IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH LTD.,	:	
	:	CIVIL ACTION
Plaintiff,	:	
	:	
v.	:	
	:	
BARR LABORATORIES INC.	:	NO. 09-CV-0318-LDD
	:	
Defendant.	:	

MEMORANDUM ORDER

AND NOW, this 16th day of March, 2012, upon consideration of Plaintiff's Motion to Amend our opinion and judgment (Doc. No. 262) and Defendant's opposition thereto (Doc. No. 267), as well as Defendant's Motion to Amend our judgment (Doc. Nos. 264-65) and Plaintiff's opposition thereto (Doc. No. 266), it is hereby ORDERED that both motions (Doc. Nos. 262, 264-65) are DENIED in their entireties.

I. Factual Background and Procedural History

After a bench trial in this Hatch-Waxman patent infringement suit, we found in favor of Plaintiff Alcon Research, Ltd. ("Alcon") in some respects and Defendant Barr Laboratories Inc. ("Barr") in others. (See Doc. No. 255). For the reasons set forth in our opinion, we entered judgment of (1) infringement of the asserted claims of U.S. Patent Nos. 6,503,497 ("the '497 patent") and 6,849,253 ("the '253 patent") and (2) non-infringement and invalidity of the asserted claims of U.S. Patent Nos. 5,631,287 ("the '287 patent") and 6,011,062 ("the '062 patent"). (Doc. No. 261). We also denied Barr's oral motion for judgment as a matter of law ("JMOL") of non-infringement of U.S. Patent Nos. 5,510,383 ("the '383 patent") and 5,889,052 ("the '052 patent"), as these patents were never litigated or fairly placed at issue during trial.

(See Doc. No. 255, at 52-54).

Apparently, neither party was pleased. Both have now filed post-judgment motions asserting that we made serious errors that need correction. As explained herein, we deny both motions in their entireties.

II. Legal Analysis

A. Plaintiff Alcon's Motion

Pursuant to Federal Rules of Civil Procedure 52(b) and 59(e), Plaintiff Alcon moves to amend certain findings of fact in our December 13, 2011 Opinion (Doc. No. 255) and to amend our Final Judgment of January 9, 2012 (Doc. No. 261) accordingly. The Third Circuit recently emphasized that the "scope of a motion for reconsideration . . . is extremely limited." Blystone v. Horn, 664 F.3d 397, 415 (3d Cir. 2011). "The purpose of a Rule 52(b) motion is to 'correct manifest errors of law or fact or, in some limited situations, to present newly discovered evidence.'" Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 762 F. Supp. 2d 710, 717 (D. Del. 2011) (citations omitted). Furthermore, we allow a Rule 52(b) motion to amend only "when the issues are 'basic or essential' to the litigation." Id. (citation omitted). Importantly, Rule 52(b) *does not* permit a party to get a "second bite at the apple," e.g., by re-litigating old issues or advancing new theories not presented at trial. Id. at 717-18 (citations omitted). Here, as set forth below, Alcon has not met its high burden of showing that we made a manifest error of law or fact.

Before turning to the particular factual findings Alcon asks us to amend, we first address Alcon's general contention that we overstepped by making findings that neither party's experts explicitly requested. (Doc. No. 262, at 2, 4-5). We fundamentally disagree with this position.

As a basic proposition, we may in our discretion make findings of fact relevant to our decision, whether or not the parties expressly request such findings. Power Integrations, 762 F. Supp. 2d at 717 (citing Kelley v. Everglades Drainage Dist., 319 U.S. 415, 422 (1943)). This makes good sense. As the factfinder in this bench trial, it is our job to seek the truth. To do so, we must determine whether to believe the given testimony in whole, in part, or not at all. With respect to expert testimony, our evaluation of an expert's opinion necessarily entails a critical, searching analysis of the underlying basis for that opinion. This remains true, even if that basis includes scientific or technical documents. And we must be particularly diligent in a patent case such as this, in which competing experts look at the same information and invariably come to opposite conclusions. While we certainly rely on well-supported expert testimony to guide us, in the end, we must make up our own mind. We would not act prudently by merely parroting the position of one expert or another, especially when we have concerns about those experts (as we did here).

