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ENFORCEMENT OF PATENT RIGHTS: EXPANDING THE POTENTIAL FOR PATENT OWNERS TO FACE ANTITRUST LIABILITY

*Angela Oliver**

I. INTRODUCTION

IN *Tyco Healthcare Group v. Mutual Pharmaceutical*, the U.S. Court of Appeals for the Federal Circuit broadened the avenues by which patent owners may be found liable under antitrust laws when attempting to enforce their patent rights against competitors.¹ Although the Federal Circuit addressed four antitrust counterclaims by a patent infringement defendant, this Note argues that through two of those counterclaims the court improperly burdens patent owners who are attempting to enforce their patents against infringing competitors.

II. FACTUAL BACKGROUND

Tyco Healthcare Group LP (“Tyco”) owns patents on the formulations and uses of the brand-name drug Restoril, generically entitled temazepam, which is used to treat insomnia.² Mutual Pharmaceutical Company, Inc. (“Mutual”) sought to produce a generic version of Restoril.³ Tyco’s patents claim a formulation of temazepam with a specific surface area (“SSA”) between 0.65 and 1.1 square meters per gram (m²/g).⁴ The patent claims do not recite a method to measure the SSA, but the specifications explain that measurements are made according to the standard Brunauer, Emmet, and Teller procedure (“B.E.T.”).⁵ To perform the measurement, the sample is outgassed (gas and vapor are removed from the surface of the sample).⁶ The particular outgassing tem-

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1. *See Tyco Healthcare Grp. v. Mut. Pharm. Co.*, 762 F.3d 1338 (Fed. Cir. 2014).

2. *Id.* at 1340.

3. *Id.* at 1341.

4. *Id.* at 1340.

5. *Id.*; *see generally*, Brunauer et al., *Adsorption of Gases in Multimolecular Layers*, 60 J. AM. CHEM. SOC. (ISSUE 2) 309 (1938) (describing the B.E.T. procedure).

6. *Tyco Healthcare*, 762 F.3d at 1340.

perature used may affect the final measurement—specifically, a temperature too high may physically alter the sample by softening or melting it.⁷ Tyco measured the SSA of Restoril with an outgassing temperature of 105 °C.⁸ Mutual, however, used an outgassing temperature of 40 °C when testing its generic version of temazepam.⁹ The parties agreed that the SSA of Mutual’s temazepam fell *within* the SSA range specified in Tyco’s patent claims when the outgassing temperature was 105 °C.¹⁰ However, evidence indicated that Mutual’s drug fell in the infringing range only because the high temperature (105 °C) physically altered the chemical, which decreased the SSA.¹¹ Also, Mutual’s expert claimed that a lower outgassing temperature underestimates SSA.¹² If true, this would have indicated that Mutual’s measurements (2.2 m²/g at 40 °C) point away from infringement; anything greater than 2.2 m²/g still falls outside the claimed range of 0.65 to 1.1 m²/g.¹³

Mutual provided the FDA an Abbreviated New Drug Application (“ANDA”) to gain approval for manufacturing and selling a generic version of temazepam.¹⁴ Mutual’s ANDA claimed the generic drug would have an SSA of at least 2.2 m²/g—far greater than the SSA claimed in Tyco’s patents (0.65–1.1 m²/g).¹⁵ Mutual certified to the FDA that its generic drug was not protected by any U.S. patents—indicating under “Paragraph IV” that the relevant existing patents were either invalid or that the generic product would not infringe.¹⁶ Mutual notified Tyco of its ANDA, as required,¹⁷ and explained that the generic drug would not infringe the Restoril patents because of the different SSA values.¹⁸

III. PROCEDURAL HISTORY

Upon learning of Mutual’s ANDA application, Tyco sued Mutual alleging the ANDA infringed Tyco’s patents under the special infringement provision of the Hatch-Waxman Act.¹⁹ Mutual counterclaimed alleging antitrust violations, which the district court stayed until it could resolve the infringement issue.²⁰ As required, the FDA stayed approval of the ANDA.²¹ In August 2009, the district court found Mutual did not infringe Tyco’s ’954 Patent (Tyco’s other patents had expired and were no longer at issue). The court held that because the SSA listed in the ANDA was

7. *Id.*

8. *Id.* at 1341.

9. *Id.* at 1342.

10. *Id.* at 1345.

11. *Id.*

12. *Id.* at 1345.

