

standard B.E.T. procedure.” ’954 patent at 2:1-4. The ’954 patent issued on May 18, 1993, and expired on May 18, 2010. The ’954 patent was originally issued to Sandoz Ltd.; Plaintiff Tyco acquired ownership of the patent in 2001.

Tyco holds an FDA-approved Supplement to New Drug Application No. 18-163 for Restoril® temazepam capsules. On November 1, 2006, Mutual filed ANDA No. 78-581, seeking approval from the FDA to engage in the manufacture and sale of certain temazepam products. Mutual’s ANDA, which includes a Paragraph IV certification, specified that its product must have a maximum SSA of at least 2.2 m²/g.

On March 20, 2007, Plaintiffs responded to Mutual’s ANDA filing by filing this patent infringement action [Docket Entry 1]. Plaintiffs originally asserted infringement of four patents, all of which have expired; during the pendency of the patent infringement portion of this case, the ’954 patent was at issue. Mutual answered and asserted antitrust counterclaims [Docket Entry 56]. The parties agreed to bifurcate the case by staying the antitrust claims, while proceeding forward with the merits of the patent claims [Docket Entry 114].

In January 2009, this Court ruled in favor of Mutual on all issues raised in claim construction. *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, No. 7-1299, 2009 WL 44745 (D.N.J. Jan. 5, 2009) [Docket Entry 193]. Of relevance to this motion, the Court found that the term “consisting essentially of” did not operate to broaden the scope of the surface area beyond the exact limits specified in the patent. Furthermore, the method for measurement of “surface area” was not limited to the method described in Example 1 of the patent, as Tyco had requested.

The 30-month stay of FDA approval of Mutual’s ANDA expired on August 12, 2009. On July 14, 2009, Tyco filed a motion for a preliminary injunction, seeking to prevent Mutual’s

entry onto the market once the 30-month stay expired. *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, No. 07-1299, 2009 WL 2422382 (D.N.J. Aug. 4, 2009) [Docket Entry 294]. The Court denied Tyco's motion for a preliminary injunction, granted Mutual's motion for judgment on partial findings, and entered judgment in favor of Mutual on Tyco's § 271(e)(2)(A) infringement claim. *Id.* at *7-8. The Court based this finding on its conclusion that, under the teachings of *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), Tyco was unlikely to prove that Mutual's generic product (as described in Mutual's ANDA) would infringe Tyco's patent. *Id.* at *7. The Court specifically did not rule on Tyco's § 271(a) infringement claim at this stage of the litigation. *Id.*

One of the major disputes in this action related to the methods used for testing the SSA of Mutual's generic temazepam product. Mutual based its ANDA SSA specifications on a small biobatch of temazepam, prepared specifically for ANDA testing [Docket Entry 476-1, at ¶ 26]. Mutual purchased a batch of temazepam for its proposed commercial ANDA product in July 2007, and the first two SSA tests of this batch gave results that were non-compliant with Mutual's ANDA specifications (with an SSA of less than 2.2 m²/g) [Docket Entry 476-1, at ¶ 31]. In December 2008, Mutual requested that the testing facility complete additional SSA tests on its product under a variety of conditions [Docket Entry 463-7]. Some of these results showed that the original batch did not comply with the ANDA specifications (with an SSA of less than 2.2 m²/g), and some results in fact showed that Mutual's original batch infringed Tyco's patent, with a SSA of less than 1.1 m²/g [Docket Entry 463-7, at Table 11]. In January 2009, Mutual rejected its original testing batch, due to non-compliance with its ANDA specifications for SSA.

At the preliminary injunction hearing in July 2009, the parties presented evidence on the outgassing technique used in SSA testing, as it applied to Mutual's testing of its generic product.

Mutual performed outgassing at 40°C, while both Sandoz and Tyco performed outgassing at 105°C. The Court declined to rule on whether performing outgassing at 105 °C was mandatory, but observed that “[t]he parties appear not to dispute that the [Mutual] samples manifest an infringing SSA when tested with outgassing at 105°C, but a noninfringing SSA when tested with outgassing at 40°C.” *Tyco*, No. 07-1299, 2009 WL 2422382, at *5 (D.N.J. Aug. 4, 2009).

