United States Court of Appeals for the Federal Circuit

TYCO HEALTHCARE GROUP LP AND MALLINCKRODT INC.,
Plaintiffs-Appellees,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC. AND UNITED RESEARCH LABORATORIES, INC.,
Defendants-Appellants.

2013-1386

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

Decided: August 6, 2014

PETER E. STRAND, Shook, Hardy & Bacon, L.L.P., of Washington, DC, argued for plaintiffs-appellees. With him on the brief were JOHN D. GARRETSON and REBECCA J. SCHWARTZ, of Kansas City, Missouri.

STEFFEN N. JOHNSON, Winston & Strawn LLP, of Washington, DC, argued for defendants-appellants. With him on the brief were CHARLES B. KLEIN, JOHN K. HSU, and EIMERIC REIG-PLESSIS, of Washington, DC, and JAMES F. HURST, of Chicago, Illinois.

Before NEWMAN, BRYSON, and MOORE, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* BRYSON.
Dissenting opinion filed by *Circuit Judge* NEWMAN.

BRYSON, *Circuit Judge*.

Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc., (collectively, "Mutual") appeal from a summary judgment entered by the United States District Court for the District of New Jersey in favor of Tyco Healthcare Group LP and Mallinckrodt, Inc., (collectively, "Tyco"). In the order on appeal, the district court held that Tyco did not violate the antitrust laws by filing suit against Mutual or by filing a "citizen petition" with the Food and Drug Administration ("FDA") seeking to bar Mutual from obtaining FDA permission to market its generic version of one of Tyco's drugs. We affirm in part, vacate in part, and remand.

I

Tyco is the owner of several patents directed to formulations or methods of treatment with temazepam, a drug used to treat insomnia. Tyco markets temazepam under the brand name Restoril. Tyco acquired Restoril and several related patents from Sandoz Limited in 2001. The patents all claim 7.5 mg formulations of temazepam having a specific surface area between 0.65 and 1.1 square meters per gram (m^2/g). Specific surface area is a measure of the surface area of a drug per unit of weight. Generally, as chunks of drug material are ground down into smaller particles, the specific surface area increases because more of the drug is exposed to the surrounding environment.

The claims of the temazepam patents do not recite any particular measurement technique. However, the specifications of each of the patents state that "[s]urface

area measurements are made essentially in accordance with the standard B.E.T. procedure of Brunauer, Emmet and Teller." *E.g.*, U.S. Patent No. 5,211,954 ("the '954 patent"), col. 2, ll. 1-4.

B.E.T. testing is a gas-adsorption technique for measuring specific surface area. The procedure measures the amount of an adsorbate gas that has bound to the surface of the test material. In order to prepare a sample of a drug for measurement, a process of outgassing is performed, during which gas or vapor is removed from the surface of the sample to produce a clean surface that can be measured accurately. Outgassing is performed at a particular temperature, and the selection of that temperature can affect the ultimate specific surface area measurement. Increasing the outgassing temperature speeds the process of cleaning the test material's surface and allows measurements to be obtained more quickly. It is important, however, to avoid selecting a temperature so high that the heat physically alters the test material, for example by softening or melting it.

Sandoz conducted specific surface area testing while seeking FDA approval for Restoril. Tyco also performed testing after acquiring Restoril and the temazepam patents. In both cases, the testers used the B.E.T. procedure with an outgassing temperature of 105°C.

In November 2006, Mutual filed an Abbreviated New Drug Application ("ANDA") with the FDA, seeking approval to manufacture and sell a generic 7.5 mg version of temazepam. Mutual's ANDA represented that its product would have a specific surface area of not less than 2.2 m^2/g, which was well above the specific surface area range claimed in the temazepam patents. Mutual's ANDA included a certification representing that the generic drug was not protected by a U.S. patent, as required by 21 U.S.C. § 355(j)(2)(A)(vii). Mutual's certification was filed under paragraph IV of section 355(j)(2)(A)(vii), which

permits a generic manufacturer to assert that the patent or patents at issue are invalid or that the generic product that is the subject of the ANDA would not infringe those patents. Such certifications are known as "paragraph IV certifications." On February 5, 2007, Mutual sent Tyco a "paragraph IV certification letter" notifying Tyco of its ANDA. The letter set forth Mutual's position that the proposed ANDA product would not infringe the temazepam patents because the generic product's specific surface area would not fall within the 0.65-1.1 m^2/g range claimed by those patents.

In response to Mutual's paragraph IV certification, Tyco filed an action alleging that Mutual's ANDA infringed Tyco's patents under 35 U.S.C. § 271(e)(2)(A), the special infringement provision of the Hatch-Waxman Act. Pursuant to the automatic stay provision of the Act, 21 U.S.C. § 355(j)(5)(B)(iii), Tyco was entitled to an automatic stay of the FDA's approval of Mutual's ANDA until the earlier of 30 months from the date Tyco filed its complaint or the date that a court determined that Tyco's patents were invalid or not infringed by Mutual's ANDA. In its amended answer, Mutual raised antitrust counterclaims, which the district court temporarily stayed pending the resolution of Tyco's infringement claims.

On August 4, 2009, the district court granted judgment of noninfringement under Fed. R. Civ. P. 52(c). At that point only the '954 patent was at issue because Tyco's other temazepam patents had expired.

Based on this court's decision in *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), the district court found that Mutual did not infringe the '954 patent under section 271(e) because Mutual's ANDA "defines the proposed temazepam product in a manner that directly addresses the issue of infringement" and because a "product manufactured to the ANDA's specification," i.e., a product having a specific surface area

of not less than 2.2 m^2/g, "could not literally infringe the '954 Patent." *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, No. 2:07-cv-01299, slip op. at 6, 13 (D.N.J. Aug 4, 2009).

