

accompanying this opinion. The parties should meet and confer on the proposed redactions before the submission is made.

IV. AMGEN'S RENEWED JMOL

Amgen seeks judgment as a matter of law that Hospira infringed the '349 patent. (D.I. 358). Alternatively, Amgen seeks a new trial on infringement of the '349 patent because the jury's verdict was against the weight of the evidence, and was based on what Amgen characterizes as Hospira's improper argument to the jury that the '349 claims require RIA evidence for infringement. (*Id.*).

A. JMOL

The only limitations in the '349 patent at issue during trial required cells "capable of producing" EPO at a rate of 100 U, 500 U, and 1000 "U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay." (*Id.* p. 5). It was Amgen's burden at trial to prove by a preponderance of the evidence that Hospira's EPO-producing cells met this limitation. To prevail on its motion, Amgen must demonstrate that "there is insufficient evidence for permitting" a finding that Hospira does not infringe the asserted claims of the '349 patent. *Fireman's Fund Ins. Co.*, 540 F.2d at 1177.

Amgen contends, "The only evidence introduced at trial about the production rate of Hospira's cells established that they were capable of producing EPO at a rate of more than 3500 Units per million cells in 48 hours," because "Hospira's expert, Dr. Hamilton, did not offer any affirmative evidence or an opinion that Hospira's cells were not capable of producing EPO at the rates recited in the '349 claims." (*Id.* pp. 1-2). As further support, Amgen points to a Hospira report submitted to the FDA as part of Hospira's BLA stating that Hospira's cells produce EPO "in the range of 100 μg or higher" per day based on dot-blot analysis. (*Id.* p. 7 (citing PTX-293,

p. 28)). Amgen's expert, Dr. McLawhon, testified that Hospira's 100 μg/mL rate could be converted into the "U" of EPO recited in the '349 patent claims, and that his calculations resulted in a rate of 3,534 U of EPO per 10^6 cells in 48 hours. (*Id.* (citing Trial Tr. 525:1-536:11)). Essentially, since Hospira's expert, Dr. Hamilton, admitted that it was theoretically possible to convert μg/mL EPO production to U of EPO, and since Dr. Hamilton "did not offer any affirmative evidence . . . that Hospira's cells were incapable of producing EPO at the claimed production levels," Amgen asserts that no reasonable jury could have found that Hospira's cells did not infringe. (*Id.* pp. 9-10).

Amgen also argues that no reasonable jury could have found Dr. Hamilton's testimony adequate to rebut Amgen's evidence of infringement. (D.I. 358, pp. 11-14). First, Amgen argues that Dr. Hamilton's criticisms are "inconsistent with the written description of the '349 patent, in which Dr. Lin described using an RIA to assay crude 'culture fluids,' and converted the resulting data to 'U' of EPO using a purified EPO standard." (D.I. 380, p. 3).[13] Amgen's responds to Dr. Hamilton's testimony that the RIA and dot blot testing at issue here are not comparable by arguing that Dr. Hamilton "failed to tie these alleged deficiencies to any limitation recited in the claims: the '349 claims do not require the same standard or antibody used by Dr. Lin when he tested his inventions, nor are the production-rate limitations limited to testing a purified EPO sample." (D.I. 358, pp. 12-13). Amgen further argues that Dr. Hamilton's testimony should not be credited because he "did not interpret the claims, or opine on whether a person of ordinary skill in the art would have understood the claims to require the use of the same EPO standard or anti-EPO antibody preparation that the '349 inventor, Dr. Lin, used." (*Id.* p. 13). Essentially, Amgen argues,

[13] In response, Hospira points to Dr. Hamilton's testimony that "the '349 patent examples use a standard curve," but "that curve was not compared to Hospira's sample in this case." (D.I. 373, p. 13 (citing Trial Tr. 1226:3-23, 1227:21-1228:10)). Therefore, the '349 patent examples further demonstrate a "lack of comparability [that is] another reason that the dot blot from Hospira's BLA does not prove infringement." (*Id.*).

Hospira did not offer any evidence to suggest that the differences identified by Dr. Hamilton actually matter.