Mutual then moved for summary judgment of noninfringement, but the Court denied the motion as moot when it entered summary judgment that the ’954 patent was invalid as obvious. *Tyco Healthcare Grp. LP v. Mutual Pharm Co., Inc.*, No. 07-1299, 2010 WL 1799457 (D.N.J. May 5, 2010) [Docket Entry 376]. The Court’s invalidity ruling was based on a prior art reference from the British National Formulary that taught doses in a range that included the ’954 patent’s 7.5 mg dose. The Federal Circuit unanimously affirmed this decision in June 2011. *Tyco Healthcare Grp. LP v. Mutual Pharm Co., Inc.*, 642 F.3d 1370 (Fed. Cir. 2011).

On August 5, 2009 (the day after this Court entered its judgment of noninfringement on Tyco’s § 271(e)(2)(A) claim), Tyco filed a citizen petition with the FDA, urging a change in the criteria for evaluation of temazepam products to “help ensure therapeutic equivalence” of generic temazepam products with Restoril. After the FDA approved Mutual’s ANDA on September 8, 2009, the FDA denied Tyco’s citizen petition, finding no basis for adopting the proposed bioequivalence criteria Tyco had proposed.

Following the Federal Circuit’s 2011 patent infringement decision, the Court lifted the stay on Mutual’s antitrust claims [Docket Entry 427]. The Court granted partial summary judgment to Tyco on all of Mutual’s antitrust counterclaims, except for the inequitable conduct claim [Docket Entry 501]. The Court rejected Mutual’s arguments that Tyco’s § 271(e)(2)(A) claim was a sham. Further, the Court rejected Mutual’s assertions that no reasonable litigant

could have expected Tyco's patents to withstand a validity challenge. The Court also rejected Mutual's argument that Tyco's FDA citizen petition was a sham. Finally, the Court rejected Mutual's assertions that Tyco should be liable for fraud on the Patent and Trademark Office under the doctrine of fraud explained in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

Mutual appealed this decision to the Federal Circuit, which affirmed in part, vacated in part, and remanded the case for further proceedings. *Tyco Healthcare Group LP v. Mut. Pharm. Co.*, 762 F.3d 1338 (Fed. Cir. 2014). Although the Federal Circuit affirmed this Court's decision as to Mutual's claim that Tyco's assertion of its patents was a sham and with respect to the *Walker Process* fraud claim, it vacated: (1) the grant of summary judgment that Tyco's infringement claims were not sham litigation; and (2) the grant of summary judgment that Tyco's citizen's petition to the FDA was not a sham. *Id.* at 1345.

On remand, after further inquiry into the effects of outgassing temperature on the SSA of Mutual's generic temazepam, this Court concluded that summary judgment was appropriate on the issue of the availability of the sham litigation exception to Noerr-Pennington immunity in this case, and that the filing of Tyco's Complaint for patent infringement is protected by Noerr-Pennington immunity. *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, No. 7-1299, 2015 WL 3460790, at *8 (D.N.J. May 29, 2015) [Docket Entry 554]. The Court denied Tyco's motion for summary judgment regarding the availability of Noerr-Pennington immunity for its FDA citizen petition, and that issue remains before the Court. *Id.* at *9.

II. LEGAL STANDARD

The governing statute for attorney's fees in a patent case states that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285.

The Supreme Court has defined an “exceptional” case as “simply one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.” *Octane Fitness, LLC v. Icon Health & Fitness*, 134 S. Ct. 1749, 1756 (2014). “[A] district court may award fees in the rare case in which a party’s unreasonable conduct—while not necessarily independently sanctionable—is nonetheless so ‘exceptional’ as to justify an award of fees.” *Id.* at 1757.