On August 5, 2009, the day after the district court entered its judgment of noninfringement, Tyco filed a citizen petition with the FDA. The citizen petition urged the FDA to change the criteria for evaluating the bioequivalence of proposed generic temazepam products in order to "help ensure therapeutic equivalence" of generic temazepam to Restoril. Tyco proposed guidelines that would require generic temazepam manufacturers to demonstrate bioequivalence to Restoril through a series of pharmacokinetic parameters considerably more extensive and complex than the parameters traditionally required by the FDA for a bioequivalence determination. Tyco reasoned that the safety and efficacy of Restoril was likely linked to its pharmacokinetic profile, and that changes to parameters such as specific surface area in a generic version could alter that profile and thereby affect the safety and efficacy of the generic version as compared to Restoril.

On September 8, 2009, although the citizen petition was still pending, the FDA approved Mutual's ANDA, which allowed Mutual to bring its generic temazepam product to market. Five months later, the FDA denied Tyco's citizen petition in its entirety. The FDA concluded that Tyco "had not provided adequate evidence to support any of the actions requested in the petition" and that there was "no basis" for adopting Tyco's proposed bioequivalence criteria. In addition, the FDA found that the citizen petition "relie[d] entirely on uncorroborated generalities and theoretical speculation." The FDA explained that it "require[s] additional bioequivalence criteria" in "very rare circumstances." Those circumstances, according to the FDA, have arisen only in the case of "complex extended-release or otherwise modified-release products

for which there was a known and clinically significant connection between release characteristics and clinical performance." Temazepam, the FDA explained, "is not such a drug."

On May 5, 2010, the district court granted summary judgment on Mutual's invalidity counterclaim, holding the claims of the '954 patent invalid for obviousness. This court affirmed that decision. *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 642 F.3d 1370, 1377 (Fed. Cir. 2011). We held that the only feature of the '954 claims not found in the prior art 15 mg Restoril capsules was the 7.5 mg temazepam dosage level. That dosage level, however, was disclosed in a 1983 volume of the British National Formulary ("BNF") that recommended administering between 5 and 15 mg of temazepam for the treatment of insomnia in the elderly. *Id.* at 1372. This court rejected Tyco's argument that various prior art references taught away from that 7.5 mg dosage level. *See id.* at 1374-76. We also rejected Tyco's argument that the BNF reference did not teach the 7.5 mg dose because it did not provide evidence of the efficacy of that dose. *See id.* at 1373-74.

After our disposition of the first appeal, the district court lifted the stay of Mutual's antitrust counterclaims. The court then granted summary judgment to Tyco on all of those counterclaims. *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, No. 2:07-cv-1299 (D.N.J. Jan. 18, 2013).

The district court first rejected Mutual's claim that Tyco's section 271(e)(2)(A) infringement claim constituted sham litigation that subjected Tyco to antitrust liability for using illegitimate means to keep the product of its competitor, Mutual, off the market. The court noted that the dispute over infringement turned on the specific surface area limitation. Mutual claimed that the specific surface area of its generic product was 2.2 m^2/g and thus outside the range of 0.65 to 1.1 m^2/g claimed in the '954 patent. The evidence showed, however, that in testing its

proposed ANDA product, Mutual had used an outgassing temperature of 40°C, while Tyco had used an outgassing temperature of 105°C in its tests of the product. Because of that difference in temperatures used during the measurement process, the court concluded that it was reasonable for Tyco to proceed with its infringement action.

The district court also rejected Mutual's argument that no reasonable litigant could have expected Tyco's patents to withstand a validity challenge. The court reasoned that, given the presumption of validity and the clear-and-convincing evidence standard for proving invalidity, Mutual had failed "to submit evidence sufficient to demonstrate a material factual question about whether Plaintiffs objectively had a reasonable basis to believe that they had a *chance* to succeed." *Tyco*, No. 2:07-cv-1299, slip op. at 9 (D.N.J. Jan. 18, 2013) (emphasis in original).

The district court next rejected Mutual's claim that Tyco's citizen petition was a sham. The court reasoned that Mutual had put forward an inadequate legal theory because, according to the court, antitrust liability for sham claims "is expressly limited to litigation" and therefore does not apply to conduct such as the filing of an administrative petition. The court also found that Mutual had failed to put forward evidence that would allow the inference that the citizen petition was an attempt to interfere directly with the business relationships of a competitor.

Finally, the district court rejected Mutual's claim that Tyco was subject to antitrust liability because its action was the product of fraud within the meaning of the Supreme Court's decision in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). The court found that Mutual's evidence supported two factual assertions: (1) that Tyco had read the relevant patents' prosecution histories and (2) that Tyco knew of

the "Memo for the Record," which documented a 1984 teleconference between Sandoz and the FDA during which an FDA doctor told Sandoz that temazepam doses from 5 to 15 mg were recommended in Great Britain for the elderly. That evidence, according to the district court, "at most . . . supports the inference that Plaintiffs were aware that relevant prior art existed that could impact the validity or enforceability of the patents." According to the district court, however, that was "a far cry . . . from demonstrating that [Tyco] knew that Sandoz had engaged in a deliberately planned and carefully executed scheme to defraud the Patent Office." Mutual subsequently took this appeal from the district court's summary judgment order.