Hospira responds that the jury was reasonable in declining to credit Amgen's circumstantial evidence of infringement of the '349 patent. (D.I. 373, p. 1). Hospira maintains that Amgen failed to carry its burden to prove infringement because Amgen never established the comparability of the dot-blot and RIA testing at issue. (*Id.* p. 4). First, Dr. Wall offered no testimony on the comparability of dot-blot and RIA testing. (*Id.* (citing Trial Tr. 271:5-22, 275:19-276:23)). Second, Dr. McLawhon did not "explain[] how the dot blot works or how it compares to an RIA," instead converting mass to units "like a 'currency converter.'" (*Id.* p. 5 (citing Trial Tr. 527:24-530:1)). Third, "Dr. McLawhon d[id] not know whether the same antibody was used in the standard he used for the conversion and the dot blot, although he admit[ted] that should be done if one is going to make a comparison and that he would have known which antibody was used if he had run an experiment." (*Id.* (citing Trial Tr. 545:3-546:2)). Fourth, a former Amgen scientist who conducted RIA testing on Amgen's EPO project testified that the same standard should be used to compare assays, because the standard sets the potency measurement. (*Id.* p. 6 (citing Trial Tr. 1163:5-24)).

Hospira notes that Dr. Hamilton "provided several reasons why [RIA and dot blot] do not yield similar results." (*Id.*). First, "Hospira's BLA contained rough information that some of the vertebrate cells tested could produce 100 μg of EPO per mL of cell-culture medium, [i.e., supernatant]." (*Id.* p. 7; Trial Tr. 540:18-541:3). Second, Hospira argues that Dr. Hamilton "explained that the dot blot was done as a rough measurement of the amount of EPO." (*Id.* p. 8 (citing Trial Tr. 1193:18-1194:8)). Third, as Dr. Hamilton explained, "converting from mass units to biological activity units as measured in the claims is not like converting currency because these

units are not standardized like money." (*Id.* p. 7). Fourth, "a sample taken directly from the supernatant, as done in the dot blot assay, will likely contain biologically inactive impurities and EPO fragments that indiscriminately bind to the antibody, and thus will not be an appropriate sample to use in the conversion calculation." (*Id.* p. 8). Fifth, one "can't rely on a purified standard to give [] an estimate of what's present in the crude mixture of impurities and isoforms as well as active EPO on the dot blot." (Trial Tr. 1198:2-6). Sixth, the standards used in Hospira's BLA and in the '349 patent were not the same. (*Id.* 1198:19-1198:22). In summary,

> [T]he standard was different, the antibodies were different, the assay design was different, the relative degree of quantification was different, and based on all of those variables, one can't accurately assess the level of EPO in a culture supernatant cell preparation, which is really what claims 1 through 6 in the patent are requiring.

(*Id.* 1198:23-1199:6).

I agree with Hospira that substantial evidence supports the jury's verdict that Hospira does not infringe the asserted claims of the '349 patent. That Amgen's calculation was the only one offered at trial did not mean that the jury was obligated to credit it. And the fact that the '349 patent describes using a purified EPO standard to convert RIA assay data obtained from a crude sample to "U" does not compel the conclusion that one could do the same with dot-blot data obtained from a crude sample. Additionally, Amgen's argument that Hospira's BLA documents disclosing dot-blot measured rates of 100 μg/mL constitute an admission that Hospira's cells meet the production limitations is not persuasive. It ignores that the "admission" is explicitly dependent on the measurement technique used, and does not address issues of whether the dot blot testing and RIA testing at issue are comparable. Though Dr. Hamilton acknowledged that one could theoretically convert the dot-blot μg/mL measurement to a measurement in "U," he qualified that statement by saying that the material resulting from Hospira's dot-blot test would need to be purified to get a proper conversion against the pure standard. (Trial Tr. 1214:18-21). Dr. Egrie, a

former Amgen scientist, confirmed that the same standard should be used to compare assays. (*Id.* 1163:21-1164:5). Dr. McLawhon admitted that he did not run any experiments to convert Hospira's dot-blot results to a measurement in "U." (*Id.* 545:3-546:2).