13. *Id.* at 1341, 1345.

14. *Id.* at 1341.

15. *Id.*

16. *Id.*; see 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

17. See 21 U.S.C. § 355(j)(2)(B).

18. *Tyco Healthcare*, 762 F.3d at 1341.

19. *Id.*; see 35 U.S.C. § 271(e)(2)(A) (2012).

20. *Tyco Healthcare*, 762 F.3d at 1341.

21. See *id.*; 21 U.S.C. § 355(j)(5)(B)(iii).

outside the range claimed in the '954 Patent, the ANDA “directly address[ed] the issue of infringement” and, thus, a “product manufactured to the ANDA’s specifications could not literally infringe the '954 Patent.”²²

The day after the non-infringement decision, Tyco filed a citizen petition with the FDA, urging the FDA to amend its criteria for determining the bioequivalence of proposed generic temazepam products to ensure those products were therapeutically equivalent to Restoril.²³ In its petition, Tyco advocated for the use of more extensive pharmacokinetic parameters to demonstrate bioequivalence.²⁴ In September 2009, with Tyco’s citizen suit still pending, the FDA approved Mutual’s ANDA, allowing Mutual to market its generic version of temazepam.²⁵ Five months later, the FDA denied Tyco’s citizen petition.²⁶

In May 2010, the district court granted summary judgment for Mutual on its invalidity counterclaim, finding Tyco’s '954 patent claims obvious.²⁷ The Federal Circuit affirmed.²⁸ The district court then lifted the stay of Mutual’s antitrust counterclaims and granted summary judgment to Tyco.²⁹

The court found Tyco did not violate any antitrust laws, noting that: (1) Tyco’s infringement claim was not a sham; (2) it was reasonable for Tyco to have expected its patent claims to withstand a validity challenge; (3) Tyco’s citizen petition was not a sham because it was an administrative petition rather than litigation; and (4) Tyco was not subject to antitrust liability for fraud.³⁰ In this case, Mutual appealed from that court’s summary judgment decision.³¹

IV. LEGAL LANDSCAPE

Patent owners may face antitrust liability under § 2 of the Sherman Act in certain circumstances.³² If found liable for antitrust violations, a party

22. Tyco Healthcare Grp. v. Mut. Pharm. Co., No. 07-1299 (SRC), 2009 WL 2422382, at *1-8 (D.N.J. Aug. 4, 2009).

23. *Tyco Healthcare*, 762 F.3d at 1341.

24. *Id.* at 1341-42.

25. *Id.* at 1342; see also U.S. Food and Drug Administration, *Drugs@FDA: FDA Approved Drug Products*, FDA.GOV, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=078581&DrugName=TEMAZEPAM&ActiveIngred=TEMAZEPAM&SponsorApplicant=MUTUAL%20PHARM&ProductMktStatus=1&goto=Search.DrugDetails (last visited Oct.23, 2014).

26. *Tyco Healthcare*, 762 F.3d at 1342; see also Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration, to David B. Clissold (February 2010), available at http://orangebookblog.typepad.com/files/fda_cder_to_hyman_phelps_and_mcnamara_p_c_-_petition_denial.pdf.

27. Tyco Healthcare Grp. v. Mut. Pharm. Co., No. 07-1299 (SRC), 2010 WL 1799457, at *9 (D.N.J. May 5, 2010).

28. Tyco Healthcare Grp. v. Mut. Pharm. Co., 642 F.3d 1370, 1377 (Fed. Cir. 2011).

29. *Tyco Healthcare*, 762 F.3d at 1342.

30. *Id.* at 1342-43.

31. *Id.* at 1340.

32. 15 U.S.C. § 2 (2012) (“Every person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce . . . shall be deemed guilty of a felony.”).

may owe treble damages.³³ *Noerr-Pennington* immunity traditionally protects parties from antitrust liability for filing suit against a competitor, based on the right rooted in the First Amendment to petition the government for redress.³⁴ A few limited exceptions to *Noerr-Pennington* immunity exist. Most notably, a party surrenders *Noerr-Pennington* immunity if its lawsuit is a sham.³⁵ In *Professional Real Estate Investors v. Columbia Pictures Industries* (“PRE”), the Supreme Court developed a two-part test to evaluate whether a lawsuit is a sham: (1) the action must be “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits”; and (2) if the objective prong is met, the litigation must conceal a subjective attempt “to interfere directly with the business relationships of a competitor.”³⁶ Under the first prong, the Court emphasized that “[t]he existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation.”³⁷ In *City of Columbia v. Omni Outdoor Advertising, Inc.*, the Court further explained the sham exception focuses on “us[ing] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.”³⁸ Courts determine whether a lawsuit is a sham based on the reasonableness of bringing the action at the time it was filed.³⁹