II

1. A party is ordinarily exempt from antitrust liability for bringing a lawsuit against a competitor. That principle is known as "*Noerr-Pennington* immunity," because it originated with the Supreme Court's decisions in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). There is a recognized exception to *Noerr-Pennington* immunity for "sham litigation," which the Supreme Court has defined as litigation that (1) is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" (the objective element), and (2) is motivated by a desire "to interfere *directly* with the business relationships of a competitor" (the subjective element). *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) ("*PRE*").

On appeal, Mutual asserts that there is a disputed issue of fact concerning whether Tyco's infringement suit was "objectively baseless" so as to fall within the sham-litigation exception to *Noerr-Pennington* immunity. According to Mutual, the section 271(e)(2)(A) infringe-

ment claim rejected by this court in *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), is legally and factually indistinguishable from Tyco's claim. In *Elan*, we held that an ANDA that recited a drug's specific surface area falling outside the range claimed in the relevant patents could not infringe those patents under section 271(e)(2)(A). Despite the patent owner's argument that the generic manufacturer had not specified a validated test protocol in its ANDA to measure specific surface area, we found that the only drug the generic manufacturer could legally produce under the ANDA was a drug that does not infringe. *See id.* at 1248-50.

Mutual's argument, which is based on *Elan*, ignores other decisions of this court, and language in *Elan* itself, that could give a patentee in Tyco's position a reasonable expectation of a favorable outcome even though the generic manufacturer's ANDA application describes a generic drug with characteristics that take it outside the patent's claims. The question addressed in *Elan* and similar cases is whether the product that the ANDA applicant will likely market if its application is approved will infringe. *Elan*, 212 F.3d at 1248. That can occur in spite of the ANDA specification if, for example, the ANDA is based on faulty testing or screening procedures.

In *Bayer AG v. Biovail Corp.*, 279 F.3d 1340 (Fed. Cir. 2002), this court addressed infringement, under section 271(e)(2)(A), of the same patent at issue in *Elan*, by the same generic drug at issue in *Elan*, but for a different dose of that drug. Although the legal and factual issues in *Biovail* were similar to those in *Elan*, we found that the factual evidence proffered in *Biovail* called for a different result. In *Elan*, neither party submitted evidence that the commercial ANDA product would contain active ingredients falling within the patent's specific surface area range and outside the range specified in the ANDA. In *Biovail*, however, the patent owners "introduced evi-

dence of actual infringement by a commercial tablet made under the specifications of an allegedly identical ANDA." *Biovail*, 279 F.3d at 1346. That evidence "raise[d] a legitimate question" under section 271(e)(2)(A) whether the generic manufacturer would "make a . . . product that literally infringes Bayer's . . . patent upon approval of the ANDA." *Id.* at 1346-47.

Even before *Elan*, this court held in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), that section 271(e)(2) "requires an infringement inquiry focused on what is likely to be sold following FDA approval," an inquiry that "must be based on all of the relevant evidence *including* the ANDA." *Id.* at 1568 (emphasis added). Nothing in *Elan* is contrary to that holding. *See Elan*, 212 F.3d at 1248-49 (in considering infringement under section 271(e)(2)(A), "it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder"). We found it significant in *Elan* that the patent owner did not allege that the generic manufacturer's commercial product would infringe in spite of the ANDA specification. *See* 212 F.3d at 1249 & n.6. Similarly, in *Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002), another post-*Elan* case, we stated that "other evidence may directly contradict the clear representations of the ANDA and create a dispute of material fact regarding the identity of the compound that is likely to be sold following FDA approval." *Id.* at 1373.

Therefore, we agree with Tyco that it is 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.

That does not end our inquiry into whether Tyco's section 271(e)(2)(A) infringement claim was objectively baseless, however. Tyco's infringement claim is based on its theory that Mutual's use of 40°C as the outgassing temperature was inappropriate and that 105°C—the temperature at which Tyco and Sandoz tested Restoril—should have been used instead. The parties do not dispute that the specific surface area of Mutual's temazepam falls within the infringing range when the outgassing temperature is set at 105°C. However, expert testimony and other evidence, including images from a scanning electron microscope, suggest that exposing Mutual's temazepam to a temperature of 105°C physically alters the temazepam material itself, resulting in larger temazepam particles and decreased specific surface area.

In addition, testimony from Mutual's expert tends to establish that lower outgassing temperatures result in measurements that underestimate specific surface area. If that is true, the difference between the actual specific surface area of the tested product and the infringing range would actually be greater than indicated by the measurement of the tested product obtained at a lower outgassing temperature. According to Mutual's expert, increasing the outgassing temperature merely serves to accelerate the removal of contaminants from the surface of the tested material. If full outgassing is not achieved, the measured specific surface area may be reduced, because less surface area is available for the test gas to adsorb to. It therefore stands to reason that, barring physical alteration to Mutual's temazepam, Tyco's demand that Mutual increase the outgassing temperature would not decrease—but would potentially increase—the specific surface area measurement due to the removal of more surface contaminants. Barring physical alteration of the material, an increased outgassing temperature would thus make it more likely that Mutual's commercial product would measure outside of the infringing range,

not more likely that it would measure within the infringing range, as Tyco suggests. Tyco's theory of why Mutual's as-marketed ANDA product will infringe therefore appears to be based on a theory contrary to what the underlying scientific principles dictate. Put simply, even if Mutual's specific surface area measurements are wrong, they would appear to be wrong in a way that does not help Tyco.