First, consider Alcon's expert Dr. Levinson. In this patent suit, Dr. Levinson submitted a CV replete with errors about the patents on which he purportedly worked. (Tr. 507-14). In addition, the core dispute in this matter concerns whether or not polyethoxylated castor oil ("PECO") chemically stabilizes the prostaglandin Travoprost, yet Dr. Levinson admitted that he is no expert in prostaglandin chemistry or chemical changes in prostaglandins. (Tr. 527:22-528:12; 529:9-14; 534:7-15; 532:11-18; 536:4-19; 542:24-543:2). Finally, to support his infringement contentions, Dr. Levinson relied primarily on *two (2) data points* in a table reflecting the *control sample* results of a "soaking study" that, on its face, had *nothing to do with the chemical stabilization of Travoprost* and tested a composition *markedly different* from the Travatan Z® formulation at issue here. (Tr. 492-504; 549:3-550:7; PTX 45; DTX 1012). Under

the circumstances, we could not blindly rely on Dr. Levinson's testimony; we needed to, and did, explore its underpinnings.

We also found Barr's experts unconvincing in several respects. In particular, although Barr's experts had no trouble transcribing the correct legal standards into a slide show, we harbor some doubt that they actually used the proper standards in practice. For example, regarding § 112, second paragraph, Dr. Stern testified that the patentee must disclose enough information to design a drug "as close to ideal as possible" for a claim to be definite. (Tr. 636:14-23). That is, of course, incorrect. And regarding obviousness, Dr. Kent testified that combining bits and pieces of the cited references to construct the claimed invention is not "an impossible reach." (Tr. 891:12-17). This, too, reflects an incorrect understanding of the law. We point out these problems to stress the need for our own independent evaluation of all the evidence in this matter. We conducted such an evaluation and made findings accordingly.

Coming now to the specific findings Alcon challenges, Alcon first argues that our statement that "one of Alcon's own patents, U.S. Patent No. 6,235,781 ('the '781 patent'), undercuts Dr. Levinson's conclusions regarding physical loss of prostaglandins" is flawed. Therefore, Alcon asks us to strike paragraph III.B.20 of our opinion, which relates to that patent. As an initial matter, we note that Alcon makes a blatantly false statement about the '781 patent. Specifically, Alcon incorrectly asserts that "[t]he testing in the '781 patent was conducted in plastic, not in glass. . . ." (Doc. No. 262, at 8). In truth, Figures 1-4 of the '781 patent, as well as their respective descriptions, show that the inventors conducted testing in *plastic and glass*. We recognized this and found, correctly, that "[t]he graphs depicted in Figures 1-4 of the '781 patent show that, in fact, a substantial amount of prostaglandin physical loss may occur, even in glass

containers." (Doc. No. 255 ¶ III.B.20). Thus, Alcon's arguments in this regard are wholly unpersuasive.

Alcon also asserts that we erroneously inferred from Figures 1-4 of the '781 patent that "physical loss [of the prostaglandin] occurs rather steadily over time" because the figures depict a "linear decrease in prostaglandin concentration over a four (4) week period," as the figures do not contain enough information to draw that conclusion. Alcon misreads our finding. We simply stated that "the *'781 patent inventors apparently believed* that physical loss occurs rather steadily over time ('781 patent, Figures 1-4, which depict a linear decrease in prostaglandin concentration over a four (4) week period)." (Doc. No. 255 ¶ III.B.20) (emphasis added). Apparently, the inventors did so believe based on the representations in Figures 1-4.

We recognize that each figure contains data from only two (2) points in time, and we appreciate Alcon's citation to Euclid for the proposition that connecting two points makes a line. However, no principle of geometry requires the line to be straight. If the '781 patent inventors had reason to doubt that a linear decrease illustrated the invention's effect on stability, then they could have said so; or run tests at various intervals; or left the data alone; or depicted a non-linear decrease between the two data points. The inventors did none of these things; rather, they submitted drawings to the Patent Office showing a linear decrease in prostaglandin concentration over a four (4) week period. As such, the evidence reasonably supports our inference that "the '781 patent inventors apparently believed that physical loss occurs rather steadily over time." See Roadmaster (USA) Corp. v. Calmodal Freight Sys., Inc., 153 Fed. App'x 827, 829 (3d Cir. 2005) (holding that it is well within a district court's broad discretion to clarify a party's incorrect interpretation of, and inferences drawn from, the court's findings); Torres-Lazarini v.

United States, 523 F.3d 69, 72 (1st Cir. 2008) ("When the evidence presented at a bench trial supports plausible but competing inferences, the court's decision to favor one inference is not clearly erroneous.") (citation omitted); Fontenot v. Mesa Petroleum Co., 791 F.2d 1207, 1220 (5th Cir. 1986) (no error in district court's reliance on reasonable inference in making findings of fact).

