UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NO. 2013-1386

TYCO HEALTHCARE GROUP LP AND
MALLINCKRODT INC.,

Plaintiffs-Appellees,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC. AND
UNITED RESEARCH LABORATORIES, INC.,

Defendants-Appellants

Appeal from the United States District Court for the District of New Jersey
in Case No. 07-CV-1299
United States District Judge Stanley R. Chesler

NONCONFIDENTIAL RESPONSE BRIEF FOR PLAINTIFFS-APPELLEES

Peter E. Strand
SHOOK, HARDY & BACON L.L.P.
1155 F Street, N.W., Suite 200
Washington, DC 20004
202.783.8400 Telephone
202.783.4200 Facsimile

John D. Garretson
Rebecca J. Schwartz
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816.474.6550 Telephone
816.421.5547 Facsimile

Counsel for Plaintiffs-Appellees

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellees Tyco Healthcare Group LP & Mallinckrodt Inc. certifies the following:

The full name of every party or amicus represented by me is:

Tyco Healthcare Group LP

Mallinckrodt Inc.

The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Covidien LP (formerly Tyco Healthcare Group LP)

Mallinckrodt LLC (formerly Mallinckrodt Inc.)

All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Tyco Healthcare Group LP (which is now known as Covidien LP) is a non-governmental, wholly owned subsidiary of Covidien plc, a publicly held corporation. Mallinckrodt Inc. (which is now known as Mallinckrodt LLC) is a non-governmental, wholly owned subsidiary of Mallinckrodt plc, which is publicly held.

The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Peter E. Strand Shook, Hardy & Bacon LLP 1155 F Street, NW, Suite 200 Washington, D.C. 20004-1305 (202) 783-8400 E-mail: pstrand@shb.com	John D. Garretson Shook, Hardy & Bacon LLP 2555 Grand Blvd. Kansas City, MO 64108-2613 (816)474-6550 E-mail: jgarretson@shb.com

Bart A. Starr Formerly with Shook, Hardy & Bacon LLP 2555 Grand Blvd. Kansas City, Missouri 64108-2613 (816)474-6550 E-mail: bstarr@shb.com	Rebecca J. Schwartz Shook, Hardy & Bacon LLP 2555 Grand Blvd. Kansas City, MO 64108-2613 (816)474-6550 E-mail: rschwartz@shb.com
Aaron Hankel Shook, Hardy & Bacon LLP 2555 Grand Blvd. Kansas City, MO 64108-2613 (816)474-6550 E-mail: ahankel@shb.com	Nathan Muyskens Formerly with Shook, Hardy & Bacon LLP 1155 F Street, NW Suite 200 Washington, D.C. 20004-1305 (202) 783-8400 E-mail: nmuyskens@shb.com
David T. Fischer Shook, Hardy & Bacon LLP 1155 F Street, NW, Suite 200 Washington, D.C. 20004-1305 (202) 783-8400 E-mail: dfischer@shb.com	Jason R. Mudd Formerly with Shook, Hardy & Bacon LLP 2555 Grand Blvd. Kansas City, MO 64108-2613 (816)474-6550 E-mail: jmudd@shb.com
Carissa L. Rodriguez McCarter & English, LLP Four Gateway Center 100 Mulberry Street PO Box 652 Newark, NJ 07102-0652 973-639-2025 Email: crodriguez@mccarter.com	William J. Heller McCarter & English, LLP Four Gateway Center 100 Mulberry Street PO Box 652 Newark, NJ 07102-0652 (973) 622-4444 E-mail: wheller@mccarter.com
Jonathan M.H. Short McCarter & English, LLP Four Gateway Center 100 Mulberry Street PO Box 652 Newark, NJ 07102-0652 (973) 622-4444 Email: jshort@mccarter.com	John Edmund Flaherty McCarter & English, LLP Four Gateway Center 100 Mulberry Street PO Box 652 Newark, NJ 07102-0652 (973) 622-4444 Email: jflaherty@mccarter.com

Symone J. Redwine McCarter & English, LLP Four Gateway Center 100 Mulberry Street PO Box 652 Newark, NJ 07102-0652 (973) 639-7992 Email: sredwine@mccarter.com	Mark H. Anania McCarter & English, LLP Four Gateway Center 100 Mulberry Street PO Box 652 Newark, NJ 07102-0652 (973) 848-5302 Email: manania@mccarter.com
Herbert W. Rea Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, New York 10112 (212) 218-2100	Henry J. Renk Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, New York 10112 (212) 218-2100
Joseph B. Divinagracia Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, New York 10112 (212) 218-2100	John C. Heuton Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, New York 10112 (212) 218-2100

Dated: September 3, 2013

/s/ *Rebecca J. Schwartz*

REBECCA J. SCHWARTZ
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816.474.6550 Telephone
816.421.5547 Facsimile
jgarretson@shb.com
rschwartz@shb.com

Counsel for Plaintiffs/Appellees

TABLE OF CONTENTS

STATEMENT OF GENERAL NATURE OF REDACTED MATERIAL

Pursuant to Federal Circuit Rule 28(d)(1)(B), confidential information that is the subject of a protective order entered by the district court has been redacted in this brief. This information generally relates to the parties' research and development, regultary approval, and internal business practices.

TABLE OF AUTHORITIES

CASES **Page(s)**

STATUTES

OTHER AUTHORITIES

STATEMENT OF RELATED CASES

This Court earlier affirmed the district court's judgment that a patent at issue was invalid. 642 F.3d 1370.

INTRODUCTION

A private party's act of petitioning the government to protect patent rights is presumptively immune from antitrust liability under the *Noerr-Pennington* doctrine. *See E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *Nobelpharma AB v. Implant Innovations*, *Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). That doctrine, which derives from the First Amendment to the U.S. Constitution, protects litigants who petition the government for relief – regardless of whether their efforts are ultimately successful. Given the constitutional protections involved, exceptions to *Noerr-Pennington* immunity carry a heavy burden of proof and are rarely applicable.

This appeal arises from the claims of Defendants-Appellants (collectively "Mutual") that Plaintiff-Appellees (collectively "Tyco") violated antitrust laws by taking legal action to enforce its patent rights against Mutual in response to Mutual's request for FDA approval to market a generic version of 7.5 mg Restoril®, Tyco's patented 7.5 mg temazepam drug product. Tyco's infringement action against Mutual was extensively litigated, but ultimately unsuccessful.

Mutual now seeks to impose antitrust liability by way of counterclaims filed against Tyco. Those counterclaims are premised on two exceptions to *Noerr-Pennington* immunity. The first exception only applies when an antitrust claimant can establish that the enforcement action taken by the patent holder was a "sham." *See Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993) ("*PRE*"). The second only applies when the antitrust claimant can demonstrate that the patentee's petition seeks to enforce a patent obtained by fraud on the U.S. Patent and Trademark Office ("USPTO"), commonly referred to as "*Walker Process*" fraud. *See Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176 (1965).

Tyco moved for summary judgment on Mutual's antitrust claims, arguing that based on the undisputed facts and the applicable legal standards, there was no genuine issue of material fact as to whether the exceptions to immunity would apply. Specifically, Tyco successfully argued that Mutual could not prove by clear and convincing evidence that Tyco's patent enforcement action was objectively meritless, and therefore a sham, because Tyco easily satisfied the civil probable cause test with respect to both its Complaint and its (subsequent) Citizen Petition filed with the FDA. As such, Mutual was foreclosed from proving a key element of the *PRE* sham litigation test. Tyco also successfully argued that Mutual could not meet its burden to prove the *Walker Process* fraud exception to *Noerr-Pennington*

immunity because there was no genuine issue of disputed fact as to whether Tyco's predecessor in ownership of the Tyco Patents had committed fraud on the USPTO, much less that Tyco knew of such alleged fraud at the time it filed its Complaint.

The district court's judgment should be affirmed. The existence of *Noerr-Pennington* immunity is a question of law to be determined by the trial court. *See Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1008 (Fed. Cir. 2012). In order to proceed under the sham litigation exception, Mutual must satisfy a two-tier test starting with an objective threshold; namely, it must first be able to prove that Tyco's infringement action and Citizen Petition were "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *PRE,* 508 U.S. at 61 n.5. Because that test incorporates the notion of civil probable cause, it can be (and in this case was) overcome by proof that a reasonable litigant, possessing the facts as known to Tyco *at the time of its filing*, could have a mere "reasonable belief that there is *a chance* that a claim may be held valid upon adjudication." *Id*. at 62-63 (quotations omitted) (emphasis added).

Tyco moved for summary judgment in district court based on undisputed facts demonstrating satisfaction of the objective probable cause threshold. Having made such a showing under Rule 56, the burden shifted to Mutual to point to evidence sufficient to prove that Tyco lacked objective bases (i.e., civil probable

cause) to enforce its patent rights. The district court properly found that Mutual had not and could not meet that burden, and, accordingly, granted summary judgment in favor of Tyco on Mutual's sham litigation antitrust counterclaims.