Based on the evidence of record and this analysis, we conclude that further inquiry is needed into the effect of the outgassing temperature on the specific surface area of Mutual's generic product. We leave it to the district court to determine whether that inquiry can be performed within the context of a summary judgment proceeding or requires a trial. Accordingly, on remand, the district court should determine whether Tyco's factual theory of infringement is objectively baseless. If necessary, the court should then determine whether Mutual has shown that the subjective element of the sham-litigation test has been satisfied.

2. Mutual next argues that the district court erred by granting summary judgment for Tyco with respect to Mutual's sham-litigation claim because Tyco lacked a reasonable prospect of success in defending the validity of its patents. On that issue, we uphold the district court's ruling.

Given the presumption of patent validity and the burden on the patent challenger to prove invalidity by clear and convincing evidence, it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation. Only if the exacting standards of *PRE* are satisfied will the patentee lose its *Noerr-Pennington* immunity in that setting. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368-69 (Fed. Cir. 1998) ("Conduct prohibited under

antitrust law includes bringing suit to enforce a patent with knowledge that the patent is invalid or not infringed . . . . In such events the antitrust immunity of [*Noerr* and *Pennington*] does not apply to those who seek redress through judicial process. . . . [A]bsent the PRE criteria, the patentee must have the right of enforcement of a duly granted patent . . . .").

Mutual contends that a reasonable litigant in Tyco's position would have known that the asserted patents would be found invalid for obviousness because the only difference between the prior-art 15 mg Restoril capsule and the claimed capsules is the 7.5 mg dose of temazepam. That 7.5 mg dose, Mutual asserts, was clearly disclosed in the prior art BNF reference and the Memo for the Record, both of which disclosed temazepam doses in the 5 to 15 mg range. Mutual contends that a reasonable litigant would not have sought to defend against an invalidity challenge because the claimed invention fell within a range disclosed in the prior art, giving rise to a presumption of obviousness.

Mutual's argument is both legally and factually flawed. When 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. *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737-38 (Fed. Cir. 2013) ("[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations."); *Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1322 (Fed. Cir. 2013) ("After an accused infringer has put forth a prima facie case of invalidity, the burden of *production* shifts to the patent owner to produce sufficient rebuttal

evidence to prove entitlement to an earlier invention date. . . . The ultimate burden of proving invalidity by clear and convincing evidence—i.e., the burden of *persuasion*—however, remains with the accused infringer."); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1352-53 (Fed. Cir. 2013).

Mutual also ignores the evidence Tyco offered to meet its burden of production. Tyco argued that the BNF reference did not teach a dose in the 5 to 15 mg range because it did not provide any efficacy evidence for such a dose. *See Tyco*, 642 F.3d at 1373-74. Mutual does not address whether that argument was objectively baseless. Likewise, Tyco argued that several prior-art references taught away from the 7.5 mg dose because such a low dose was thought to be ineffective. *See id.* at 1374-76. For example, Tyco argued that one prior-art reference taught away from a 10 mg dose because it reduced sleep onset latency but did not increase total sleep time. *See id.* at 1374. Tyco's teaching away argument was not objectively baseless, nor does Mutual suggest on appeal that it was.

We conclude that Mutual has not met its burden to establish that Tyco's validity arguments were objectively baseless, even though those arguments were ultimately unsuccessful. *See PRE*, 508 U.S. at 60 n.5 ("[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.'"). We therefore affirm the district court's grant of summary judgment for Tyco with respect to the invalidity portion of Mutual's sham-litigation counterclaim.

3. Mutual next argues that the district court erred by granting summary judgment for Tyco with respect to Mutual's claim that Tyco's citizen petition to the FDA was

a sham that stripped Tyco of its *Noerr-Pennington* immunity. Because the district court applied the wrong legal standard and because disputed issues of material fact remain, we vacate that portion of the district court's judgment.

The district court concluded that the sham exception to *Noerr-Pennington* immunity and the test set forth in *PRE* are "expressly limited to litigation" and that Mutual had therefore failed to set forth a legal standard applicable to sham administrative petitions. *PRE*'s two-part test, however, is not limited to court litigation; it has been applied to administrative petitions, including FDA citizen petitions. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999) (applying *PRE* to petitions to the International Trade Commission and the Department of Commerce); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 686 (2d Cir. 2009) (*PRE* applies to FDA citizen petitions); *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *22 (D.N.J. Sept. 5, 2013) (FDA citizen petition); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 n.11 (E.D. Pa. 2011) (collecting cases and noting that "every court that has considered whether a petition to the FDA is entitled to Noerr-Pennington immunity has applied the PRE test").

Tyco does not defend the district court's ruling that *PRE*'s two-part test is inapplicable to Tyco's citizen petition. Instead, Tyco argues that any error in that regard was inconsequential because it was not unreasonable for Tyco to file the citizen petition. We conclude, however, that there are disputed issues of fact that preclude summary judgment with respect to whether the citizen petition was objectively baseless.

Particularly probative of whether the citizen petition was reasonable is the FDA's response, which denied the petition in terms indicating that, in the FDA's view, it was wholly without merit. The FDA found that Tyco had

"provided no evidence from clinical trials, pharmacokinetic studies, bioequivalence testing, or any other source . . . . Instead the petition relies entirely on uncorroborated generalities and theoretical speculation to support its critical point." The FDA also concluded that the petition "fail[ed] to provide any evidence at all about the existence, extent, or significance of surface area variations for any other generic temazepam products at any dosage strength." Furthermore, the FDA noted that it has not required generic manufacturers to demonstrate additional bioequivalence criteria except in "very rare instances," all of which have involved "complex extended-release or otherwise modified-release products for which there was a known and clinically significant connection between release characteristics and clinical performance" and that "[t]emazepam is not such a drug."