As an aside, given that *Alcon's expert Dr. Levinson raised the issue of linearity in the first place*, we find it somewhat ironic that Alcon now chooses to characterize the issue as a "red herring," deriding our observations about the non-linearity of the PTX 45 data as "irrelevant." (Doc. No. 262, at 7 n.4). As we mentioned in our December 13th opinion, Dr. Levinson opined that the data in the castor oil patents shows chemical stability, not physical stability, because the data plotted linearly on a log scale, which indicates a first-order chemical reaction. (Tr. 479-83). We discussed the non-linearity of the data in PTX 45 in response to that assertion. Now, facing this problem with Dr. Levinson's testimony, Alcon has done an about-face and seeks to trivialize the issue that its expert once trumpeted. Under the circumstances, it is disingenuous for Alcon to label the linearity question as a "red herring," and our discussion about the non-linearity of the data on which Dr. Levinson relied was certainly not "irrelevant."

Alcon also takes exception to our rhetorical question, "[i]f physical loss occurs so rapidly (mere hours or days, as Dr. Levinson opined), why wait four (4) weeks to test for it?" (Doc. No. 262, at 8). Specifically, Alcon believes it has a good answer to this question, i.e., absorption occurs in plastic, so "there is good reason to run the experiment over a longer period of time so as not to miss the absorption that takes more time to occur." (Id.). Perhaps this is true, perhaps not. The record certainly does not contain any persuasive evidence to support Alcon's

proposition that one would want to wait four (4) weeks to capture all the absorption (or other physical loss) that takes place in the plastic tested in the '781 patent. In fact, Dr. Levinson's testimony suggests that the '781 patent inventors aimed to reduce *adsorption*, not *absorption*. (Tr. 559:11-560:3). Thus, we had a reasonable basis to ask this rhetorical question.

Next, Alcon moves to strike paragraphs III.B.34, III.B.35, and III.B.36 because, according to Alcon, DTX 1283 demonstrates the existence of chemical degradation products. Alcon is incorrect. What DTX 1283 actually shows are several "unknown" chemical substances that Alcon believes might be Travoprost degradation products. But Alcon is just guessing. The authors of the DTX 1283 study did not determine that the unknown substances were degradation products, and no one testified to that effect at trial. In fact, Alcon admits that "one cannot conclusively exclude the possibility that these chemical substances are not degradation products of travoprost." (Doc. No. 262, at 10). As such, our statement that "7% of the Travoprost went missing, but it was *not* due to chemical degradation" in reference to DTX 1283 is sound.

The second purported "scientific error" we made with respect to paragraphs III.B.34, III.B.35, and III.B.36 is based on an entirely new theory that Alcon never suggested at trial or raised in its post-trial brief. Therefore, Alcon's argument is improper under Rule 52(b), and we need not even address it. See Power Integrations, 762 F. Supp. 2d at 717-18 (Rule 52(b) does not allow a party to obtain a "second bite at the apple" by advancing new theories not presented at trial). However, we make the following comments for the sake of thoroughness.

In brief, Alcon now argues that the fact that "no or trace" amounts of two known Travoprost degradation products were detected (as was the case in DTX 1283) does not imply that none of the Travoprost had ever degraded into those degradation products because chemical

degradants may themselves degrade. (Doc. No. 262, at 11). This argument fails to persuade us, primarily because Alcon has presented absolutely no evidence, testimonial or otherwise, to support it. This is not surprising, since Alcon did not even raise this theory at trial. We will not amend our findings to accommodate Alcon's unfounded speculation.

Finally, Alcon moves to strike paragraph III.B.21 of our opinion, which reads as follows:

> In the end, the difference in missing Travoprost between the "no PECO" sample and the "0.50% PECO" sample is 4% – after eight (8) weeks, 92% of the Travoprost remains in the PECO-containing sample, while 88% of the Travoprost remains in the sample without PECO. We do not know for sure where the missing Travoprost went in either sample. However, this is an extremely small difference which could be attributed to a number of factors other than PECO enhancing the chemical stability of the Travoprost, e.g., experimental error or uncertainty, adsorption, precipitation, or other physical loss. These factors take on particular importance here because the Travoprost concentration is so low – 0.005% w/v in the Table 7 samples and 0.004% in Travatan Z® and Barr's generic version of the same. (PTX 45, Table 2). Therefore, even a small absolute amount of experimental error or physical instability (adsorption, etc.) would lead to a relatively large variation, percentage-wise, in Travoprost concentration.