This Court should reject Mutual's effort to rely in its appeal on a *post hoc* analysis of its (successful) infringement defense and/or the merits of Tyco's (unsuccessful) Citizen Petition to try to prove that Tyco's enforcement actions were objectively meritless at the time they were filed. The Supreme Court forbids such a hindsight-based approach. *PRE*, 508 U.S. at 61 n.5. Moreover, Mutual's approach represents an attempt to invoke an improper legal standard. In effect, Mutual urges this Court to set aside the two-tiered sham litigation test dictated by *PRE,* which considers subjective evidence *only* in the event the patentee's enforcement action is objectively baseless*,* and to replace it with a one-tier, wholly subjective test.

Under Mutual's subjective formulation, it argues that prior to filing its Complaint, Tyco could and should have known what facts would be revealed during discovery, and, based on those facts, would be able to predict how the district court would interpret distinguishable legal authority; how it would apply countervailing legal authority; and how it would reconcile conflicting opinions from experts not yet disclosed. Had Tyco done that, Mutual asserts, Tyco could have known its infringement claims would not succeed, and thus would not have bothered to file suit. Such a sham litigation standard is neither fair nor practical, particularly given

the constitutional immunity enjoyed by a patent owner entitled to assert its rights. More importantly, it is not the law. Accepting Mutual's arguments would effect a drastic change to *PRE*'s well-established legal standard that is neither appropriate nor warranted. It would also make virtually every patent owner who unsuccessfully attempts to enforce its rights subject to an antitrust claim.

Mutual's argument that Tyco's Citizen Petition filed with the FDA in defense of the Tyco Patents was a sham because it was unsuccessful also fails as a matter of law for the same reasons as Mutual's claim based on the filing of the Complaint. The undisputed facts demonstrate that the Petition was not objectively baseless at the time it was filed; there is therefore no reason to even reach a subjective assessment under the *PRE* standard that Mutual contends must apply. *See PRE*, 508 U.S. at 60.

Mutual's attempt to invoke the even more strenuous *Walker Process* fraud exception to *Noerr-Pennington* immunity likewise fails as a matter of law, and the district court's summary judgment ruling should be affirmed. In support of such a claim, Mutual must prove a "rigorous standard of deceit" by "clear, convincing proof." *C.R. Bard v. M3 Sys.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). Tyco's motion for summary judgment established a lack of record evidence demonstrating that Sandoz (Tyco's predecessor patent owner) had the requisite intent to deceive the USPTO when it prosecuted the Tyco Patents. Having satisfied its initial showing on

summary judgment, the burden shifted to Mutual to show that there is a genuine issue for trial.

Mutual failed to demonstrate such an issue, much less to demonstrate a genuine issue as to whether Tyco knew the patents were obtained by fraud on the part of Sandoz. Again, Mutual failed to adduce the proof required to prevent entry of summary judgment. As the district court aptly put it, Mutual "failed to point to even a scintilla of evidence that [Tyco] knew at the time they initiated [the infringement suit] that they were seeking to enforce patents which had been procured by knowing and willful fraud." (A15).

The evidence Mutual cites on appeal is no different from that which failed to amount to "even a scintilla" of proof supporting either component of *Walker Process* fraud, and is no more compelling this time around. Rather than concede the issue, Mutual persists in arguing an alternative legal standard – namely, that summary judgment on the *Walker Process* fraud claim should have been denied because "a jury could infer knowledge from evidence that Tyco was aware of [a] significant risk that Sandoz had engaged in fraud and was deliberately indifferent to that risk." App. Br. at 59. This represents a clear departure from Mutual's actual legal burden to provide clear and convincing proof that Tyco knew of an intentional fraud by Sandoz at the time it filed its infringement action against Mutual. Mutual cannot

avoid summary judgment by simply re-crafting the legal standard and, in the process, relaxing its own burden of proof.

Mutual has not met, and cannot possibly meet, its burden to demonstrate a genuine issue for trial with respect to the applicability of either the sham litigation or *Walker Process* fraud exceptions to *Noerr-Pennington* immunity. Mutual's attempts to succeed on this appeal by citing its successful infringement defense and/or the FDA's rejection of Tyco's Citizen Petition as proof that Tyco's claims were objectively baseless when filed, and by arguing for application of incorrect or non-existent legal standards, must be rejected. The district court's order applying *Noerr-Pennington* immunity and granting summary judgment in favor of Tyco on Mutual's antitrust counterclaims should be affirmed.

COUNTERSTATEMENT OF THE ISSUES

I. Whether the district court properly found that Mutual's antitrust claim premised on the sham exception to *Noerr-Pennington* immunity is precluded as a matter of law because a reasonable litigant, in possession of the facts known to Tyco at the time it filed its Complaint could hold a reasonable belief that such claims could be found valid upon adjudication given that: Mutual's ANDA relied upon a test procedure different from Tyco's and known to produce inconsistent test results; particle surface area affects bioavailability; and application of existing law to the unique facts at issue was uncertain.

II. Whether *Noerr-Pennington* immunity applies to bar Mutual's antitrust counterclaim based on Tyco's filing of its Citizen Petition given ample, undisputed, and objectively reasonable bases for a reasonable petitioner to believe the Petition might succeed. Specifically, nothing in Mutual's produced ANDA materials explained how Mutual's formulation could be achieving the claimed bioequivalence given its purported surface area, and Mutual subsequently argued during the infringement action that its product having more than double the surface area of Tyco's Restoril® would improve bioavailability.

III. Whether the district court's order granting summary judgment on Mutual's *Walker Process* fraud claim should be affirmed given that no reasonable factfinder could conclude that Tyco knew the Tyco Patents were obtained through knowing and willful fraud by a predecessor owner given an absence of proof that an intentional fraud was committed on the USPTO through a deliberately planned and carefully executed scheme, much less that Tyco actually knew of such a fraud when it filed its Complaint.

COUNTERSTATEMENT OF FACTS AND OF THE CASE

Mutual's Statement of Facts and of the Case is in several key respects incomplete, and also inappropriately argumentative. Tyco therefore offers the following counterstatement to clarify and supplement Appellant's Statement of Facts and of the Case:

The antitrust counterclaims that are the subject of this appeal were asserted by Appellant ("Mutual") in response to a patent infringement complaint that Appellees (collectively "Tyco") filed against Mutual in the U.S. District Court for the District of New Jersey in March of 2007. (A5235-50). Tyco's patent infringement suit initially involved a total of four patents including U.S. Patent No. 5,211,954 (the "'954 patent") and U.S. Patent Nos. 5,030,632 (the "'632 patent"), 5,326,758 (the "'758 patent"), and 5,629,310 (the "'310 patent") (collectively, the "Tyco Patents").[1] (A5084; A5087; A5089; A5091). Mutual responded to Tyco's complaint raising the antitrust counterclaims and other counterclaims in its Amended Answer. (A5190-250). On May 20, 2008, the district court temporarily stayed litigation of Mutual's antitrust counterclaims pending resolution of Tyco's patent infringement claims. (A332).

The district court concluded that Mutual's ANDA did not infringe Tyco's '954 patent related to low dose temazepam under §271(e)(2)(A) and granted Mutual's motion for judgment of non-infringement on August 4, 2009. (A5274). It subsequently granted Mutual's motion for summary judgment of invalidity for obviousness on May 5, 2010. (A3820). This Court later affirmed the district court's finding that the Tyco patent was invalid due to obviousness. *Tyco Healthcare Grp.*

[1] The '954 patent expired on May 18, 2010. (A5263; A5536 at ¶6). The other three patents expired on July 9, 2008 and, accordingly, became irrelevant to this lawsuit. (A5264; A5536 at ¶6). The '954 patent became the focus of the underlying case because it expired only after end of the 30-month stay in August 2009. (A5264).

LP v. Mutual Pharm. Co., 642 F.3d 1370 (Fed. Cir. 2011). Following that decision, the district court lifted the stay of Mutual's antitrust counterclaims. (A4268).

THE TYCO PATENTS

The Tyco Patents originally issued to a company called Sandoz Ltd. ("Sandoz"), which is listed on the face of the patents as the assignee. (*See, e.g.*, A4380). Tyco's acquisition of these patents from Sandoz as part of an agreement to transfer Sandoz's Restoril® temazepam products to Tyco occurred in 2001, long after the prosecution of the patents had been finalized. (A5536 at ¶5; A4501-08). The '954 patent expired on May 18, 2010; the other three Tyco Patents expired on July 9, 2008. (A5536 at ¶6).

The '954 patent, which became the focus of the underlying infringement litigation after the other Tyco Patents expired, claims:

> A hard gelatin capsule containing a temazepam formulation consisting essentially of 6 to 8 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m2/g and 95% of the temazepam having a particle size of less than 65 microns in admixture with a pharmaceutically acceptable carrier therefor.