Mutual's expert reviewed the citizen petition and concluded that "Tyco did not have a scientific basis to conclude that Mutual's product would not be bioequivalent to Restoril." She found that some of the criteria Tyco proposed had "limited to no application in bioequivalence studies" because they "have no relationship to the process of drug absorption." The testimony of Mutual's expert and the FDA's response to the citizen petition are sufficient evidence from which a reasonable finder of fact could conclude that Tyco's citizen petition was objectively baseless.

With respect to the subjective element of the *PRE* test, the district court found that Mutual did not produce any evidence "to support an inference that [the citizen petition] was an attempt to interfere directly with the business relationships of a competitor." Mutual, however, produced evidence that the citizen petition was filed just one day after the district court granted Mutual summary judgment of noninfringement—an event that results in lifting the automatic stay of the FDA's approval of the ANDA, 21 U.S.C. § 355(j)(5)(B)(iii)(I)—and just one week

before the end of the 30-month stay period. According to Mutual, filing the citizen petition at that late date caused the FDA to delay the approval of Mutual's ANDA, and thus resulted in a further period of market exclusivity for Tyco.

Tyco argues that anticompetitive intent cannot be inferred from the timing of the citizen petition because a protective order was in effect that limited Tyco's ability to disclose information about Mutual's ANDA product. According to Tyco, it was unable to file the citizen petition until Mutual made representations in open court about the ANDA product and its increased surface area. Those representations, according to Tyco, had the effect of releasing Tyco from its confidentiality obligations. Specifically, Tyco points to representations Mutual made in open court on July 16, 2009, that the proposed ANDA product was a "different product" from Restoril and that its specific surface area was more than twice that of Restoril. That information about Mutual's ANDA product, however, had already been publicly disclosed on the district court's docket as early as January 22, 2008. Tyco's argument that it had to wait until after July 16, 2009, to file the citizen petition is therefore unpersuasive.

Mutual also points to an email from Tyco's research and development department to Tyco's vice president of intellectual property. That email assessed the strength of the temazepam patents in aid of Tyco's decision whether to purchase those patents from Sandoz. In the email, the research and development department stated that a temazepam formulation that was bioequivalent to Restoril could be made that would have a particle size and specific surface area different from Restoril. The email thus constitutes evidence that could support a finding that Tyco knew the theory in its citizen petition lacked merit.

The timing of the citizen petition and the email are sufficient evidence from which a reasonable finder of fact could determine that Mutual had satisfied the subjective element necessary to show that Tyco's citizen petition was a sham. It was therefore error for the district court to grant summary judgment against Mutual on the citizen petition issue.

There remains an open issue, however, as to whether the filing of the citizen petition caused any antitrust injury to Mutual. In this court, neither party has pointed to anything in the record establishing that the citizen petition was the cause of a delay in the approval of the ANDA. In support of its contention that the FDA's approval was delayed "solely because of Tyco's petition," Mutual cites only the ANDA approval letter. The letter, however, does not say anything about a delay due to the citizen petition. On remand, the district court should determine whether Mutual suffered an anticompetitive harm in the form of a delay in the approval of its ANDA due to the filing of Tyco's citizen petition with the FDA. Tyco would be entitled to summary judgment if there is no evidence that the citizen petition caused a delay in the approval of Mutual's ANDA.[1]

4. Mutual's final claim is that Sandoz fraudulently obtained the temazepam patents from the Patent and Trademark Office ("PTO") and that Tyco had knowledge of that fraud when it sought to enforce the patents against Mutual in this lawsuit. Asserting that Tyco was aware of the fraud, Mutual argues that under the Su-

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[1] The dissent states that the majority "effectively holds that Tyco violated the antitrust laws by filing its 'citizen petition.'" That is incorrect. We have made no finding of antitrust liability, but hold only that Mutual's evidence was sufficient to withstand Tyco's motion for summary judgment.

preme Court's decision in *Walker Process*, filing the suit stripped Tyco, as a patent holder, of its immunity from the antitrust laws. *See Walker Process*, 382 U.S. at 177 & n.5; *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068-69 (Fed. Cir. 1998).

Mutual contends that Sandoz committed fraud on the PTO by omitting information material to the patentability of temazepam at the 7.5 mg dosage level. First, Mutual alleges that Sandoz concealed the fact that the claimed invention used the same specific surface area and particle size as the prior-art high-dose version of Restoril. Sandoz disclosed that information to the FDA when seeking approval for Restoril, but allegedly redacted portions of the "FDA Approvable Letter" submitted to the PTO that would have revealed that information. Second, Mutual alleges that Sandoz knew about the use of temazepam doses in the 5-15 mg range in Great Britain for the elderly from its 1984 teleconference with the FDA, which was documented in the Memo for the Record. References to the Memo for the Record were also redacted from the version of the FDA Approvable Letter that Sandoz supplied to the PTO.

According to Mutual, Tyco had at least constructive knowledge of Sandoz's fraud because Tyco conducted a careful due-diligence review of the patents, their prosecution histories, and the record of correspondence with the FDA related to Restoril on multiple occasions, including once before acquiring the patents and once before filing this lawsuit. Mutual argues that a reasonable finder of fact could conclude that Mutual had at least constructive knowledge of Sandoz's alleged fraud because Tyco reviewed that record and because the record contained the Memo for the Record, the unredacted version of the FDA Approvable Letter, and the redacted version of that letter sent to the PTO.