“District courts may determine whether a case is ‘exceptional’ in the case-by-case exercise of their discretion, considering the totality of the circumstances.” *Id.* at 1756; *see also Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S. Ct. 1744, 1748 (2014) (“[T]he determination of whether a case is ‘exceptional’ under § 285 is a matter of discretion.”). In examining the totality of the circumstances under § 285’s fee-shifting framework, courts may consider the following nonexclusive list of factors: “frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence.” *Octane Fitness*, 134 S. Ct. at 1756 n.6 (citation omitted).

“After determining that a case is exceptional, the district court must determine whether attorney fees are appropriate,” a decision that is within the discretion of the district court. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1460 (Fed. Cir. 1998) (citations omitted). The party seeking an award of attorney’s fees must show their entitlement by a preponderance of the evidence standard. *Octane Fitness*, 134 S. Ct. at 1758.

III. DISCUSSION

Mutual, as the prevailing party, argues that the Court should find this case to be exceptional, and in its discretion award attorney's fees. Mutual asserts that Tyco's case was objectively unreasonable, and that Tyco litigated this case in an unreasonable manner. Comparing this case to other patent infringement litigation before this Court, the Court disagrees with Mutual's assertions, and finds that this case was not exceptional.

a. SUBSTANTIVE STRENGTH OF TYCO'S LITIGATING POSITION

"A party's position on issues of law ultimately need not be correct for them to not 'stand[] out,' or be found reasonable." *SFA Sys., LLC v. Newegg, Inc.*, 793 F.3d 1344, 1348 (Fed. Cir. 2015) (citing *Octane Fitness*, 134 S. Ct. at 1756). Also, whether a party's arguments are successful at trial is not dispositive in the assessment of the strength of the arguments. *Id.* "[W]here a party has set forth some good faith argument in favor of its position, it will generally not be found to have advanced 'exceptionally meritless' claims." *Small v. Implant Direct Mfg. LLC*, No. 06-683, 2014 WL 5463621, at *3 (S.D.N.Y. Oct. 23, 2014), *aff'd*, 609 F. Appx. 650 (Fed. Cir. 2015). Instead, "a case presenting either subjective bad faith or exceptionally meritless claims may sufficiently set itself apart from mine-run cases to warrant a fee award." *See Octane Fitness*, 134 S. Ct. at 1757. That being said, something less than bad faith may mark a case as exceptional. *Id.*

Mutual attacks Tyco's litigation positions as extremely weak or unreasonable. Based on its review of Tyco's positions over the course of the litigation, the Court disagrees with these conclusions. On Tyco's infringement positions, the Federal Circuit found that, in this case, "it [was] not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) if the patent owner has evidence that the as-marketed commercial ANDA product will infringe,

even though the hypothetical product specified in the ANDA could not infringe,” under the teachings of *Elan, Bayer AG v. Biovail Corp.*, 279 F.3d 1340 (Fed. Cir. 2002), and *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). *Tyco*, 762 F.3d at 1344. It was plausible at the outset that Mutual used the claimed methods of the ’954 patent, especially given that Mutual had difficulty formulating a non-infringing batch of generic temazepam product, experienced variability in its batches, and in fact produced testing batches that infringed the ’954 patent [Docket Entry 501]. Mutual concedes that it had to drop its original supplier, because its initial testing batches did not work—on three occasions, the testing laboratory obtained results that infringed the ’954 patent. (*Id.* at 7-8.) Therefore, at the time Tyco filed the suit, the applicability of *Elan* was unclear because the “methods of measuring SSA” were different in the ANDA and in the ’954 patent. (*Id.*)

The issue of infringement in this case turned on whether Mutual’s outgassing temperature of 40°C was inappropriate for testing the SSA of its product, as Tyco and Sandoz had tested Restoril®’s SSA using an outgassing temperature of 105°C. There is no dispute that Mutual’s temazepam product infringes the ’954 patent due to its SSA falling within the infringing range, when the outgassing temperature used in testing is 105°C. The parties engaged in a battle of the experts on this issue, and based on the record it is clear that “the method to be used for the measurement of the particle surface area of temazepam is a subject on which scientific experts could and did disagree” [Docket Entry 501, at 7]. In its review of Mutual’s antitrust counterclaims, the Federal Circuit remanded this issue for review at the district court level, concluding “that further inquiry is needed into the effect of the outgassing temperature on the specific surface area of Mutual’s generic product.” *Tyco*, 762 F.3d at 1345. Upon remand, this Court found, “based on a fuller evidentiary record . . . the underlying scientific evidence is not as