(A4382 at Claim 1). Each of the Tyco Patents included details concerning determination of specific surface area ("SSA") claimed by the patents: 0.65 to 1.1 m^2/g. (*See, e.g.*, A4381-82). The common specification shared by all of the Tyco Patents provides the following example regarding the test protocol to be used in determining the SSA:

> White crystalline temazepam having a purity of not less than 98% is prepared according to the procedure described in U.S. Pat. No. 3,296,245. The bulk temazepam obtained is fed into an Alpine 160 UPZ mill with a stainless steel pin at a rate of about 40 kilograms (kg) per hour using a mill speed of about 11,000 RPM to obtain temazepam particles having a specific surface area of 0.65 to 1.1 m2/g area and 95% of the particles having a particle size diameter of less than 65 µ. The surface area measurement is made with the Quantector Gas Flow System and Quantasorb Surface Area Analyser at the temperature of liquid nitrogen - 196º C using krypton as the absorbant and helium as the carrier gas. The particle size diameter is determined with the Malverne Particle Sizer at an obscuration value of 0.2 to 0.25 using a 0.1% Tween 80 solution in water saturated with temazepam in which 1 to 2 grams of temazepam sample to be tested has been dispersed. After the feed rate and mill speed of the Alpine mill have been set, they are monitored at regular intervals to maintain the required particle size and surface area.

(A4381 at Column 2, lines 43-63). Moreover, the common specification states that "[s]urface area measurements are made essentially in accordance with the standard B.E.T. procedure of Brunauer, Emmett and Teller (J. Am. Chem. Soc. 59, 2682, 1937 and J. Am. Chem. Soc. 60, 309, 1938)." (A4381 at Column 2, lines 1-5).

SANDOZ AND TYCO'S TESTING

Prior to the 2001 transfer of the Tyco Patents, [redacted]

Contains Confidential Information

[redacted]

Contains Confidential Information

[redacted]

MUTUAL'S ANDA AND PARAGRAPH IV CERTIFICATION LETTER

On October 31, 2006, Mutual filed Amended New Drug Application ("ANDA") 78-581 with the FDA seeking approval to sell a generic version of Tyco's 7.5 mg Restoril® (temazepam) prior to the expiration of the Tyco Patents. (A4545-46). [redacted]

Contains Confidential Information

[redacted]

On February 5, 2007, more than three months after filing its ANDA, Mutual sent Tyco a Paragraph IV certification letter regarding ANDA 78-581 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); Tyco received the letter on February 7, 2007. (A4498-99). T[redacted]

[redacted]

Contains Confidential Information

[redacted]

(

P

And nowhere in Mutual's Paragraph IV certification letter or in Mutual's ANDA did Mutual provide an explanation for the difference in the test results PTL obtained for Mutual's ANDA temazepam product and Tyco's 7.5 mg Restoril® temazepam product. (A5542-43 at ¶18).

Contains Confidential Information

Mutual's Paragraph IV certification letter failed to specify the testing that would occur. (A4497-515). In fact at the time it sent that letter, [redacted]

TYCO'S PATENT INFRINGEMENT ACTION

Although the testing protocols were not clear from either Mutual's ANDA or its Paragraph IV certification letter, its transmission nonetheless created a statutory deadline for Tyco to take action under 21 CFR 314.107(b)(3). Tyco had just 45 days after receiving the Paragraph IV certification letter, or until Monday, March 26, 2007, to file a lawsuit to enforce the Tyco Patents, thereby inducing an automatic thirty-month statutory stay of the FDA's approval of ANDA 78-581. Failing to do so would have resulted in the forfeiture of the opportunity to assert the '954 patent against Mutual and obtain the automatic 30 month stay allowed by statute.

Although Tyco did not ultimately prevail on its infringement claims against Mutual, the adversarial process involved served to establish that [redacted]

Contains Confidential Information

[redacted] In fact, the first time Mutual alleged that the Tyco Patents were invalid as obvious over the prior art was November 13, 2007. (A4471-76). Moreover, in determining invalidity, the district court found the 7.5 mg dose to be the only distinction over the prior art and determined that the BNF [British National Formulary (A4541-43)] reference was key to the invalidating combination because it taught doses that included the claimed range. (A5295; A5298; A5304-07). Mutual did not obtain that BNF reference until June of 2009, (A5555 at ¶54; A4815 at 92:15-93:4), then failed to disclose it until July 22, 2009. (A5555 at ¶54).

The litigation of the infringement claims also brought to light facts and opinion testimony concerning the proper testing methodology of temazepam. [redacted]

Contains Confidential Information

[redacted]

n[redacted] Shortly thereafter Mutual did just that. [redacted]

Approximately six months later, in July 2009, the parties presented their evidence concerning the sufficiency of the testing performed on the various temazepam samples at a preliminary injunction hearing conducted by the district court below. While both parties agreed that the U.S. Pharmacopeia ("USP") requires degassing of a sample prior to performing the SSA measurement, the parties ultimately disagreed about the temperature at which the degassing should occur. (A5130 at 35:22-36:22; A5142 at 81:11-21; A5268-71). [redacted] Mutual, however, degassed its temazepam samples at 40°C as indicated in its ANDA. (A5148 at 105:19-21; A4787). Because [redacted]

[2] The SSA measurements included 0.96, 0.99, and 1.03 m^2/g.

Contains Confidential Information

[redacted]

During the preliminary injunction proceedings, both parties offered expert testimony by their respective infringement experts concerning their tests of Mutual's temazepam particles in regard to the temperature at which to degas the material. (A5131 at 37:14-38:22; A5148 at 105:19-21). Tyco's expert, Dr. Luk, testified that the SSA test should be performed with outgassing at 105ºC, not 40ºC, to be consistent with the original patent owner's test conditions and the USP's standards. (A5131-32 at 37:14-38:22, 40:22-41:2, 41:12-1; A5133 at 47:18-23, 48:5-11). Mutual's expert, Dr. Williams, testified that the SSA test should be performed with outgassing at 40ºC, not 105ºC. (A5148 at 105:19-21). However, Dr. Williams, previously stated in his deposition that, "If I, if I knew what Sandoz conditions were [i.e. degassing at 105ºC], that seems logical that one could use that [testing protocol]." (A5269-70).

Tyco's expert, Dr. Luk, further testified that outgassing Mutual's temazepam at 105ºC/two hours, whether by Tyco or Mutual's laboratory, yielded SSA values falling within the claimed range of the '954 patent. (A5132 at 42:13-44:18; A5133 at 45:8-47:14). Mutual's expert, Dr. Williams, agreed that if 105ºC was the correct outgassing temperature, then Mutual's temazepam product infringed the '954 patent.

(A5479-80 at 12:25-14:4). The district court observed that "[t]he parties appear not to dispute that the samples manifest an infringing SSA when tested with outgassing at 105ºC, but a noninfringing SSA when tested with outgassing at 40ºC." (A5270). Ultimately, the district court entered a judgment of non-infringement under 35 U.S.C. § 271(e)(2)(A). (A5274). While the district court did not accept Dr. Luk's opinion, it did not find that degassing test samples at 105°C was *per se* unreasonable. (A5270-72). The district court specifically stated that its judgment did not "constitute a judgment of noninfringement under 35 U.S.C. § 271(a)." (A5274).

As to Tyco's § 271(a) infringement claim, the district court recognized that determining the proper outgassing conditions for testing Mutual's temazepam would need to be resolved at a full trial on the merits:

> Thus, were this Court to agree that the infringement analysis at this juncture should be based on product samples rather than ANDA specifications, this Court would have before it a factual dispute between experts on an obscure scientific point, the temperature at which outgassing should be conducted in a particular chemical analysis. Such a factual dispute would likely need to be resolved at trial by a battle of the experts.

(A5270). The district court further suggested at the hearing that infringement of Mutual's commercial temazepam under § 271(a) would be relevant to defeating

Mutual's antitrust counterclaims premised on Tyco's § 271(e) claim. (A4396-98 at 13:8-15:6).

TYCO'S CITIZEN PETITION

It was only after the district court conducted the preliminary injunction hearing in phase one of the litigation that Tyco filed its Citizen Petition on August 5, 2009. (A5004-16). The Citizen Petition relied on information regarding Mutual's ANDA product that had been subject to a protective order, and that Mutual only finally permitted to become public during the hearing. Specifically, during the hearing, Mutual made representations in open court concerning the drug product described in Mutual's ANDA as compared to Tyco's Restoril® temazepam product. (*See, generally,* A5121-79; A4382-410).

On July 16, 2009, for instance, Mutual represented that its proposed ANDA product was "a different product" that used different control testing for SSA than Tyco's temazepam product. (A5077 at 14:21-16:20). Mutual also stated that its product's SSA was more than double that of Tyco's temazepam product, and that increasing the surface area of a poorly-soluble drug will alter bioavailability. (A5141-42 at 80:14-81:3). Mutual also publically represented that increasing the surface area or decreasing the particle size generally would improve the bioavailability of the drug once administered into the body and that as one increases

the surface area for drugs like temazepam, which are not water soluble, one would improve the bioavailability. (*Id.*)

STANDARD OF REVIEW

Tyco does not dispute Mutual's Standard of Review insofar as it relies upon Fed. R. Civ. P. 56. Tyco adds that where the nonmoving party fails "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 (3d Cir. 1992) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)).