The district court focused on the issue of Tyco's knowledge and found that there was insufficient evidence that Tyco knew at the time it initiated this suit that it was "seeking to enforce patents which had been procured by knowing and willful fraud." *Tyco*, No. 2:07-cv-1299, slip op. at 13 (D.N.J. Jan. 18, 2013). The district court determined that Mutual's evidence "at most . . . supports the inference that [Tyco was] aware that relevant prior art existed that could impact the validity or enforceability of the patents." *Id.* We agree with the district court.

The redacted FDA Approvable Letter submitted to the PTO was offered for the limited purpose of overcoming an obviousness rejection. The applicant referred to the Approvable Letter only to demonstrate that the 7.5 mg dose was effective in treating insomnia, which the applicant contended was unexpected in light of other prior art. The redactions were not focused on material related to the Memo for the Record or the characteristics of the prior-art high-dose Restoril. Instead, large sections of the letter irrelevant to the applicant's main point were removed, leaving just two pages of material from the original seven-page letter. That redacted material includes a passing reference to the November 29, 1984, teleconference that resulted in the Memo for the Record and a reference to an FDA recommendation for the specific surface area for 15 mg and 30 mg Restoril. A reasonable finder of fact could not conclude that Tyco had knowledge of any alleged fraud by Sandoz just because Tyco had reviewed the record and thereby presumably had knowledge of those redactions from the materials supplied to the PTO. Even under Tyco's proposed constructive-knowledge theory, the redaction evidence is insufficient.

Likewise, the fact that the record reviewed by Tyco included the Memo for the Record does not support an inference that Tyco had knowledge—constructive or otherwise—of Sandoz's alleged fraud, especially in light of Mutual's burden to show "no less than clear, convincing

proof of intentional fraud involving affirmative dishonesty." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). Mutual's evidence supports at most an inference that Tyco knew that its temazepam patents would be subject to a strong validity challenge. *See Nobelpharma, Inc.*, 141 F.3d at 1069 ("[A] distinction must be maintained between patents procured by 'deliberate fraud' and those rendered invalid or unenforceable for other reasons.").

Mutual argues that its ANDA notice letter put Tyco on notice that the examiner had originally allowed the temazepam patents based on a mistaken belief that the claimed specific surface area and particle size were novel. To support that argument, Mutual points to a single sentence in its notice letter that refers to the examiner's reasons for allowance. The notice letter did not claim, however, that the examiner's statement was based on a mistake, that Mutual was challenging the validity of the temazepam patents, or that the patents were obtained by fraud. Accordingly, the notice letter is not probative evidence that Tyco had knowledge of Sandoz's alleged fraud. We therefore affirm the judgment of the district court with respect to Mutual's *Walker Process* counterclaim.

In summary, we affirm the judgment of the district court with respect to Mutual's claim that Tyco's assertion of the validity of its patents was a sham and with respect to Mutual's *Walker Process* fraud claim. We vacate the summary judgment that Tyco's infringement claims were not a sham and remand for further proceedings on that issue, with particular attention to the effect of the differences in outgassing temperatures on the specific surface area of Mutual's product. We also vacate the summary judgment that Tyco's citizen petition to the FDA was not a sham and remand for further proceedings, including a determination as to whether the citizen petition caused

any injury to Mutual in the form of a delay in the approval of Mutual's ANDA.

Each party shall bear its own costs for this appeal.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

TYCO HEALTHCARE GROUP LP AND MALLINCKRODT INC.,
Plaintiffs-Appellees,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC. AND UNITED RESEARCH LABORATORIES, INC.,
Defendants-Appellants.

2013-1386

NEWMAN, *Circuit Judge, dissenting.*

With its reversal of the district court's summary judgment dismissing Mutual's antitrust counterclaims, this court now creates several new grounds of antitrust liability. The panel majority holds that antitrust issues are raised by Tyco's Hatch-Waxman suit, although the suit is for infringement of presumptively valid patents asserted against a product whose ANDA and Paragraph IV Certification constituted a technical act of infringement under 35 U.S.C. §271(e). The constitutional right to petition government, as well as the patent right to exclude, does not dissipate between competitors.

My colleagues search for a Sherman Act violation in the evidence concerning how surface area measurement is affected by outgassing temperature. Such an issue does

not convert routine patent litigation into an antitrust cause. And by remanding for determination of antitrust injury based on Tyco's report to the FDA, this court holds that such communication can violate antitrust law.

Tyco's Hatch-Waxman litigation and Tyco's report to the FDA are in accordance with law and the Constitution. They do not raise Sherman Act issues. From the court's conversion of routine patent litigation into antitrust violation, I respectfully dissent.

DISCUSSION

The district court correctly held that this case did not raise antitrust issues, and summarily dismissed Mutual's antitrust counterclaims. Although Tyco lost on the merits, its Hatch-Waxman suit was not "sham." Enforcement of a presumptively valid patent against a product that infringes by statute cannot be deemed objectively baseless. The district court held that the criteria were not met, criteria whereby litigation is deemed "sham" when "'no reasonable litigant could realistically expect success on the merits'" and there was no "probable cause to initiate suit." *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, No. 2:07-cv-1299, slip op. at 5, 6 (D.N.J. Jan. 18, 2013) (quoting and citing *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* [hereinafter *PRE*], 508 U.S. 49, 60-62 (1993)).

The filing of a Paragraph IV Certification with an Abbreviated New Drug Application (ANDA) in and of itself constitutes probable cause to initiate suit, *see id.*, for the Hatch-Waxman statute authorizes the filing of an infringement suit in response to a Paragraph IV filing. It is also plain that Tyco had the right to communicate with the FDA concerning public information on matters within the agency's authority and responsibility without incurring antitrust liability.