one-sided as Mutual had suggested to the Federal Circuit. Both sides have theories, and supporting evidence.” *Tyco*, No. 7-1299, 2015 WL 3460790, at *6 (D.N.J. May 29, 2015). The Court concludes that it would be inappropriate to find this case to be exceptional based on the “battle of the experts” the parties conducted on this issue.

Furthermore, in the context of this litigation, Tyco’s claim construction and invalidity positions were not so weak as to “stand out.” Although Tyco lost on its claim construction arguments, “[r]easonable minds can differ as to claim construction positions and losing constructions can nevertheless be nonfrivolous.” *Raylon, LLC v. Complus Data Innovations, Inc.*, 700 F.3d 1361, 1368 (Fed. Cir. 2012). Tyco’s positions drew support from the specification of the patent, and although unsuccessful, were not so weak as to be frivolous. Furthermore, this case is not automatically exceptional because the Court invalidated the ’954 patent for obviousness. At the outset, patents are presumed valid, and the burden rests on the accused infringer to demonstrate invalidity by clear and convincing evidence. Furthermore, the Federal Circuit has previously held in this case that, “[w]hen an invention falls within a range disclosed in the prior art, the burden of production shifts to the patent holder, but not the burden of proof, which remains with the patent challenger throughout.” *Tyco*, 762 F.3d at 1346 (citations omitted). Tyco offered evidence to meet its burden of production, including the BNF reference itself which allegedly did not provide efficacy evidence for a 7.5 mg dose, and several prior art references that allegedly taught away from the 7.5 mg dose. Although these arguments did not succeed, Mutual has not shown by a preponderance of the evidence that Tyco’s invalidity position stood out as frivolous or objectively unreasonable. In addition, this Court and the Federal Circuit acknowledged that Restoril® 7.5 mg capsules have had commercial success, a factor that ordinarily supports a finding of non-obviousness. *Tyco*, 642 F.3d at 1377.

The patent claims in this case presented a number of substantive issues that required careful examination and analysis by this Court. There is insufficient evidence on the record to establish that Tyco's litigation positions "stood out," in comparison to other patent cases. The Court finds that this case is analogous to other post-*Octane* cases in which the losing party failed to prove its case, but did not "descend to the level of frivolous argument or objective unreasonableness" under § 285. See, e.g., *Otsuka Pharm. Co. Ltd. v. Sandoz, Inc.*, No. 07-1000, 2015 WL 5921035, at *7 (D.N.J. Oct. 9, 2015); *Gametek LLC v. Zynga, Inc.*, No. 13-2546, 2014 WL 4351414, at *3 (N.D. Cal. Sept. 2, 2014) (conceding that plaintiff's briefing on the issue of its substantive claims was inadequate, but concluding that plaintiff's conduct fell short of "conduct that has been found to justify fee-shifting even post-*Octane*").

b. UNREASONABLE MANNER IN WHICH THE CASE WAS LITIGATED

"[A] district court may award fees in the rare case in which a party's unreasonable conduct—while not necessarily independently sanctionable—is nonetheless so 'exceptional' as to justify an award of fees." *Octane Fitness*, 134 S. Ct. at 1757. The Court notes that "most cases awarding fees continue to involve substantial litigation misconduct." *Small*, No. 06-683, 2014 WL 5463621, at *4 (S.D.N.Y. Oct. 23, 2014) (citations omitted). "District courts have awarded attorney fees in cases where the losing party made false statements to the PTO, used litigation as a means to extort a larger settlement, or used motion filings as a means to re-litigate what was presented at trial." *Otsuka*, No. 07-1000, 2015 WL 5921035, at *7 (D.N.J. Oct. 9, 2015) (citing *Intellect Wireless, Inc. v. Sharp Corp.*, 45 F. Supp. 3d 839, 853 (N.D. Ill. 2014); *Chalumeau Power Sys. LLC v. Alcatel-Lucent*, No. 11-1175, 2014 WL 4675002, at *3 (D. Del. Sept. 12, 2014); *Cognex Corp. v. Microscan Sys., Inc.*, No. 13-2027, 2014 WL 2989975, at *4 (S.D.N.Y. June 30, 2014)); see also *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 726 F.3d