Additionally, application of the *Noerr-Pennington* immunity doctrine is a question of law. *See FTC v. Hospital Bd. of Directors of Lee County,* 38 F.3d 1184, 1187 (11th Cir. 1994); *Kearney v. Foley & Lardner, LLC*, 590 F.3d 638 (9th Cir. 2005).

SUMMARY OF ARGUMENT

I.A-C. *Noerr-Pennington* immunity for Tyco's assertion of its patents can be overcome by the sham litigation exception only if Mutual can provide clear and convincing proof that Tyco's filing was objectively baseless. *PRE*, 508 U.S. at 60. Under the objective "probable cause" standard articulated by the U.S. Supreme

Court in *PRE*, Tyco can establish that its infringement claims were *not* objectively baseless simply by establishing that a reasonable litigant, knowing the facts in Tyco's possession at the time of its filing, could reasonably believe it had *a chance* its claims would be held valid upon adjudication. Here, because probable cause exists, Mutual cannot meet *PRE's* objective first-tier requirement of the sham litigation exception, and the second (subjective) tier need never be reached. The district court's summary judgment ruling in favor of Tyco should be affirmed.

The relevant legal standard is an objective one, and as such depends not upon the relative strength of Tyco's patent enforcement claims or their ultimate success. Courts are precluded from engaging in the sort of *post hoc* analysis of the plaintiffs' infringement claims urged by Mutual throughout its brief. *PRE,* 508 U.S. at 61. In this case, a straightforward and narrow set of undisputed facts known to Tyco at the time of its filing establishes that Tyco's claims were not objectively baseless.

I.D. Mutual's argument that *Bayer AG et al. v. Elan Pharm. Research Corp. et al.,*212 F.3d 1241 (Fed. Cir. 2000) foreclosed *any* possibility of Tyco prevailing on its infringement claims is completely refutable. Where "the law is unsettled, the action is arguably warranted by existing law, or there is an objectively good faith argument for extending existing law," a sham litigation finding is precluded. *ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1292

(Fed. Cir. 2010). *Elan* was not controlling authority because it did not involve any dispute over the appropriate test protocol parameters for measuring specific surface area ("SSA"). *See Elan,* 212 F.3d at 1248. Other valid legal authorities suggested that testing of Mutual's Commercial Batch was the correct approach. The district court's comment, made in dicta, that Mutual did not move for summary judgment based on non-infringement under *Elan*, is not material to the district court's otherwise well-supported conclusion regarding *Elan's* effect on the existence of probable cause.

I.E. [redacted], is immaterial to this appeal. The question for purposes of the sham litigation analysis under *PRE*, and specifically the probable cause standard the Supreme Court recognized therein, is not whether there was a possibility that Mutual's proposed ANDA would *not* infringe, but rather whether there was an objectively reasonable basis for a reasonable litigant to believe it *might* infringe. [redacted] This ambiguity, paired with other related facts, objectively supported Tyco filing suit.

I.F. Mutual's attempt to redeploy its affirmative defenses from the infringement action below, including invalidity as to obviousness, in the service of its sham litigation claim only further reinforces Mutual's erroneous understanding of the relevant (probable cause) legal standard. Although Mutual ultimately prevailed against Tyco's Complaint, it only met its burden of proof as to obviousness with evidence produced in July, 2009, more than two years *after* Tyco's filing, and long after the point at time to which the objective probable cause assessment applies.

I.E. A 2001 communication indicating Tyco's awareness that it might be possible to formulate a non-infringing product is not sufficient to establish that Mutual's ANDA product would not infringe; Tyco's decision to file its Complaint was not objectively baseless.

I.F. Mutual's affirmative defenses, which were supported primarily by evidence developed during the infringement action, are immaterial to the sham litigation standard.

II. Mutual's argument in support of a "sham" exception to *Noerr-Pennington* immunity for an antitrust claim based on Tyco's filing of its Citizen Petition fails for essentially the same reasons as the same claim made in connection with Tyco's infringement action. Assuming the applicability of *PRE*'s two-tier standard, which Mutual expressly advocates based on Third Circuit precedent, a straightforward set of facts known to Tyco at the time it filed its Citizen Petition

easily satisfies *PRE's* objective first tier: a reasonable patent owner possessing the knowledge Tyco had at the time of its filing could reasonably believe it had a chance of success with the Citizen Petition. The subjective element of the *PRE* test, which requires proof of intent to interfere with the business relationships of a competitor through the use of the governmental process as an anticompetitive weapon, need never be reached. Even if it were, the proof cited by Mutual still fails to give rise to a genuine issue for trial.

III. Mutual's effort to invoke an exception to immunity based on *Walker Process* fails for an utter lack of proof both as to the alleged underlying fraud by the original patentee (Sandoz) in the procurement of the Tyco Patents, and as to Tyco's knowledge of that (alleged) fraud at the time it filed its infringement Complaint. *See Therasense, Inc. v. Becton, Dickinson and Co.,* 649 F.3d 1276, 1290-91 (Fed. Cir. 2011); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998). Mutual has not met its burden, particularly given the applicable "clear and convincing" evidentiary standard, to establish a triable issue as to whether Sandoz willfully defrauded the USPTO, much less evidence that Tyco was aware of that fraud.

ARGUMENT

I. Tyco's Infringement Suit Easily Clears the Objective Baselessness Threshold, Precluding Any Possibility of a Successful Antitrust Claim Under the "Sham Litigation" Exception to *Noerr-Pennington* Immunity.

A. The Sham Litigation Exception Requires Satisfaction of *PRE's* Two-Prong Test.

The United States Constitution expressly permits the government to grant exclusive monopolies in the form of patents. *See* U.S. Const. art. I, §8, cl. 8. The Sherman Act cannot be read to impede a litigant from seeking to defend constitutionally-permitted patent rights. *See PRE,* 508 U.S. at 56; *see also Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1234 (11th Cir. 2005). In the absence of a recognized exception, the *Noerr-Pennington* doctrine immunizes those who petition courts from statutory liability for their petitioning conduct. *See Noerr Motor Freight*, 365 U.S. at 127; *Pennington*, 381 U.S. at 657; *In re Mushroom Direct Purchaser Antitrust Litig*., 655 F.3d 158, 165 (3d Cir. 2011).

Here, to proceed under the sham litigation exception to *Noerr-Pennington* immunity, Mutual must meet the objective first tier of *PRE* by proving that Tyco's infringement action was "*objectively baseless* in the sense that no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 62 (emphasis added). If, and only if, it satisfies the first prong of the *PRE* test, Mutual would then be required to prove the second prong: that Tyco filed suit with a "subjective

motivation . . . to interfere *directly* with the business relationships of a competitor." *See id.* (emphasis added).

As the Supreme Court explained, the objective first prong of the *PRE* test is analogous to the "probable cause [standard] to institute civil proceedings." *Id.* at 62-63. Under that standard, to survive summary judgment, Mutual must be able to prove that a reasonable litigant, possessing the facts known to Tyco at the time it filed its infringement Complaint, could not have possessed "a *reasonable belief* that there [was] a *chance* that [its] claim *may* be held valid upon adjudication." *Id.* (quotations omitted) (emphasis added).[3] In other words, the antitrust claimant "must prove, by clear and convincing evidence, that a [patentee's] activities were not really efforts to vindicate its rights in court." *Braintree Labs. v. Schwarz Pharma, Inc.*, 568 F. Supp. 2d 487, 495 (D. Del. 2008); *see also C.R. Bard, Inc.*, 157 F.3d at 1368-69 (sham litigation requires more than a failed legal theory).

The existence of sham litigation is a question of law for the court. Where the relevant facts are not controverted, probable cause is a matter of law for the court to decide. *See Bard Peripheral Vascular, Inc.*, 682 F.3d at 1008 ("the ultimate legal question" of a litigant's reasonable belief in a chance that its patent infringement

[3] The Supreme Court also endorsed application of a Rule 11-type threshold analysis in which the question was simply whether the claim "was arguably 'warranted by existing law' or at the very least was based on an objectively 'good faith argument for the extension, modification, or reversal of existing law.'" *See PRE,* 508 U.S. at 65 (quoting Fed. R. Civ. P. 11).

claim may be successfully adjudicated "should always be decided as a matter of law by the judge"); *see also PRE,* 508 U.S. at 62-63. Thus, where Tyco can demonstrate, based on undisputed facts, that it satisfied the objective civil probable cause standard, and Mutual is unable to present actual evidence that creates a genuine issue as to a material fact concerning Tyco's satisfaction of that standard, Mutual is effectively foreclosed as a matter of law from being able to satisfy the first prong of *PRE's* sham litigation test, and summary judgment is appropriate. *Id.* at 61. "This two-tiered process requires the [antitrust] plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability." *Id.* at 50.