Specifically, Alcon argues that the evidence does not support any of the four possibilities we identified – experimental error or uncertainty, adsorption, precipitation, or other physical loss – "that might explain the loss of travoprost reflected in Table 7." (Doc. No. 262, at 12). Again, Alcon misstates our findings. We mentioned these four alternatives to chemical instability as examples of factors that could account for the *extremely small difference* in missing Travoprost between the "no PECO" and the "0.50% PECO" samples. Contrary to the premise of Alcon's argument, we did not find that any of these factors explained the entire Travoprost loss seen in the Table 7 data. More fundamentally, Alcon's hyper-technical arguments disregard the main point of paragraph III.B.21, namely that Alcon failed to meet its burden of proving infringement, in part because Alcon failed to show that the "extremely small difference" in Travoprost loss

between the two samples was due to the *chemically*-stabilizing effect of PECO as opposed to physical stabilization of some sort. In any event, Alcon's argument is flawed because the alternatives we mentioned could indeed have led to the small difference in Travoprost loss recorded in Table 7.

With respect to precipitation, Table 5 of PTX 45 indicates that 0.1% Travoprost solutions containing no PECO, 0.01% PECO, 0.05% PECO, and 0.1% PECO are "milky white with precipitates" at room temperature. Thus, Travoprost may precipitate out of solution, even if the solution contains a surfactant such as PECO. At a higher PECO concentration (0.5%), precipitation is less of a problem.[1] (See PTX 45, Table 5, which states that a room temperature 0.5% PECO / 0.1% Travoprost solution is "clear"; PTX 45, at ALCON-0188410 ("The solubility of the drug substance increases as the concentration of [PECO] in the buffer solution is increased.")). Dr. Kent also testified that precipitation could explain the data in Table 7, i.e., the difference between the "no PECO" and the "0.50% PECO" sample results. (Tr. 746-50). Since the sample without PECO has a lower Travoprost solubility to begin with, it makes sense that precipitation in the "no PECO" sample over the course of the eight (8) week, elevated temperature study involved in PTX 45 may have contributed to the slightly higher amount of Travoprost loss in that sample.

Regarding experimental error or uncertainty, Alcon contends that "[t]here is similarly no basis in the trial record for asserting that the measured loss of travoprost might be attributable to 'experimental error.'" Alcon is mistaken. In our prior opinion, we explicitly set forth a basis for

[1]This is further evidence that PECO enhances the physical stability of Travoprost, not its chemical stability.

finding experimental error or uncertainty in the Table 7 data. (Doc. No. 255 ¶ III.B.15).

Alcon also asserts that there is "no record evidence whatsoever that smaller absolute concentrations of the substance being measured increases the likelihood of experimental error." Once again, Alcon either misstates or misunderstands our finding. We did not find that a lower concentration increases the *likelihood* of experimental error. Rather, we recognized that, at the low Travoprost concentrations at issue here, "even a small absolute amount of experimental error or physical instability (adsorption, etc.) would lead to a relatively large variation, percentage-wise, in Travoprost concentration." Although we believe this statement speaks for itself, we provide the following example for clarity's sake.

Suppose a solution contains only 10 molecules of Travoprost. If three (3) molecules stick to the wall of a container, then the Travoprost concentration has fallen by 30%. Now suppose the solution contains 100 Travoprost molecules. If those same three (3) molecules adsorb to the container wall, the concentration has fallen by only 3%. Similar reasoning applies to experimental error or uncertainty. Suppose a concentration detection method has an error rate of +/- three (3) molecules. If we use that method to measure the concentration of Travoprost in a 10-molecule solution, the uncertainty is +/- 30%. In a 100-molecule solution, the uncertainty is only +/- 3%. All this is germane to our analysis because Alcon asks us to find infringement based on *very small concentration differences* between two Travoprost-containing solutions, one with PECO and one without. Because these solutions contain Travoprost in such low absolute concentrations, factors other than chemical stability (physical stability, or experimental error or uncertainty) need only play a small role, absolutely speaking, to have a large effect on the Travoprost concentration, relatively speaking.

Finally, in regards to adsorption and other physical loss, Alcon argues that the uncontradicted testimony of Alcon's witnesses (Mr. Schneider and Dr. Levinson) reflects that adsorption occurs quickly and cannot explain the disappearance of Travoprost over a span of weeks. (Doc. No. 262, at 13). However, as we pointed out in our prior opinion, Dr. Levinson admitted that some adsorption onto glass could occur, and Alcon cited "no authority or documentary evidence to support [Dr. Levinson's] assertion that adsorption would occur rapidly." (Doc. No. 255 ¶ III.B.19). Even assuming that adsorption does occur only over a short period of time, it still could explain at least some of the extremely small difference in missing Travoprost between the "no PECO" sample and the "0.50% PECO" sample in Table 7, especially given the low Travoprost concentrations involved.