The panel majority inserts a strong antitrust presence into routine patent litigation, adding the potential of antitrust penalties for patent enforcement. Recently the Supreme Court reviewed a case where this court imported antitrust criteria into patent litigation, in the context of attorney fee awards under 35 U.S.C. §285; the Court explained the antitrust view of "sham" litigation:

> We crafted the *Noerr–Pennington* doctrine—and carved out only a narrow exception for "sham" litigation—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances. But to the extent that patent suits are similarly protected as acts of petitioning, it is not clear why the shifting of fees in an "exceptional" case would diminish that right.

Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749, 1757-58 (2014). The Court referred to the chilling effect of the threat of antitrust liability:

> The threat of antitrust liability (and the attendant treble damages, 15 U.S.C. §15) far more significantly chills the exercise of the right to petition than does the mere shifting of attorney's fees. In the *Noerr–Pennington* context, defendants seek immunity from a judicial declaration that their filing of a lawsuit was actually unlawful; here, they seek immunity from a far less onerous declaration that they should bear the costs of that lawsuit in exceptional cases.

Id. My colleagues again intermingle antitrust and patent issues, distorting the balance stated in *Simpson v. Union Oil Co., of California*, 377 U.S. 13, 24 (1964), that the patent laws "are *in pari materia* with the antitrust laws and modify them *pro tanto*." The panel majority improperly inserts antitrust issues into the issues of infringe-

ment, validity, and communication to the government, contravening precedent and the Constitution.

A. Infringement

Tyco filed this Hatch-Waxman suit in response to Mutual's Paragraph IV Certification for its generic counterpart to Tyco's patented drug Restoril®. The district court granted summary judgment on the antitrust counterclaims, applying the Court's exhortation to "'resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation.'" *Tyco*, No. 2:07-cv-1299, slip op. at 8 (quoting *PRE*, 508 U.S. at 60 n.5).

The basis for Tyco's infringement suit was Mutual's challenge to Tyco's patents in accordance with the Hatch-Waxman Act. The panel majority acknowledges that "[t]he parties do not dispute that the specific surface area of Mutual's temazepam falls within the infringing range when the outgassing temperature is set at 105ºC." Maj. Op. at 11. Nonetheless, the majority revives the antitrust counterclaim that the infringement suit was "objectively baseless," and remands for "further inquiry . . . into the effect of the outgassing temperature on the specific surface area of Mutual's generic product." *Id.* at 12. The panel majority orders the district court to make findings, if need be with additional trial proceedings, stating that this information is needed for the court to determine whether this Hatch-Waxman suit violates antitrust law as "sham" litigation. *Id.*

The purpose of this remand is not to elucidate the question of infringement, for that issue was finally resolved. Instead, my colleagues seek new findings and authorize further trial, now to provide evidence of antitrust violation. While the difference in the measured surface area was the basis for the district court's holding

of non-infringement, the role of outgassing temperature in surface area measurement is not antitrust fodder. Here, Mutual is seeking ANDA approval for a product that is required to be identical to Tyco's FDA-approved product in order to rely on that product's data of safety and efficacy. The panel majority focuses on asserted "sham" litigation in its antitrust "inquiry into whether Tyco's §271(e)(2)(A) infringement claim was objectively baseless." *Id.* at 11. However, on Mutual's representation that its product meets the ANDA requirements, accompanied by a Paragraph IV Certification challenging Tyco's patent, a Hatch-Waxman infringement suit in accordance with §271(e)(2)(A) is not "sham." The district court correctly so held.

The panel majority's curiosity as to the scientific effect of changes in outgassing temperature on the measurement of surface area is neither appropriate appellate process, nor a matter for invoking the Sherman Act. *See PRE*, 508 U.S. at 62 ("The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation."). As this court reiterated in *FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 938 (Fed. Cir. 1995), "[t]he [Supreme] Court requires an inquiry into the reasonableness of the antitrust defendant's litigation when filed." Despite clear precedent that any question of "sham" litigation is decided as of when the complaint is filed, the panel majority remands for trial and possibly new evidence that might support the majority's argument that Tyco misunderstood the role of temperature in outgassing, and that this is evidence of antitrust violation in the filing of this Hatch-Waxman suit.

This court errs in converting this routine patent infringement case into an antitrust cause.

B. Validity

Mutual also argued in the district court that Tyco should have known that it would not succeed in defending the validity of its patents. The district court correctly dismissed this argument. *Tyco*, No. 2:07-cv-1299, slip op. at 9. The presumption of validity of a duly granted patent negates ruling that the routine defense of a patent's validity constitutes "sham" litigation.

Although the panel majority recites the presumption of validity and the placement of the burden of proof, the majority introduces a new concept of antitrust liability. The majority now creates a "burden of production" whereby the patent owner must come forward with affirmative evidence of validity, such as of "teaching away" or "unexpected results" or "other pertinent secondary considerations," whereby if this burden of production is not met with "an argument that is not objectively baseless" then the patentee becomes a violator of antitrust law. Maj. Op. at 13-14.

Thus the panel majority creates another new antitrust dimension of patent litigation, whereby failure to meet some general "burden of production" converts the defense of one's patent into a ground of antitrust liability. Although the panel majority finds that in this case Tyco's "teaching away argument was not objectively baseless, nor does Mutual suggest on appeal that it was," *id.* at 13-14, the majority's premise is that if this criterion were not met, Tyco could have violated the Sherman Act.