I think that the testimony from Dr. Hamilton and Dr. Egrie provides substantial evidence from which the jury could have concluded that the evidence presented did not establish that Hospira's dot-blot results could be reliably converted to RIA results. Without comparability, the dot-blot production rate in Hospira's BLA would be meaningless to establish infringement, leading the jury to the reasonable conclusion that Amgen had failed to carry its burden. Amgen's assertions that Hospira failed to provide affirmative evidence of noninfringement do not change this result. (*See* D.I. 373, p. 5). Amgen's contention that Dr. Hamilton's comparability testimony should not be credited because he failed to tie it to the claim language also does not change the result. Rather, Amgen's arguments represent an attempt to improperly shift the burden of proving noninfringement to Hospira. To rebut Amgen's infringement argument, Dr. Hamilton need only have presented testimony that called into question Dr. McLawhon's testimony such that a reasonable jury could conclude that Amgen failed to prove infringement by a preponderance of the evidence.[14] Dr. Hamilton's testimony was corroborated in part by Dr. Egrie. (Trial Tr. 1163:21-1164:17). I decline to supplant the jury's determinations of credibility with my own. Thus, I conclude Amgen has failed to show that there is insufficient evidence for the jury's verdict that Hospira did not infringe the asserted claims of the '349 patent.

Accordingly, I will deny Amgen's motion for JMOL that Hospira infringed the asserted claims of the '349 patent.

B. New Trial

[14] Alternatively, if the jury found Dr. Hamilton at least as credible as Dr. McLawhon, Amgen would not have proven that it was more likely than not that Hospira infringed the '349 patent.

First, Amgen asserts that it is entitled to a new trial because, "The great weight of the evidence provided by Amgen established that Hospira's dot blot assays were comparable to an RIA, and that Hospira's cells satisfied every limitation in the '349 claims." (D.I. 358, p. 15). This argument essentially repeats Amgen's JMOL arguments.

Hospira responds that Dr. McLawhon "improperly converted the dot blot assay results into biological activity units without testifying as to why the dot blot assay and the RIA are similar or comparable." (D.I. 373, p. 14). According to Hospira, the jury's verdict is supported by Dr. Hamilton's testimony "present[ing] several reasons why the two tests are not comparable," including that "the dot blot assay used an unpurified sample whereas the standard used in Amgen's calculations was a purified sample of EPO," and the dot blot assay and the RIA in the '349 patent did not use the same standard or the same antibody. (*Id.* (citing Trial Tr. 1197:18-1198:2)).

I conclude that the jury's verdict was not against the great weight of the evidence for the same reasons expressed with respect to Amgen's motion for JMOL of infringement of the '349 patent. Accordingly, I will deny Amgen's motion for a new trial on infringement of the '349 patent on this ground.

Second, Amgen asserts that a new trial is warranted based on Hospira's statements during its closing argument that "based on the evidence [] what is inside the fence is as determined by RIA," while "outside the fence is dot blot." (D.I. 358, p. 15; Trial Tr. 1641:11-1642:8). According to Amgen, these statements were "legally improper, because [they] asked the jury to construe the claims to require evidence produced during an RIA to prove infringement: that is, construing the claims in such a way that they could never be infringed based on evidence from a dot-blot assay." (D.I. 358, p. 15).[15] By contrast, Hospira characterizes its statements as "not ask[ing] the jury to

[15] Amgen also cites *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1385 (Fed. Cir. 2009) as further support for its assertion that Hospira's statements in closing arguments were improper, because that case held that proof of

make a claim construction decision" and "merely point[ing] out, correctly, that 'as determined by radioimmunoassay' is literally recited in the claims." (D.I. 373, p. 15). As support for its "outside the fence" statements, Hospira's counsel pointed to Dr. Hamilton's testimony that Amgen had not adequately established that the dot-blot testing was sufficiently comparable to the RIA testing recited in the '349 claims for the dot-blot results to prove infringement. (*Id.*; Trial Tr. 1641:24-1642:8). Further, "Hospira's counsel never said that dot blot could not be used or that circumstantial evidence was not allowed." (D.I. 373, p. 15).