Alcon similarly argues that "Barr never alleged – and no evidence at trial supports – that solutions such as those tested in Table 7 experience any type of physical instability *other than adsorption or absorption*. Indeed, it is not clear to what 'other physical loss' might refer." (Doc. No. 262, at 13) (emphasis added). Alcon has answered its own question; "other physical loss" refers to absorption, which we did not expressly mention in the four-element list to which Alcon objects. For all the aforementioned reasons, we deny Alcon's Rule 52(b) motion to amend our findings.

Alcon bases its Rule 59(e) motion to amend the judgment on the assumption that we would amend our findings as Alcon requested. For the reasons discussed *supra*, we did not amend or strike any of our findings, and we deny Alcon's Rule 59(e) motion accordingly. See Blystone, 664 F.3d at 415 (emphasizing that "a judgment may be altered or amended only if the party seeking reconsideration shows at least one of the following grounds: (1) an intervening

change in the controlling law; (2) the availability of new evidence . . . or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.") (citation omitted). Alcon has shown no grounds to warrant an amended judgment in this matter. On the contrary, Alcon simply failed to prove infringement by a preponderance of the evidence.

We end by noting that we would not have reversed our judgment of non-infringement, even if we had amended our findings in the manner proposed by Alcon. In other words, even after removing the challenged findings from the infringement scale, it still tips in favor of Barr. (See Section III.B of Doc. No. 255, which delineates the many reasons for our holding that Barr does not infringe the asserted claims of Alcon's castor oil patents).

B. Defendant Barr's Motion

Unlike Alcon, Barr does not move under Rule 52(b) for amended findings. Instead, Barr urges us to amend our judgment under Rule 59(e) to hold that Barr's Travatan Z® ANDA product does not infringe U.S. Patent Nos. 5,510,383 ("the '383 patent") and 5,889,052 ("the '052 patent"). Remember, Barr moved for a JMOL of non-infringement of these two (2) patents at the close of Alcon's case-in-chief, and we declined to enter such a judgment because the patents were never litigated or fairly placed at issue during trial. (See Doc. No. 255, at 52-54). Barr submits that our refusal to enter JMOL on the '383 and '052 patents constitutes a clear error of law because Alcon never formally dismissed these patents from the case and did not introduce any evidence of infringement. Barr worries that, without a judgment of non-infringement, Alcon may use the '383 and '052 patents to prevent Barr from launching its generic version of Travatan Z®. Barr's rather clever argument fails to persuade us because Federal Circuit law, as it currently stands, is contrary to Barr's position. If Barr wanted a judgment of non-infringement

of these patents, then Barr should have given fair notice to Alcon by filing a declaratory judgment counterclaim. Barr *did not* file such a counterclaim and therefore must shoulder the blame for its current predicament.

As a preliminary matter, the parties should have fleshed-out their respective positions on this issue at an earlier stage in the litigation. As noted *supra*, Barr's counsel orally moved for a JMOL of non-infringement of the '383 and '052 patents at the close of Alcon's infringement case. (Tr. 563:2-15). However, Barr cited no legal authority to support its motion. Alcon's counsel opposed Barr's request for JMOL, stating "[w]e advised the defendants that we were not going to be asserting those patents at trial. There is no counterclaim that's been asserted so I don't believe the defendant is entitled to any judgment of non-infringement." (Tr. 563:16-21). Like Barr, Alcon cited no legal authority for its position.[2] We held the motion under advisement, and Barr proceeded to present its case. (Tr. 563:25-564:1).

The parties paid scant attention to this issue in their post-trial briefs. Each party devoted a single paragraph to the '383 and '052 patents and essentially reiterated what was said at trial. (See Doc. Nos. 247, at 24-25; 248, at 25). Again, neither party cited any legal authority for its position. We resolved the issue in favor of Alcon based on applicable Federal Circuit precedent. (See Doc. No. 255, at 52-54). Now, Barr has filed a Rule 59 motion and a lengthy supporting memorandum citing no fewer than twenty-two (22) cases and arguing that our resolution of the matter constituted a clear error of law that we must correct to prevent manifest injustice. (See Doc. Nos. 264-65). This stretches the bounds of permissible Rule 59 practice. Rule 59(e) is

[2]We have no doubt that Barr's motion caught Alcon by surprise, so we do not fault Alcon's counsel for failing to cite supporting authority at this point in time.

properly used for error correction, not litigation in the first instance. However, since the parties did raise this issue at trial and in their post-trial briefs, albeit in a cursory manner, we will reach the merits of Barr's motion.