Although this unprecedented new ground of antitrust liability is not clearly developed, the implication is only too clear. This court holds that a patentee's validity arguments are subject to routine consideration not only for their effect on the validity debate, but for their strength on Sherman Act criteria. Heretofore, patent validity was not of antitrust interest unless the patent

was obtained by fraud. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). The district court referred to "the presumption of validity of an issued patent" and held that the Tyco patents were not obtained by fraud. *Tyco*, No. 2:07-cv-1299, slip op. at 9, 12. The court held that the Sherman Act was not here invoked.

The panel majority now transplants the antitrust criteria of "sham" litigation as set forth in *PRE* into routine patent validity litigation, adding a *de facto* adverse inference if the patentee chooses to rely on the presumption of validity and does not meet my colleagues' newly contrived antitrust standard of "burden of production." Maj. Op. at 13-14. My colleagues again import the "chilling effect" of antitrust litigation, *Octane Fitness*, 134 S. Ct. at 1757, into routine patent debates.

This further insertion of antitrust issues into patent cases is as unnecessary as the court's reasoning is unclear. The only thing that is clear is that it will be the rare patent suit that will not include assertions of Sherman Act violation patterned on the court's theories today. So dramatic an enlargement of patent litigation should not be casually made, even in dictum.

C. The Citizen Petition

After Tyco lost its infringement case, it informed the FDA of Mutual's successful position that the generic product is not the same as the Tyco patented product. Tyco proposed to the FDA that additional tests should be required of Mutual's assertedly different product, and that Mutual should not be permitted to rely on data for the Tyco product.

Mutual's counterclaim charged that Tyco's communication to the FDA violated the antitrust laws. My colleagues state that "a reasonable finder of fact could

conclude that Tyco's citizen petition was objectively baseless," Maj. Op. at 16, and remand to the district court for determination of antitrust injury. The panel majority misstates that the Tyco petition is "seeking to bar Mutual from obtaining FDA permission to market its generic version of one of Tyco's drugs." *Id.* at 2. The petition communicated to the FDA the public information that the Mutual generic product is not the same as the FDA-approved Tyco product. An accurate communication cannot be an antitrust violation, even if it relates to competitors, as firmly established by *Noerr-Pennington*.

Nonetheless, this court remands for determination of antitrust injury flowing from the filing of this petition, an action effectively requiring the predicate determination of violation of antitrust law.[1] *Id.* at 18 ("On remand, the district court should determine whether Mutual suffered an anticompetitive harm in the form of a delay in the approval of its ANDA due to the filing of Tyco's citizen petition with the FDA."). Antitrust violation is a prerequisite to determination of antitrust injury. *See, e.g.*, *J. Truett Payne Co., Inc. v. Chrysler Motors Corp.*, 451 U.S.

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[1] The panel majority, responding to this dissent, protests that it has not ruled that Tyco's filing of the citizen petition is "effectively" an antitrust violation, even as the majority remands for determination of antitrust injury. The law is clear that antitrust violation must exist before consideration of antitrust injury becomes applicable. *See*, *Atl. Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 342 (1990) ("The purpose of the antitrust injury requirement . . . . ensures that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place . . . ."). Thus my colleagues "effectively" find antitrust violation in remanding for determination of antitrust injury.

557, 568 (1981) ("If the court determines on remand that respondent did violate the [antitrust statute], the court should then consider the sufficiency of petitioner's evidence of injury in light of the cases discussed above.").

No antitrust law was violated by Tyco's communication to the FDA. The FDA is charged with establishing and securing drug safety and efficacy, for a new drug and for its generic counterparts. There can be no doubt as to a citizen's right to communicate with the government on matters of concern. "The right of petition is one of the freedoms protected by the Bill of Rights, and we cannot, of course, lightly impute to Congress an intent to invade these freedoms." *E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 138 (1961). Such right is not eliminated when the petitioner is in a competitive relationship.

The majority protests that it is not finding antitrust liability for Tyco's petition, but only that "Mutual's evidence was sufficient to withstand Tyco's motion for summary judgment." Maj. Op. at 18 n.1. It is plain that Tyco had the right to communicate with the FDA concerning this matter within the agency's authority and responsibility. The majority's remand for determination of antitrust injury is necessarily premised on the position that the communication was contrary to antitrust law. *Id.* at 18 ("There remains an open issue, however, as to whether the filing of the citizen petition caused any antitrust injury to Mutual.").

The Court has reminded that "[t]hose who petition government for redress are generally immune from antitrust liability," *PRE*, 508 U.S. at 56, although competitors may be affected, *see Noerr Motor Freight*, 365 U.S. at 139; *United Mine Workers v. Pennington*, 381 U.S. 657, 669 (1965). My colleagues offer the archetype for failing to "avoid chilling the exercise of the First Amendment right

to petition the government for redress of grievances" with the imposition of this antitrust liability. *Cf. Octane Fitness*, 134 S. Ct. at 1757.

CONCLUSION

The intrusion of antitrust issues into routine patent cases has been controlled in precedent. *See FilmTec*, 67 F.3d at 938 ("As noted, the Supreme Court has forbidden us to equate loss on the merits with objective unreasonableness."). My colleagues now hold otherwise, although the nation's history of innovation has been built on the balanced foundation that:

> The patent and antitrust laws are complementary, the patent system serving to encourage invention and the bringing of new products to market by adjusting investment-based risk, and the antitrust laws serving to foster industrial competition.

Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1362 (Fed. Cir. 1999).

The court's rulings today are contrary to law, precedent, and the Constitution. I respectfully dissent.