1359, 1367 (Fed. Cir. 2013) (holding that the patentee misrepresented the date of key evidence, and attempted to hide false testimony through baseless motion practice); *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1324-25 (Fed. Cir. 2011) (holding that the patentee submitted incomplete and misleading extrinsic evidence); *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 920 (Fed. Cir. 2012) (holding that the patentee misrepresented legal concepts related to the law of claim construction, as well as the court's constructions). In addition, "the need for the deterrent impact of a fee award is greater where there is evidence that the plaintiff is a 'patent troll' or has engaged in extortive litigation." *Small*, No. 06-683, 2014 WL 5463621, at *4 (S.D.N.Y. Oct. 23, 2014) (citations omitted). These examples are instructive to the Court in its examination of Tyco's conduct.

After a thorough review, the Court concludes that Tyco's conduct in this case was not unreasonable. First, Tyco did not engage in unreasonable litigation tactics by failing to conduct an adequate pre-suit investigation. Tyco only had 45 days to make a decision about pursuing this suit, pursuant to the requirements of Hatch-Waxman. At the time the suit commenced, although Mutual's ANDA could not have literally infringed the '954 patent, Tyco still had a reasonable basis to believe that its infringement claims could succeed, given the uncertainty surrounding the measurement of SSA on Mutual's generic temazepam product. As reviewed above, the teachings of *Elan* and its progeny do not refute this conclusion.

Second, there is no evidence on the record that Tyco prolonged this case unreasonably. As Tyco notes, it is routine for patent infringement cases to proceed forward when one party has failed to secure its preferred claim constructions, particularly when, as in this case, the adopted claim constructions do not prevent that party's success on the merits. Even after the Court entered judgment of noninfringement under § 271(e)(2)(A), Tyco's § 271(a) infringement claim

was still pending. Tyco's requests for relief following the Court's judgment of noninfringement similarly do not reach the level of litigation misconduct, when compared to the examples cited above.

Finally, Mutual asserts that the Federal Circuit's remand of a portion of the antitrust case confirms that this case is exceptional, because Tyco has demonstrated bad faith in the pursuit of its claims. The Court disagrees with this conclusion. There is no evidence before the Court that Tyco has engaged in extortive litigation; rather, Tyco appears to have been motivated to protect its entitlement to a monopoly based on its ownership of the '954 patent. No court has held that Tyco pursued its patent infringement claims in bad faith, and indeed this Court has found that Tyco had probable cause to bring its suit, and did not engage in sham litigation with respect to its infringement and validity claims. *Tyco*, No. 7-1299, 2015 WL 3460790, at *8 (D.N.J. May 29, 2015); Docket Entry 501. Tyco's communications with the FDA are not a part of the patent infringement suit that the Court must review in its determination of the exceptionality of the case, and furthermore, the antitrust claims related to Tyco's citizen petition are still at issue before the Court.

IV. CONCLUSION

The Court must exercise its sound discretion in determining whether, given the totality of the circumstances, a case is exceptional under the meaning of § 285. *Octane Fitness*, 134 S. Ct. at 1756. Mutual has not shown by a preponderance of the evidence that Plaintiffs' litigation positions stand out from others with respect to the substantive strength of their arguments, or that Plaintiffs litigated this case in an unreasonable manner. Finding this case to not be "exceptional," the Court declines to exercise its discretion to award attorney's fees to Defendants.

For the reasons stated above, Defendants' motion for attorney's fees, pursuant to 35 U.S.C. § 285 [Docket Entry 563], will be denied. An appropriate Order will be filed herewith.

s/Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: July 22, 2016