First, the facts. Alcon initially sued Barr for infringement of a number of patents, including the '383 and '052 patents at issue in this motion. (See Alcon Research, Ltd. v. Barr Laboratories, Inc., No. 09-cv-512 (D. Del. July 13, 2009), at Doc. No. 1). Barr answered Alcon's complaint, denying infringement. (Id. at Doc. No. 9). Importantly, Barr asserted affirmative defenses in its answer but *brought no counterclaims*, e.g., for a declaratory judgment of non-infringement. (Id.).

On August 4, 2010, Alcon sent a letter to Barr stating that Alcon had decided to dismiss its claims based on the '383 and '052 patents. (Doc. No. 265, at 3). However, the parties apparently could not agree on the language for a stipulation of dismissal, and Alcon never formally dismissed the claims. (Id. at 4). Nonetheless, Barr knew full well that Alcon would not put on an infringement case with respect to the '383 and '052 patents. For example, neither party placed these patents at issue during the claim construction phase of this litigation. (See Doc. Nos. 213-14 (construing the disputed claims, none of which came from the '383 or '052 patents)). In addition, the parties' joint proposed findings of fact and conclusions of law explicitly recognized that "Alcon has . . . dropped those patents [the '383 and '052 patents] from this case." (Doc. No. 221 ¶ 15). The parties' proposed joint pretrial order did likewise (See Doc. No. 204, at 2 n.4 ("Alcon is no longer asserting infringement of U.S. Patent Nos. 5,510,383; 5,889,052; or 5,849,792.").

Predictably, at trial, Alcon introduced no evidence of infringement of the '383 and '052

patents. Immediately after Alcon rested its infringement case, Barr moved for JMOL of non-infringement of the '383 and '052 patents. We conclude that granting Barr's request for JMOL under these circumstances would run counter to Federal Circuit precedent and would effectively sanction litigation by ambush. As explained below, we correctly denied Barr's motion.

Our decision here was governed largely by two Federal Circuit opinions: Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H., 945 F.2d 1546 (Fed. Cir. 1991), *abrogated on other grounds*, Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995); and 800 Adept, Inc. v. Murex Sec., Ltd., 539 F.3d 1354 (Fed. Cir. 2008). In Tol-O-Matic, the "evidence and argument at trial were directed only to the subject matter of" a single claim. 945 F.2d at 1554. Nevertheless, Tol-O-Matic took the position that the pleadings placed the other claims at issue, and since its opponent, "having the burden of proof on infringement, offered no evidence of infringement of these claims, the judgment of noninfringement should have included these claims." Id. The Federal Circuit flatly rejected this argument, enunciating the principle that "[p]leadings do not suffice to support a judgment when the subject matter was not litigated, or fairly placed in issue, during the trial." Id. (citation omitted). The court continued, explaining that "[t]here must be sufficient and explicit notice of the claims at risk. When the pleadings are not in complete harmony with the issues that were litigated and adjudicated, it is the pleadings that may be conformed to the judgment, not *vice versa*." Id. at 1554-55.

The rationale for this rule is self-evident and reflects our basic notions of fair play and due process. Unless a party has "sufficient and explicit notice of the claims at risk," it would be unfair to enter judgment against that party on those claims. The parties must know what is at

stake in order to properly litigate the dispute.

In 2008, the Federal Circuit affirmed the continuing vitality of the Tol-O-Matic principle in 800 Adept. In that case, "Adept requested a declaratory judgment with respect to the invalidity of Targus's 'asserted claims.'" 539 F.3d at 1367. After commenting that the scope of Adept's complaint was "less than clear," the court acknowledged that "[i]n any event, a reference in the complaint is not sufficient to support a judgment that particular claims are invalid; the specific validity of those claims must have been *at issue during the trial and actually litigated by the parties*." Id. (emphasis added) (citation omitted). Factually, the court "agree[d] with Targus that the unasserted claims were not at issue" and concluded that the trial judge erred in entering judgment of invalidity of those claims. Id. Relevant to our analysis in this case, the 800 Adept court relied, at least in part, on the parties' joint pretrial statement to define the scope of the claims actually at issue during trial. Id. at 1367-68. The court also relied on the trial proceedings themselves, noting that "at trial, neither party presented evidence with respect to the unasserted claims." Id. at 1368. In the end, the 800 Adept court held that "it is clear from the parties' pretrial statement and from the trial proceedings that the unasserted claims were neither litigated nor placed in issue during the trial" and reversed the district court accordingly. Id.