I agree with Hospira. Taken in context, I do not think that Hospira's "outside the fence" statements request that the jury engage in claim construction. Rather, Hospira used these statements to highlight for the jury Amgen's failure of proof of infringement of the '349 patent. Accordingly, I will deny Amgen's motion for a new trial based on Hospira's counsel's statements during closing argument.

V. AMGEN'S MOTION FOR PREJUDGMENT AND POST-JUDGMENT INTEREST

A. Prejudgment Interest

Asserting "Prejudgment interest on a damages award for patent infringement 'is the rule' under 35 U.S.C. § 284," Amgen moves to amend the judgment under Fed. R. Civ. P. 59(e) to award prejudgment interest to Amgen. (D.I. 352, pp. 1-2 (citing *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1574 (Fed. Cir. 1996); *see also General Motors Corp. v. Devex Corp.*, 461 U.S. 648 (1983))). Hospira requests that I deny Amgen's request for prejudgment interest, arguing that since "Hospira has not received FDA approval or sold its proposed EPO product, and Amgen

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infringement of the '349 patent did not require RIA evidence. (D.I. 358, p. 16). Hospira counters, "The *Roche* case does not provide any support for having a new trial because it merely held that Amgen could present its evidence to a jury—it did not say the jury had to rule in Amgen's favor." (D.I. 373, p. 15). I agree with Hospira. For the reasons stated with respect to Amgen's motion for JMOL of infringement of the '349 patent, substantial evidence supports the jury's conclusion that the dot-blot evidence presented by Amgen was insufficient to prove infringement of the '349 patent.

has suffered no economic harm," a prejudgment interest award would create a windfall for Amgen. (D.I. 376, p. 1). In other words, Hospira appears to argue that since Amgen has suffered no economic harm, prejudgment interest is not required to make Amgen whole. Hospira's argument does not fully account for the purpose of prejudgment interest "to ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." *General Motors*, 461 U.S. at 655-56 ("An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the foregone use of the money between the time of infringement and the date of the judgment."). To make Amgen whole, I will award Amgen prejudgment interest.

Assuming that prejudgment interest should be awarded, the parties dispute whether interest should be calculated as a lump sum or on a per-batch basis, and the appropriate interest rate.

Hospira asserts that prejudgment interest should be awarded on a per-batch basis, because discrete acts of infringement (i.e., manufacture) occurred on identifiable dates, justifying incremental payments of a reasonable royalty. (D.I. 376, pp. 1-2). According to Hospira, prejudgment interest on a lump sum royalty payment is inappropriate, because it "assume[s] a royalty would have been paid on EPO batches well before they even existed." (*Id.* p. 1). Amgen counters that prejudgment interest on a lump sum royalty is appropriate because, "Based on expert testimony that the lump-sum royalty would have been determined at the time of the hypothetical negotiation in late 2013, the jury awarded Amgen $70 million as lump-sum reasonable-royalty damages." (D.I. 382, p. 1). The jury could not have premised its award on Hospira's per-batch damages theory at trial, Amgen maintains, because Hospira's theory required that sales take place to trigger any damages award, and Hospira has made no sales to date. (*Id.*). I agree with Amgen.

The verdict form reflects that the jury awarded Amgen $70 million in damages, without any mention of batches or indication that the award was calculated on a per-batch basis. (*See* D.I. 325 at 4).

With respect to the applicable interest rate, Amgen submits that an award of prejudgment interest calculated at the prime rate, compounded quarterly is appropriate. (D.I. 352, p. 2). Since Hospira would have needed a license to begin manufacturing EPO batches, Amgen argues that I should award Amgen prejudgment interest starting on November 10, 2013, the date of manufacture of the first infringing batch. (*Id.* pp. 2-3). Hospira asserts that prejudgment interest should be awarded at "Amgen's average debt rate on a per-batch basis," instead of the prime rate. (D.I. 376, pp. 2, 10).[16] According to Hospira, since "Amgen's 10-Ks show loans at rates at significantly below the prime rate," the prime rate "is not supported by evidence and would create a windfall for Amgen." (*Id.* p. 2). Amgen responds that Hospira bases its calculation on "two instances in Amgen's corporate filings, identifying a term loan entered in 2013 and a revolving credit agreement entered in 2014." (D.I. 382, p. 5). This is improper, Amgen submits, because "Hospira is simply speculating that Amgen would have used the awarded royalty, had it been paid when due, to pay off these loans; or, alternatively, that Amgen would have borrowed the money to invest in its business in anticipation that one day Hospira would pay the $70 million owed." (*Id.*). Therefore, Amgen asserts, the prime rate should apply, because "awarding prejudgment interest at the prime rate is one way of compensating Amgen that numerous courts, including this Court, have found to be fair and reasonable." (*Id.* p. 1).