B. Mutual Erroneously Argues for a Subjective Sham Standard And Urges an Impermissible *Post Hoc* Analysis.

On appeal, Mutual advocates reversal of the district court's summary judgment order based on a strictly subjective standard rather than the objective threshold first tier of *PRE.* It argues, for instance, that the sham litigation exception turns on "whether Tyco 'could realistically expect to secure favorable relief' on its [infringement] claim or its citizen petition is clearly disputed." App. Br. at 31. Mutual further urges that Tyco's decision to assert its patent rights be reviewed in terms of both the relative "strength" of Tyco's infringement claims, and the district court's handling of Tyco's infringement claims. *See id.* at 39 ("Having forcefully

ruled for Mutual on infringement, the court below ignored its earlier analysis in addressing Mutual's sham litigation counterclaim.").

Mutual's approach ignores the Supreme Court's clear instruction that a subjective assessment of the patent holder's actions for purposes of the sham exception is appropriate only upon a showing of objective baselessness: "Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." *PRE*, 508 U.S. at 60-61; *see also Bard Peripheral Vascular, Inc.*, 682 F.3d at 1008 ("there is a subjective requirement that must be addressed *only after* the objective requirement is satisfied.") (emphasis in original). The applicable standard is not only objective in that it requires facts to be assessed from the point of view of a reasonable litigant,[4] but demands that the facts be assessed as they appeared to the antitrust defendant *at the time it* filed its petition. *See Stewart v. Sonneborn*, 98 U.S. 187, 195 (1878) (cited in *PRE*, 508 U.S. at 62).

Thus, Mutual's arguments based on: (1) evidence adduced during the infringement proceedings *after* the Complaint was filed; (2) judicial analysis conducted during those proceedings; and (3) the ultimate *outcome* of those

[4] Although the review contemplated by the probable cause standard requires an actual assessment of Tyco's decision-making, the inquiry is nevertheless "objective" because "[i]t is not what the parties think of the merits of their positions that matters; it is whether there are, in fact, sufficient bases for the positions taken." *In re Buspirone Patent Litig.,* 185 F. Supp. 2d 363, 375 (S.D.N.Y. 2002) (citations omitted).

extensively-litigated proceedings should be rejected because they focus on the subjective strength of Tyco's claims (established only by full litigation), while simultaneously ignoring the time period at which the objective bases of a claim are to be assessed for sham exception purposes:

> [W]hen the antitrust defendant has lost the underlying litigation, a court must 'resist the understandable temptation to engage in post hoc reasoning by concluding' that an ultimately unsuccessful 'action must have been unreasonable or without foundation.'

PRE, 508 U.S. at 61 n.5; *see also FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 938 (Fed. Cir. 1995) ("As noted, the Supreme Court has forbidden us to equate loss on the merits with objective unreasonableness."); *AstraZeneca AB v. Mylan Labs., Inc.*, No. M-21-81 (BSJ), 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010), *aff'd sub nom. In re Omeprazole Patent Litig.*, 412 F. App'x 297 (Fed. Cir. 2011) ("[A]n unsuccessful lawsuit, without more, is not a sham.").

Remarkably, Mutual even goes so far as to try to dodge the *PRE* first-tier civil litigation probable cause requirement altogether, arguing "probable cause" to sue "is often not appropriate for summary disposition." App. Br. at 26 (citing *Personnel Dept., Inc. v. Prof'l Staff Leasing*, 297 F. App'x 773, 781 (10th Cir. 2008)). Mutual conveniently fails to mention that the case it relies upon is simply quoting a 1994 law review article for the unremarkable proposition that summary disposition "is often not appropriate . . . . When there is a dispute as to the underlying facts . . . the question of probable cause must be submitted to the jury with appropriate

instructions." *Id.* (citation omitted). Tyco's summary judgment motion, in contrast, turned on a short list of *undisputed* facts. Mutual's suggestion that it be permitted to simply skip the objective probable cause threshold and proceed to a trial on the subjective intent question must be rejected.

To the extent Mutual somehow suggests that Tyco had an obligation to fully develop its case within the 45-day time limit in order to establish objective bases for its claims, that also is simply not true. A civil probable cause standard neither contemplates nor requires such an extraordinary pre-filing effort.[5] Under prevailing law, Tyco was only required to undertake a "reasonable" pre-suit investigation into the accused product. *See Honeywell Int'l Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 1001 (Fed. Cir. 2007).[6] It was not required to bolster its filing decision; an infringement suit is not considered baseless under Rule 11 even if the

[5] Tyco was not required to "pre-discover" its legal claims, and had no obligation to independently test allegedly infringing product before bringing suit. *Q-Pharma, Inc. v. Andrew Jergens Co.,* 360 F.3d 1295, 1302 (Fed. Cir. 2004); *Elan Corporation, PLC*, 421 F.3d at 1249 (stating that "the focus of the infringement inquiry under 35 U.S.C. § 271(e)(2)(A) is on the product that will be sold after the FDA's approval of the ANDA not on the biobatch that is produced to facilitate FDA approval.") (internal citation omitted); *see also Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.,* 343 F. Supp. 2d 272, 319-20 (D. Del. 2004) (holding a good faith basis to file an infringement suit "does not mean … that the litigant must have clear proof on every point of the desired outcome," nor does it require the litigant to "reverse-engineer a competitor's product to determine if it infringes").

[6] Indeed, even if Tyco had *wanted* to test Mutual's Commercial Batch prior to filing suit in March of 2007 (which was the proper material to assess), it could not have done so. Mutual did not obtain its first Commercial Batch before July, 2007 (A5545 at ¶27; A5367; A5337 at 90:22-92:7), and it ultimately rejected that batch in January, 2009 (A5548 at ¶35).

patentee's pre-suit investigation of an ANDA reveals "neither evidence of infringement nor non-infringement." *Hoffmann La Roche, Inc. v, Invamed, Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000).

C. Tyco Had Probable Cause to Assert Its Infringement Claims Against Mutual.

To secure summary judgment on Mutual's antitrust counterclaims under *PRE*, Tyco need only demonstrate the existence of "probable cause, as understood and applied in the common-law tort of wrongful civil proceedings." *PRE*, 508 U.S. at 62. That standard represents a low threshold, requiring "no more than a reasonable belief that there is *a chance* that a claim may be held valid upon adjudication." *Id*. at 62-63 (quotations omitted) (emphasis added). Here, Tyco made the necessary showing in support of its summary judgment motion on Mutual's counterclaims below, and in the absence of evidence to the contrary, that showing forecloses Mutual from being able to prove objective baselessness. Summary judgment is therefore appropriate.

In this case, a brief set of straightforward and undisputed facts known to Tyco at the time of its infringement filing establishes that a reasonable litigant would have had a reasonable belief that it had a chance of prevailing. The following facts establish probable cause for Tyco's assertion of the Tyco Patents:

- Tyco acquired the Tyco Patents from Sandoz in 2001. (A5536 at ¶5).

- The Tyco Patents are directed to a 7.5 mg dosage form and methods of treating insomnia using temazepam particles having a specific surface area of 0.65 to 1.1m^2/g. (*See, e.g.* A4381-82).
- Measurement of surface area is test-dependent. (A5453; A5270).
- Surface area may affect bioavailability. (A5141-42).
- [redacted]
- [redacted]
- [redacted]
- T[redacted]

Essentially, with a window of just 45 days to act to protect its rights,[7] Tyco had to respond to an ANDA for a generic product that was *required* to be

[7] The 45-day window Tyco had to develop potential evidence related to infringement was not sufficient to conduct comprehensive discovery. It was only during discovery, for instance, [redacted]

bioequivalent to its own Restoril® product, but whose ANDA neither effectively differentiated its product from Tyco's 7.5 mg Restoril® with respect to SSA, nor explained apparent discrepancies relating to the FDA's bioequivalence requirement. 21 C.F.R. 314.107(b)(3)(i)(A); *see also* A4497-515. Contrary to Mutual's argument,

[redacted]

Tyco was not required to accept the surface area representations presented in Mutual's ANDA as proof of non-infringement. Tyco's own previous experience with PTL testing of the 7.5 mg Restoril® product had itself generated a plethora of inconsistent results. (A5035; A5029; A5025; A5019; A4831-33). Taken as a whole, these facts, as known to Tyco at the time of its filing, easily demonstrate

[redacted]

probable cause, and therefore preclude Mutual from satisfying the objective first tier of the *PRE* sham litigation test.

D. *Bayer v. Elan* Did Not Negate Tyco's Probable Cause to Assert the Tyco Patents.

Mutual argues that given the legal precedent established by *Bayer Ag v. Elan Pharma Res. Corp.*, 212 F.3d at 1249 ("*Elan*"), a reasonable factfinder could conclude that Tyco's infringement claim was objectively baseless. App. Br. at 31-32. This argument founders for a variety of reasons. As an initial matter, it again assumes an incorrect legal standard. Mutual argues specifically that *Bayer* and its progeny "raise at least a factual dispute as to whether Tyco 'could realistically expect to secure favorable relief.'" *Id.* at 34. But the *PRE* sham litigation test does not turn on Tyco's belief in the strength of its claims. It looks instead to whether a *reasonable litigant*, given the facts as they appeared to Tyco at the time the claim was filed, could *reasonably believe* that it had *a chance* that its claim may be held valid upon adjudication. *See PRE*, 508 U.S. at 62-63.[8]

1. *Elan* Was Factually Distinguishable.