Here, as in Tol-O-Matic and 800 Adept, Alcon lacked sufficient and explicit notice of the claims at risk. Although Alcon initially asserted the '383 and '052 patents in its complaint, the parties' conduct leading up to trial made clear that these patents were no longer at issue. As in both Tol-O-Matic and 800 Adept, neither party presented any evidence on the unasserted claims at trial. And as in 800 Adept, the parties' joint pretrial submissions reflected the parties' understanding that the unasserted claims were no longer a part of the case. At bottom, we are

left with Alcon's complaint, and a complaint alone cannot support a judgment on claims not actually placed in issue at trial. Tol-O-Matic, 945 F.2d at 1554-55; 800 Adept, 539 F.3d at 1367-68.[3]

Barr attempts to distinguish Tol-O-Matic and 800 Adept, but unpersuasively. First, Barr argues that "Alcon, not Barr, first placed these patents at issue with its complaint," so unlike the patentee in Tol-O-Matic, Alcon did not lack "sufficient and explicit notice of the claims at risk." (Doc. No. 265, at 13). We disagree. As discussed *supra*, Alcon had no intention of litigating the '383 and '052 patents at trial, and Barr knew it. In fact, since the parties' joint pretrial filings explicitly recognized that Alcon had dropped the '383 and '052 patents, Alcon could not have tried infringement of these patents even if Alcon wanted to. (See Doc. No. 204, at 1 ("This order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.")). Because Barr never asserted a counterclaim, Alcon had every reason to believe that the '383 and '052 patents were not at issue at trial and had no fair notice that Barr would contend they were.

Second, Barr suggests that Tol-O-Matic is distinguishable because, unlike the plaintiff in Tol-O-Matic, Barr raised the '383 and '052 patents during trial. (Doc. No. 265, at 13). But Barr

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[3]Although neither party raised the issue, we have some concern about whether we have jurisdiction to adjudicate the '383 and '052 patents, given the arguable lack of a live case or controversy over those patents as evidenced by the parties' joint pretrial filings and conduct at trial. See Weiss v. Regal Collections, 385 F.3d 337, 340 (3d Cir. 2004) ("When the issues presented in a case are no longer 'live' or the parties lack a legally cognizable interest in the outcome, the case becomes moot and the court no longer has subject matter jurisdiction."); Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1283-84 (Fed. Cir. 2012) (holding that "the district court did not have jurisdiction over the unasserted claims" when counterclaim was limited to the "asserted claims."). However, under the present procedural posture of the case, we believe Barr's motion for JMOL on the '383 and '052 patents presents a live controversy sufficient for us to enter this Order.

"raised" these patents only to move for JMOL of non-infringement at the close of Alcon's case-in-chief, a case in which neither party so much as mentioned the patents. Barr's JMOL motion in no way put the '383 and '052 patents "at issue" during trial as envisioned by Tol-O-Matic and 800 Adept. Those cases stand for the general proposition that a party should have fair notice of the claims at stake *before* facing the possibility of an adverse judgment. Here, Barr's motion came too late to give Alcon sufficient – or indeed any – notice of the risk of a judgment of non-infringement.

Next, Barr argues that 800 Adept is distinct because it related to validity rather than infringement. (Doc. No. 265, at 11-12). In the present context, this is a distinction without a difference. As discussed *supra*, we may only enter judgment on the claims actually at issue in a case. To determine whether claims are sufficiently "at issue" to support a judgment, we take a function-over-form approach, considering factors such as the parties' pretrial filings and conduct at trial, e.g., the parties' evidentiary presentations, while discounting mere allegations in the pleadings. See Tol-O-Matic, 945 F.2d at 1554-55; 800 Adept, 539 F.3d at 1367-68. We do this to ensure that each party has fair notice of the claims at stake. Importantly, the "fair notice" rationale for this safeguard applies regardless of whether a patent suit involves infringement, validity, or both.