I agree with Amgen. "Courts have recognized that the prime rate best compensate[s] a

[16] Hospira calculates the total prejudgment interest due under its average debt rate theory on a per-batch basis at $4,843,492. (D.I. 376, p. 10). Hospira calculates the total prejudgment interest due under its average debt rate theory on a lump-sum basis at $6,276,396. (*Id.* p. 12).

patentee for lost revenues during the period of infringement because the prime rate represents the cost of borrowing money, which is 'a better measure of the harm suffered as a result of the loss of the use of money over time.'" *IMX, Inc. v. LendingTree, LLC*, 469 F. Supp. 2d 203, 227 (D. Del. 2007). Therefore, I will set prejudgment interest at the prime rate, compounded quarterly. *See, e.g.*, *Ironworks Patents, LLC v. Apple, Inc.*, 2017 WL 2535877, at *14 (D. Del. June 12, 2017); *LG Display Co. v. AU Optronics Corp.*, 722 F. Supp. 2d 466, 475 (D. Del. 2010).

Accordingly, I will award Amgen prejudgment interest using the prime rate compounded quarterly and applied against the $70 million lump-sum reasonable royalty award beginning on November 10, 2013.

B. Post-judgment Interest

The parties agree that post-judgment interest should accrue at the statutory rate as specified in 28 U.S.C. § 1961(a). (D.I. 352, p. 3; D.I. 376, pp. 12-13). They disagree, however, regarding when post-judgment interest begins to accrue on the judgment and when post-judgment interest begins to accrue on the prejudgment interest.

Amgen asserts, "prejudgment interest [should] be awarded through the date of the final judgment and [] post-judgment interest (on the jury award and the prejudgment interest) [should] be awarded after that date." (D.I. 382, p. 6). Hospira argues that post-judgment interest should begin to accrue on the damages award as of September 25, 2017, the date the Court entered judgment on the jury's verdict, and that post-judgment interest should begin to accrue on the prejudgment interest as of the date that the prejudgment interest is quantified. (D.I. 376, p. 14).

Section 1961(a) provides, "Interest shall be allowed on any money judgment in a civil case recovered in a district court. . . . Such interest shall be calculated from the date of the entry of the judgment . . . ." 28 U.S.C. § 1961(a). The Third Circuit addressed the accrual of post-judgment

interest under § 1961(a) in *Eaves v. Cty. of Cape May*, 239 F.3d 527 (3d Cir. 2001). *See Travelers Cas. & Sur. Co. v. Ins. Co. of N. Am.*, 609 F.3d 143, 174-75 (3d Cir. 2010) (declining to limit *Eaves* to the attorneys' fees context). "Given the plain language and structure of the statute, it is clear that 'the judgment' referred to in the third quoted sentence is the 'money judgment' specified in the first." *Eaves*, 239 F.3d at 532. "[T]he phrase 'any money judgment' in § 1961(a) [] requires that the judgment at issue award a fixed amount of fees to the prevailing party in order to trigger the post-judgment interest period." *Id.* at 534. Therefore, "post-judgment interest begins to run on a judgment awarding attorney's fees where that judgment fixes the amount owed to the prevailing party." *Id.* "The statute does not, by its terms, mandate that the judgment from which interest is calculated must be a final judgment." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1177-78 (3d Cir. 1993); *see also Skretvedt v. E.I. DuPont De Nemours*, 372 F.3d 193, 216 (3d Cir. 2004) ("The fact that the December 13, 2001, judgment was not a final order for purposes of appeal would not otherwise prevent postjudgment interest from running under § 1961 . . . .").