Mutual's argument wrongly assumes that *Elan,* a factually *distinguishable* legal precedent, would necessarily dictate the outcome of Tyco's infringement claims. At the time it filed suit, Tyco had an objectively reasonable basis to believe

[8] Notably, under the probable cause standard, a reasonable litigant need not have a strong chance of prevailing, or even a significant chance of prevailing – merely *a chance* of prevailing given the facts that exist at the time of filing.

Elan might not compel a finding of non-infringement. First, although test protocol issues related to specific surface area ("SSA") were a central concern to Tyco because of SSA's potential effects on bioavailability, there was nothing in the *Elan* opinion suggesting that the parties in that case *disputed* the appropriate test protocol parameters for measuring SSA. *See Elan,* 212 F.3d at 1248. *Elan* does not discuss the significant variances in SSA measurement that can occur when using different protocols.[9]

Moreover, the facts supporting Tyco's infringement action were distinguishable from those in *Bayer* and other existing legal precedents because Tyco had knowledge of inconsistent test results obtained on its own temazepam samples from PTL, [redacted] This raised a legitimate question – the outcome of which was in no way dictated by *Elan* – [redacted]

[9] [redacted], the ANDA would not "directly address" the issue of infringement as required by *Elan.*

[10] Some of these inconsistencies were observed on [redacted]

2. Interpretation of Other Relevant Legal Authorities Stood to Affect the Outcome of Tyco's Infringement Action.

Elan could not be presumed to be *the* controlling authority applicable to Tyco's infringement action. *Elan*, for instance, did not overrule *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). At a minimum, a reasonable litigant could conclude that *Elan* posed an *alternative* basis for limiting discovery when compared to the previous standard established by *Glaxo*. In *Glaxo,* this Court indicated that "especially in a case such as this, involving a compound capable of existing in various forms, the statue requires an infringement inquiry focused on what is likely to be sold following FDA approval. This inquiry must be based on *all of the relevant evidence*, including the ANDA." *Id., 1*10F.3d at 1568 (emphasis added). *Compare Elan*, 212 F.3d at 1249 (finding no literal infringement in that instance based on the ANDA specification *alone*).

Nor was Tyco required to assume that further investigation through discovery was improper. Courts have certainly allowed patentees leeway to file and investigate claims of infringement through discovery even where an ANDA might appear dispositive on its face. *See AstraZeneca AB*, 2010 WL 2079722, at *4 (holding that "a reasonable plaintiff in a Hatch-Waxman case would be expected to know few details about the accused product at the outset of litigation and plaintiff's counsel may reasonably rely on discovery to learn the material details."); *see also Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 2003 WL 22887861, at *5

(N.D. Ill. Dec. 4, 2003) (finding that "it is reasonable for a patent holder to engage in discovery to investigate representations made in an ANDA); *see also Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (suggesting that in an infringement action under 35 U.S.C. § 271(e)(2)(A), evidence obtained in discovery may contradict information in an ANDA).

Discovery in the infringement case later revealed a claim construction dispute over whether Mutual's alternative test protocol was within the claim scope, along with competing qualified expert opinions – both of which are recognized factors weighing *against* a finding of objective baselessness. *See, e.g., Mitek Surgical Prods., Inc. v. Arthrex, Inc*., 230 F.3d 1383 (Table, Text in Westlaw), Nos. 99-1004, 99-1034, 2000 WL 217637, at *4 (Fed. Cir. Feb. 22, 2000) (patentee's infringement action less likely to be found objectively baseless where there is a legitimate dispute over the construction of claims); *ClearPlay, Inc. v. Nissim Corp*., No. 07-81170-CIV, 2011 WL 3878363, at *13-14 (S.D. Fla. Sept. 2, 2011), *aff'd*, 496 Fed. Appx. 963, 2012 WL 5503668 (11th Cir. Nov. 14, 2012) (qualified experts' dueling opinions recognized as evidence of objective bases for suit); *see also Laitram Mach., Inc. v. Carnitech A/S*, 901 F. Supp. 1155, 1161 (E.D. La. 1995) (relying on expert testimony to find a dispute of fact concerning reasonableness of lawsuit); *see also* A9 (district court recognizing 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.").

Even under *Elan,* it was objectively reasonable for Tyco to expect that it could successfully argue that testing of Mutual's Commercial Batch – not Mutual's biobatch, or its rejected follow-on material, or the information incompletely disclosed in its ANDA – was the correct approach under existing law. Although this argument failed to carry the day, it was certainly not objectively unreasonable to make it. *See Elan,* 212 F.3d at 1249; *Glaxo,* 110 F.3d at 1569-70; *Ben Venue Laboratories, Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 574, 579-80, 583 (D.N.J. 2001).

3. The District Court's Well-Reasoned Analysis Confirms a Lack of Objective Baselessness Notwithstanding Due Consideration of *Elan*.

Although Mutual confidently asserts that *Elan* left "settled" the law that would apply to Tyco's infringement action, App. Br. at 2, it was certainly not so "settled" as to render the outcome of Tyco's infringement claims predictable. As the district court itself aptly acknowledged, its application of *Elan* to the particular facts of this case was "clear" only in hindsight. (A7).

While Mutual now complains that the district court erred in its offhand observation that Mutual had never moved for summary judgment based on *Elan,* App. Br. at 36, that criticism is unavailing and cannot justify reversal. The district

court's comment was mere dicta. A simple reading of its Order makes clear that its summary judgment ruling was not actually premised on a belief that Mutual had failed to move for summary judgment based on *Elan*. (*See* A7-A11). The district court's conclusion that Tyco's infringement claim was not objectively baseless was based on *numerous* findings, including that:

- the court's application of *Elan* to the facts of the case was not predictable at the time of Tyco's filing, (A7);
- the fact that the ANDA and the patents referred to methods of measuring SSA that were not identical were sufficient to raise the possibility that a court would not conclude that *Elan* precluded a finding of infringement, (A8);
- Tyco had did not have any sample of Mutual's (commercial batch) generic temazepam to test at the time the period for filing the patent infringement suit expired, (A8);
- 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, (A9);
- Mutual's own testing laboratory obtained measurements that fell within the SSA range specified in the patent at issue, (A10); and, that, as a result:

- "At the time the Complaint was filed, a reasonable litigant could have reasonably believed that *Elan* might not determine the outcome of the infringement action." (A10).

The mere existence of *Elan* as potentially controlling legal authority is not sufficient to prove that Tyco's lawsuit was objectively meritless at the time it filed its Complaint under the applicable probable cause standard.[11]

E. Tyco's Purported "Knowledge" That It May Have Been Possible for Another to Develop a Noninfringing Temazepam Product Is Immaterial to the Sham Litigation Analysis.

Mutual's argument on appeal relies heavily on [redacted] Mutual's apparent intent in making this argument is to suggest that based on [redacted], Tyco must have already known that Mutual's product did not infringe, and that Tyco's Complaint was, therefore, objectively meritless.

[11] Mutual's additional criticism of the district court's failure to take into account its ultimate conclusions concerning the weight and persuasiveness of particular evidence presented *during litigation* of Tyco's infringement claims, App. Br. at 38-39, only further evidences its disregard for the operative probable cause standard. Tyco's lack of success in asserting the Tyco Patents is not relevant to the question of objective baselessness.

[redacted] is just one of many pieces of evidence which, singularly and collectively, prove insufficient to demonstrate that Tyco's Complaint was a sham. Indeed, the issue is not whether it was *possible* that Mutual's proposed ANDA would *not* infringe, but rather whether there was an objectively reasonable basis for believing it *might* infringe. [redacted] speaks only to the former question. Despite its (undisputed) awareness of the memo, Tyco was still fully entitled to challenge whether Mutual's [redacted] temazepam would impact bioequivalence, and, if so, to what extent.

Moreover, although Mutual artfully avoids citing the full text of [redacted] Nothing in Mutual's produced ANDA materials explained how Mutual's formulation could be achieving the claimed bioequivalence in light of its purported surface area.[12]

With knowledge of these facts, a reasonable litigant could reasonably believe it had a chance to prevail in asserting the Tyco Patents in litigation or by means of an administrative petition.

[12] Tyco ultimately submitted reports from two internationally-recognized experts in pharmacokinetics and pharmaceutical formulation, Drs. Daniel Weiner and Stanley Davis addressing this (as well as other) facts. (A7297-321; A7204-20).

F. Mutual's Replay of Its Infringement Affirmative Defenses Does Nothing to Satisfy the Actual Sham Litigation Standard.

Mutual's re-argument of its obviousness infringement defenses fails to advance its sham litigation claim, and only further demonstrates its confusion of the ultimate disposition of Tyco's infringement claims with the objective legal standard that asks only whether a reasonable litigant, with the knowledge Tyco possessed at the time it filed its Complaint, could have reasonably believed that it had a chance of prevailing on such claims. *PRE*, 508 U.S. at 62-63. Mutual's only conceivable basis for arguing these defenses would be to encourage this Court to engage in an impermissible post hoc analysis of those claims.