The cases Barr cites to support its position actually undermine it. Specifically, in each of Barr's cited cases, the accused infringer – unlike Barr – filed a claim or counterclaim seeking a judgment of non-infringement or invalidity. See, e.g., Lear Auto. Dearborn, Inc. v. Johnson Controls, Inc., 528 F. Supp. 2d 654, 669 (E.D. Mich. 2007) (finding jurisdiction under the Declaratory Judgment Act over invalidity counterclaims, even though patentee offered to

provide covenant not to sue); Advance Transformer Co. v. Levinson, 837 F.2d 1081, 1084 (Fed. Cir. 1988) (concluding that district court "did not clearly err in treating infringement as at issue, and in finding noninfringement" under the "tangled procedural posture" of the case); Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1383 (Fed. Cir. 2008) (rejecting argument that "district court lacked jurisdiction to adjudicate the unasserted claims" because accused infringer asserted declaratory judgment counterclaim); Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1281-82 (Fed. Cir. 2008) (holding that patentee's "covenant not to sue did not eliminate the controversy between the parties," so district court had jurisdiction over declaratory judgment action for non-infringement); Shire Labs., Inc. v. Corepharma, LLC, No. 06-2266, 2008 WL 4822186, at *1-3 (D.N.J. Nov. 3, 2008) (noting that Corepharma "included a counterclaim for declaratory judgment of noninfringement" in its answer).

The difference between the aforementioned cases, which involved a counterclaim, and this case, which does not, is critically important in the context of Barr's motion. By asserting and continuing to prosecute a declaratory judgment claim or counterclaim of non-infringement, an accused infringer can assure that the infringement issue will remain live for trial, even if the patentee withdraws its corresponding infringement claim(s). In other words, a counterclaim puts the involved patent claims "at issue" and gives the patentee fair notice that he must introduce evidence of infringement at trial or risk an adverse judgment, *even if the patentee no longer wishes to prosecute the claims*. In essence, a counterclaim obviates the fair notice concern that motivated the Federal Circuit's Tol-O-Matic and 800 Adept opinions.

Consider the implications of a contrary rule. Patentees often bring suit asserting

infringement of numerous patents. As litigation progresses, the parties whittle down the disputed issues, sometimes without formally amending the pleadings. The accused infringer files no counterclaims, so the patentee believes it is driving the bus, so to speak. Trial begins, and the patentee, as expected and required, limits its presentation to the patents agreed upon by the parties prior to trial. Of course, if the accused infringer *had* filed and prosecuted counterclaims against particular patents, the patentee would have put on a case with respect to such patents. Instead, the patentee does not, rightfully believing that the patents are no longer at issue. Barr's proposed interpretation of the law would require courts to enter judgment adverse to the patentee on these patents, even though (1) the patents fall well outside the mutually agreed-upon scope of the trial and (2) the patentee was basically tricked into believing that there was no need to present certain evidence. Alcon styles this as an "ambush" tactic, and we agree.

Finally, Barr complains that, in the absence of a judgment of non-infringement regarding the '383 and '052 patents, Alcon may be able to use the patents to prevent Barr from entering the market. (Doc. No. 265, at 16-20). We have two answers to this. First, if Barr believed this judgment of non-infringement was so critical, then Barr should have put the respective patents at issue for trial, e.g., by filing a declaratory judgment counterclaim of non-infringement or, at the very least, by raising the issue in its pre-trial filings. Instead, Barr did nothing and cannot be heard to complain.

Second, Barr's argument is premature. To our knowledge, Alcon has not yet used the '383 and '052 patents offensively to block Barr from launching its Travatan Z® generic. If and when Alcon does, and Barr challenges Alcon's actions, the reviewing court will have to grapple

with the difficult estoppel- and preclusion-type issues that will likely arise.[4] It is not our place to decide those matters here. Further, even if we were so inclined, we could not brush aside the Federal Circuit's teachings in Tol-O-Matic and 800 Adept, regardless of our views on the Hatch-Waxman statutory framework and the so-called "pay for delay" settlements that underlie Barr's concerns in this matter. (Doc. No. 265, at 16-20).

III. Conclusion

For the aforementioned reasons, we deny both Alcon's Motion to Amend our opinion and judgment (Doc. No. 262) and Barr's Motion to Amend our judgment (Doc. Nos. 264-65) in their entireties.

BY THE COURT:

/s/ Legrome D. Davis

Legrome D. Davis, J.

[4]See, e.g., Robert L. Harmon et al., Patents & the Fed. Cir. § 21.5(c), at 1528 (10th ed. 2011) (opining that whether or not "all patents that might be infringed must be asserted . . . the first time around" is "far from clear") (citing Kearns v. General Motors Corp., 94 F.3d 1553 (Fed. Cir. 1996)).