On September 25, 2017, I entered judgment for Amgen and against Hospira on the jury's verdict in the amount of $70 million. (D.I. 327). As of that date, I entered a "money judgment" for Amgen that "include[d] both 'an identification of the parties for and against whom the judgment [wa]s being entered,' and 'a definite and certain designation of the amount . . . owed.'" *See Travelers*, 609 F.3d at 175 (quoting *Eaves*, 239 F.3d at 533) (brackets added). Accordingly, I will award Amgen post-judgment interest on the $70 million damages award beginning on September 25, 2017. Prejudgment interest, however, will not have been quantified in a money judgment until the date of the final judgment accompanying this opinion. Accordingly, I will award Amgen post-judgment interest on the prejudgment interest commencing on the date of entry

of the final judgment quantifying the amount of prejudgment interest owed to Amgen. *See Travelers*, 609 F.3d at 175 (holding that though the district court entered judgment in favor of Travelers on August 14, 2006, "post-judgment interest on Travelers' award of prejudgment interest did not begin to run until the December 5, 2007 order was entered quantifying the amount in prejudgment interest owed to Travelers.").

Amgen cites several cases from this District in which "prejudgment interest has [] been awarded through the date of entry of final judgment, rather than the date of the jury's verdict." (D.I. 382, pp. 6-8 (citing *LG Display Co., Ltd v. AU Optronics Corp.*, 722 F. Supp. 2d 466, 475 (D. Del. 2010); *Telecordia Techs., Inc. v. Cisco Sys., Inc.*, 592 F. Supp. 2d 727, 748-49 (D. Del. 2009), *vacated in part on other grounds*, 612 F.3d 1365, 1379 (Fed. Cir. 2010); *Northeast Controls, Inc. v. Fisher Controls Intern., LLC*, 2008 WL 678701, at *2 (D. Del. Mar. 12, 2008), *rev'd on other grounds*, 373 F. App'x 162 (3d Cir. 2010); *Tristrata Tech., Inc. v. Mary Kay Inc.*, 423 F. Supp. 2d 456, 471 (D. Del. 2006))). Each of these cases, with the exception of *LG Display*, was decided before the Third Circuit's *Travelers* decision. Additionally, none of these cases provide any explanation for their selection of the date through which prejudgment interest was awarded, or any indication that the parties disputed the date through which prejudgment interest would accrue. Amgen also asserts, "The cases that Hospira cites state that post-judgment interest may be awarded on a judgment that sets the amount of the damages, but they do not address the appropriate timing for switching from the prejudgment rate to the post-judgment rate." (D.I. 382, p. 7). Notably, Amgen's discussion of Hospira's cited cases omits any mention of *Travelers*. In fact, *Travelers* is not cited anywhere in Amgen's brief. Therefore, I do not find convincing Amgen's argument that pre-judgment interest should be awarded on the $70 million award through the date of final judgment.

Therefore, I will award Amgen prejudgment interest using the prime rate compounded quarterly and applied against the $70 million lump-sum reasonable royalty award beginning on November 10, 2013. I will award Amgen post-judgment interest on the $70 million award beginning on September 25, 2017, the date judgment was entered on the award. I will award Amgen post-judgment interest on the prejudgment interest beginning on the date of entry of the final judgment quantifying the amount of prejudgment interest owed to Amgen in accordance with this opinion.

VI. CONCLUSION

For the reasons set forth above, Hospira's Rule 50(a) Motion for Judgment as a Matter of Law on the Issues of Safe Harbor, Noninfringement, Invalidity, and Damages (D.I. 336) is dismissed as moot. Hospira's Motion for Judgment as a Matter of Law Under Rule 50(b) and, in the Alternative, For Remittitur or New Trial Under Rule 59 (D.I. 355), Hospira's Motion to Seal Confidential Exhibits Admitted at Trial (D.I. 361), and Amgen's Renewed Motion for Judgment as a Matter of Law of Infringement of the '349 Patent or, in the Alternative, for a New Trial (D.I. 356), are each denied. Amgen's Motion for Prejudgment and Post-judgment Interest (D.I. 352) is granted-in-part.