The subjective strength of Mutual's affirmative defenses, like that of Tyco's infringement claims themselves, has no relevance to a determination of whether Tyco's claims were objectively baseless. At the time of its filing, Tyco's infringement suit was supported by various objectively reasonable bases, including not only those enumerated at Section I.C, *supra*, but additional bases related specifically to Mutual's affirmative defenses, including that:

- Issued patents are presumptively valid.[13]

[13] Mutual's attempts to argue that the presumption of validity could not serve as an objectively reasonable basis for suit simply because it *could* be overcome by "bad faith" assertion of invalid patents, App. Br. at 42, should be disregarded. Mutual offers no evidence of such "bad faith" in the filing of the Complaint, nor does it refute the additional bases cited herein. The policy underlying the presumption of validity supports a patentee's efforts to enforce its duly issued patents. *C.R. Bard*

- Invalidity of the Tyco Patents would have had to be proven by clear and convincing evidence.[14]
- There was no evidence of invalidity as to obviousness with respect to the '954 patent at the time of filing; Mutual did not identify the BNF reference it ultimately relied upon to demonstrate obviousness until July, 2009, one month before the expiration of the 30-month stay.
- There was no evidence of invalidity as to obviousness with respect to the other three Tyco Patents asserted; those patents contained method-of-treatment claims that expired in July, 2008. Neither the district court below nor this Court on appeal ever reached the issue of whether the BNF reference – to which Tyco's arguments could apply with even greater force – rendered those patent claims obvious.

Inc., 157 F.3d at 1369 ("[T]he patentee must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent's validity or infringement not survive litigation.").

[14] Although Mutual alleged that Dr. Leber of the FDA should have been a named inventor of the '954 patent, he denied inventorship. (A6219 at 204:1-11, 19-22). Dr. Sterling was listed on the face of the patent as the only inventor. (A4380). Dr. Sterling also signed a declaration of inventorship under penalty of perjury, and devised and ran the sleep study that demonstrated that a 7.5 mg dose of temazepam significantly reduced sleep latency (*i.e.* the study which forms the basis for the content of the '954). (A994 at 99:13-17; A2846-47 at 146:25-147:4; A2864). Mutual's ANDA contained no substantive evidence that the Tyco Patents were invalid. (A4544-790).

Rarely, if ever, is obviousness so clear that a reasonable litigant can predict a particular finding. *US v. Mohsen*, No. CR. 03-0095 WBS, 2005 WL 3288651, at *4 (E.D. Cal. Dec. 2, 2005) (explaining that "[i]n the early stages of patent litigation, before the landscape of the relevant prior art is fully illuminated, a patent owner cannot usually predict the exact combinations of art that might later be deemed to render a patent obvious or anticipated."). Indeed, in this instance, Mutual's Paragraph IV certification letter did not even advance an invalidity argument, meaning that Tyco was not immediately put on notice of Mutual's claims of obviousness or improper inventorship. (A4497-515).

The district court correctly concluded that Mutual had "failed to submit evidence to demonstrate a material factual question about whether [Tyco] objectively had a reasonable basis to believe that they had a chance to succeed, given the presumption of validity." (A11). The mere potential for objectively valid bases to fail during litigation does not prove an absence of probable cause at the outset.[15]

II. Tyco's Citizen Petition Was Objectively Reasonable and a Valid Attempt to Assert Its Patent Rights.

[15] While Mutual alludes obliquely to the possibility that Tyco had "acquired sufficient information to indicate with certainty that the . . . patent was invalid on the basis of [a] prior invention," App. Br. 43, the evidence it cites is plainly insufficient to establish "bad-faith patent enforcement."

Mutual argues that the district court erred by failing to apply the two-prong *PRE* sham litigation test in connection with Tyco's Citizen Petition. App. Br. at 44 (disputing district court's observation that PRE "is inapposite because it is expressly limited to litigation" and citing Third Circuit cases that applied *PRE*'s two-part test to claimed exceptions to *Noerr-Pennington* immunity). Mutual's criticism of the district court, whether proper or not, is ultimately of no moment.

First, the district court below accurately cited binding U.S. Supreme Court authorities, including *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1978) and *City of Columbia v. Omni Outdoor Adver.*, 499 U.S. 365, 382 (1991) when acknowledging that cases of "abuse" of administrative (non-litigation) petitions "should not acquire [*Noerr-Pennington*] immunity." (A12). But while the district court's discussion of "sham" activity in relation to Tyco's Citizen Petition may indeed have been less comprehensive, it nonetheless yielded precisely the same outcome required by *PRE*.[16]

Assuming, as Mutual advocates, that *PRE*'s framework is to be applied to Tyco's Citizen Petition, the undisputed facts establish that Tyco did have probable cause for submitting the petition. Just as it argued with respect to Tyco's infringement action, Mutual again improperly urges this Court to draw conclusions about the objective bases for submitting the Citizen Petition based on its ultimate

[16] Tyco acknowledges that the cases cited by Mutual, App. Br. at 44-45 universally adopt the *PRE* two-tier test to administrative petitions.

(lack of) success. Indeed, Mutual's entire argument concerning the alleged lack of objective bases for submitting the Citizen Petition is based on FDA (and Mutual's experts') conclusions reached *after* that filing occurred.

Applying the objective test mandated by *PRE*, the facts known to Tyco at that time it submitted its Citizen Petition easily establish that a reasonable litigant in possession of those facts could reasonably believe that it had a chance of prevailing. Tyco was aware, for instance, that:

- [redacted];
- [redacted];
- At a hearing during the infringement action, Mutual argued that its product having more than double the surface area of Tyco's Restoril® would improve bioavailability. (A5141-42 at 79:11-81:10).[17]

[17] While Tyco had been privy to this assertion previously, pursuant to restrictive confidentiality terms, Tyco was not able to use this information in a Citizen's Petition. (A5004-16). It was only after Mutual made this public disclosure that Tyco could present this information to the FDA. (*Id.*; A5141-42 at 79:11-81:10) (representations in open court concerning the drug produce described in Mutual's ANDA as compared to Tyco's Restoril® temazepam product).

These additional facts supported Tyco's continuing defense of its patent rights by means of a Citizen Petition. Tyco acted as a reasonable litigant presenting a legitimate, non-frivolous scientific basis for its Citizen Petition that questioned the bioequivalence of Mutual's 7.5 mg temazepam formulation. Since bioequivalence is the most challenging part of any ANDA application and ensures a patient will be adequately treated by a generic drug, reasonable litigants can and routinely do use Citizen Petitions to question how the FDA determined the bioequivalence of two particular drugs. Tyco's Citizen Petition is therefore also protected by the *Noerr-Pennington* doctrine. The filing of that Petition was not objectively baseless, and the second (subjective) tier of the *PRE* test is therefore unnecessary.

On appeal of the Citizen Petition issue, Mutual attempts to rely on an expert opinion prepared in response to Tyco's summary judgment motion on the antitrust counterclaims and long after FDA's rejection of Tyco's Citizen Petition. App. Br. at 46, citing A6438. That expert opinion, however, is merely a subjective assessment of the strength of Tyco's Citizen Petition, and a post hoc version at that. As such, it is completely immaterial to the first (objective) prong of the PRE two-tier test.

Even if this Court were inclined to reach the subjective question of whether Tyco's Citizen Petition was merely an attempt to interfere directly with the business relationships of a competitor, Mutual's argument on this point is based exclusively on the *timing*, not the substance, of the Citizen Petition. App. Br. at 49 (arguing that

the timing of Tyco's petition "alone" indicates that it sought to "cause[] a delay in generic competition"). Specifically, Mutual asserts that "if Tyco had genuinely been concerned about Mutual's SSA – and the purported safety concerns it raised – it would have filed a petition as soon as it saw the specification. *Id.* The undisputed facts establish that the protective order precluded Tyco from filing such a petition until Mutual waived its protection by publically representing that increasing surface area or decreasing the particle size would improve the bioavailability of the drug once administered into the body, and that as one increases surface area for drugs like temazepam, one would improve the bioavailability. (A5141-42 at 79:11-81:10).

Under the objective prong of the *PRE* two-tier test that Mutual contends must govern its sham claim associated with Tyco's Citizen Petition, a reasonable petitioner possessing the knowledge Tyco had at the time of the filing could have reasonably believed it had a chance of prevailing. The district court's order should therefore be affirmed.

III. Mutual's Proof Fails to Raise a Triable Issue of Fact as to Either Fraud or Knowledge, and Tyco is Therefore Entitled to Summary Judgment on Mutual's *Walker Process* Fraud Claims.

To overcome Tyco's presumptive *Noerr-Pennington* immunity by way of *Walker Process* fraud exception, Mutual must demonstrate that it can prove, "with no less than clear, convincing proof," that Sandoz, original owner of the '954 Patent, committed "intentional fraud involving affirmative dishonesty, a deliberately

planned and carefully executed scheme to defraud the Patent Office." *C.R. Bard*, 157 F.3d at 1364. Given that *Walker Process* is a variant of common law fraud, the elements of such a fraud claim will encompass:

> (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of reliance on the misrepresentation.

In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 807 (Fed. Cir. 2000); (citations omitted).

In addition to proving an underlying fraud on the USPTO by original patent owner Sandoz, Mutual must also prove that Tyco *knew* it was seeking to enforce a patent obtained by knowing and willful fraud at the time Tyco filed suit. *See Nobelpharma AB v. Implant Innovations, Inc*., 141 F.3d at 1072-73.

In the district court below, Tyco successfully argued Mutual's failure of proof with respect to both the alleged fraud by Sandoz *and* Tyco's knowledge that it was seeking to enforce a patent obtained by the alleged fraud. The district court properly concluded that the mere fact that Tyco had performed a due diligence review of the patents' prosecution histories was "not sufficient to persuade a reasonable finder of fact that Tyco knew the patents had been procured by knowing and willful fraud." (A14). In deciding summary judgment, the district court therefore required that Mutual point to evidence that, as of March 20, 2007, Tyco knew that "Sandoz had

procured the patents through a deliberately planned and carefully executed scheme to defraud the Patent Office." (*Id.*)

Mutual failed, both then and now, to demonstrate a genuine dispute as to any material fact precluding entry of summary judgment in favor of Tyco on the *Walker Process* fraud antitrust counterclaim. In the court below, Mutual pointed to evidence supporting just two factual assertions:

1) Tyco had read the patents' prosecution histories; and

2) Tyco knew of the Memo for the Record (the Memo).

(*See* A14). The district court appropriately concluded that this evidence "does not amount to even a mere scintilla of evidence that Plaintiffs new of a deliberately planned and carefully executed scheme to defraud the Patent Office." (*Id.*). Indeed, it found that neither the Sandoz prosecution histories nor the Memo revealed a fraudulent scheme; at most, they demonstrated that Tyco was "aware that the relevant prior art existed and could impact the validity or enforceability of the patents." (A15). This showing is insufficient to meet even the sham litigation standard, much less the more stringent *Walker Process* exception.

On appeal, Mutual additionally argues [redacted] App. Br. at 56-57.

Mutual also claims that its own notice letter's discussion of obviousness was somehow sufficient to give Tyco knowledge of fraud by Sandoz, despite the fact that the letter did not substantively assert a lack of validity. (A4544-790; A4498-99).

To successfully assert the *Walker Process* fraud exception, Mutual would need to adduce facts evidencing that Sandoz had a specific *intent to deceive the USPTO* when it originally applied for and prosecuted the patents such that "the involved conduct . . . indicate[d] sufficient culpability to require a finding of *intent to deceive*." *Therasense, Inc.* 649 F.3d at 1291 (emphasis added); *see also 1st Media, LLC v. Electronic Arts, Inc.,* 694 F.3d 1367 (Fed. Cir. 2012). This Court subsequently elaborated "*Therasense* explained that in order to show that the patentee acted with the specific intent to deceive the PTO, a defendant must prove 'that the applicant knew of the reference, knew that it was material, and *made a deliberate decision to withhold it*.'" *1st Media,* 694 F.3d at 1372 (citing *Therasense,* 649 F.3d at 1290) (emphasis in original). A mere "finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement." *Id.* (citations omitted). In a case involving alleged nondisclosure of information, fraud can only be proven by clear and convincing evidence showing the applicant "*made a deliberate decision* to withhold a *known* material reference." *Id.* (emphasis in

original) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

Given this rigorous standard, neither the original facts cited by Mutual in opposition to summary judgment below nor those raised in the current appeal are sufficient to meet Mutual's burden of proof to defeat summary judgment. Mutual has not pointed, and still cannot point, to *any* evidence of the requisite "deliberately planned and carefully executed scheme" by Sandoz to defraud the USPTO in the prosecution of the Tyco Patents.

The failure of proof with respect to the alleged fraud itself should be sufficient to preclude Mutual's *Walker Process* fraud claim. But the same claim also fails by virtue of an inability to demonstrate that Tyco knew of any fraud in the procurement of the Tyco Patents. Here, Mutual argues that the district court's findings on the issue of actual knowledge can be overcome by a showing proof of *constructive knowledge* based on *inferences* drawn from *circumstantial evidence*. App. Br. at 59. This lax evidentiary formulation, if accepted, would dramatically (and needlessly) alter the established legal standard. Moreover, the cases cited by Mutual in support to advocate watering down the actual knowledge requirement, including *Jordan, Glenn Const. Co., and Brown,*[18] App. Br. at 59, are inapposite.

[18] *Jordan v. Paul Fin., LLC*, 285 F.R.D. 435 (N.D. Cal. 2012); *Glenn Const. Co., LLC v. Bell Aerospace Servs., Inc.*, 785 F. Supp. 2d 1258 (M.D. Ala. 2011); *and Brown v. Owens Corning Inv. Review Comm.*, 622 F.3d 564 (6th Cir. 2010).

None involve alleged fraud on the USPTO, which this Court expressly acknowledged in *C.R. Bard*, would be difficult to accomplish given that "the road to the Patent Office is so tortuous and patent litigation [] usually so complex." 157 F.3d at 1364. Nor do the cases relied upon by Mutual involve the standard of knowledge to be applied to subsequent third parties merely reviewing a past and presumptively valid process.

A careful reading of Mutual's brief reveals that it is actually seeking a standard so far removed from *Noblepharma's* as to be practically unrecognizable. *Noblepharma* requires Mutual to prove that Tyco knew Sandoz had procured the Tyco Patents by fraud. Mutual now argues that its claims should be allowed to proceed based on evidence it asserts will prove that "Tyco was *aware of a significant risk that Sandoz had engaged in fraud*." App. Br. 59 (emphasis added).[19] Awareness of a significant risk of fraud is not equivalent to actual knowledge of fraud, and Mutual's proposal should be rejected out of hand.

Mutual does not possess evidence sufficient to give rise to a genuine issue of disputed fact over either Sandoz' alleged fraud on the USPTO or Tyco's knowledge of that alleged fraud. The district court properly applied *Walker Process, Thereasense,* and *Noblepharma* to conclude that summary judgment on

[19] Not only is that a significantly watered down standard, but one of the key pieces of "evidence" Mutual points to is nothing more than its *own* interpretation of the USPTO examiner's belief. App. Br. at 59-60 (citing Mutual's notice letter).

the antitrust counterclaims was appropriate, and that determination should be affirmed.

CONCLUSION

The district court's judgment should be affirmed.

Dated: September 3, 2013

/s/ *Rebecca J. Schwartz*
PETER E. STRAND
SHOOK, HARDY & BACON, LLP
1155 F. Street, N.W., Suite 200
Washington, DC 20004
Phone: (202) 783-8400
Facsimile: (202) 783-4211
pstrand@shb.com

JOHN D. GARRETSON
REBECCA J. SCHWARTZ
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816.474.6550 Telephone
816.421.5547 Facsimile
jgarretson@shb.com
rschwartz@shb.com

Counsel for Plaintiffs/Appellees Tyco Healthcare Group LP and Mallinckrodt Inc.

CERTIFICATE OF SERVICE

This certifies that on September 3, 2013, a true and correct copy of the *Nonconfidential Response Brief for Plaintiffs-Appellees* was electronically filed with the Clerk of the Court using the CM/ECF system which sent a Notice of Docket Activity, via email, to all registered users.

Dated: September 3, 2013

/s/ *Rebecca J. Schwartz*
PETER E. STRAND
SHOOK, HARDY & BACON, LLP
1155 F. Street, N.W., Suite 200
Washington, DC 20004
Phone: (202) 783-8400
Facsimile: (202) 783-4211
pstrand@shb.com

JOHN D. GARRETSON
REBECCA J. SCHWARTZ
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816.474.6550 Telephone
816.421.5547 Facsimile
jgarretson@shb.com
rschwartz@shb.com

Counsel for Plaintiffs/Appellees Tyco Healthcare Group LP and Mallinckrodt Inc.

CERTIFICATE OF COMPLIANCE

I, Rebecca J. Schwartz, counsel for Plaintiffs-Appellees, certify pursuant to Fed. R. App. P. 32(a)(7) and Federal Circuit Rule 32(b) that this brief contains 13,409 words, as counted by Microsoft Word 2010. The text of the brief and footnotes are in 14-point Times New Roman font.

Dated: September 3, 2013

/s/ *Rebecca J. Schwartz*
PETER E. STRAND
SHOOK, HARDY & BACON, LLP
1155 F. Street, N.W., Suite 200
Washington, DC 20004
202.783.8400 Telephone
202.783.4211 Facsimile
pstrand@shb.com

JOHN D. GARRETSON
REBECCA J. SCHWARTZ
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
816.474.6550 Telephone
816.421.5547 Facsimile
jgarretson@shb.com
rschwartz@shb.com

Counsel for Plaintiffs/Appellees Tyco Healthcare Group LP and Mallinckrodt Inc.