As applied to patent law, the Federal Circuit has held patent owners relinquish *Noerr-Pennington* immunity when they sue to enforce a patent they know is invalid or not infringed, with an anti-competitive intent.⁴⁰ Specifically, in *C.R. Bard, Inc. v. M3 Systems, Inc.*, the Federal Circuit extended *PRE*’s generic sham litigation test to determine whether a patent infringement suit constitutes sham litigation.⁴¹ Previously, some courts had used what is known as the *Handgards* line of cases from the Ninth Circuit when determining whether an attempt to enforce patent rights constituted an antitrust violation.⁴² Under the *Handgards* decisions, an antitrust plaintiff must prove by “clear and convincing evidence” that the patent owner brought the infringement suit in bad faith.⁴³ The

33. 15 U.S.C. § 15(a) (2012).

34. *See* E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 138 (1961) (protecting the right to petition government); *United Mine Workers v. Pennington*, 381 U.S. 657, 669–70 (1965) (extending *Noerr* immunity to petitioning executive officials); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510–11 (1972) (extending immunity to petitioning administrative agencies and courts).

35. *See* *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993) (“PRE”).

36. *Id.* at 60–61 (internal quotation marks omitted).

37. *Id.* at 62.

38. *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991).

39. *FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 938 (Fed. Cir. 1995).

40. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998).

41. *Id.* at 1368–69.

42. *Handgards v. Ethicon, Inc.*, 743 F.2d 1282 (9th Cir. 1984) (“Handgards II”); *Handgards v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979) (“Handgards I”); *see, e.g., Vaughn Co. v. Global Bio-Fuels Tech., LLC*, No. 1:12-CV-1292, 2013 WL 5755389, at *8 (N.D.N.Y. Oct. 23, 2013) (applying *Handgards II*).

43. *Handgards II*, 743 F.2d at 1294 (citation omitted).

Ninth Circuit's decisions indicated such a heightened burden of proof would comport with the statutory presumption of patent validity.⁴⁴

Furthermore, in the context of pharmaceutical patents, in *Glaxo, Inc. v. Novopharm, Ltd.*, the Federal Circuit indicated that § 271(e)(2) of the Hatch-Waxman Act focuses the infringement inquiry on “what is likely to be sold following FDA approval.”⁴⁵ Later in *Bayer AG v. Elan Pharmaceutical Research Corp.*, the Federal Circuit confirmed that a patent owner may reasonably expect a successful infringement outcome—even though an ANDA application describes a drug with a characteristic preventing the drug from infringing on the patent owner's claims—if the drug the generic company will likely *market* will infringe.⁴⁶

V. ANALYSIS

The Federal Circuit addressed each of Mutual's four antitrust counterclaims in turn. I address two of those counterclaims here. Regarding Mutual's claim that Tyco's infringement suit was sham litigation, the Federal Circuit found it “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.”⁴⁷ However, the court indicated that antitrust liability *would* attach if Tyco's factual theory of infringement—the effect of outgassing temperatures on the SSA—turned out to be objectively baseless and if Tyco's conduct satisfied the subjective prong of the *PRE* test.⁴⁸

Regarding Mutual's claim that Tyco's validity defense was a sham, the court briefly recognized the “presumption of patent validity” and the patent challenger's burden to prove invalidity by clear and convincing evidence.⁴⁹ However, the court then extended potential antitrust liability to a patent owner's validity defense if the defense satisfied the *PRE* test by allowing “a patentee's assertion of its patent in the face of a claim of invalidity” to be found “so unreasonable as to support a claim that the patentee has engaged in sham litigation.”⁵⁰ In this case, because Mutual failed to contest the evidence Tyco presented in defense of validity, the court found Tyco's validity defense to be legitimate.⁵¹ Thus, the court affirmed the summary judgment in favor of Tyco on the invalidity aspect of Mutual's sham litigation counterclaim.⁵²

44. See 35 U.S.C. § 282 (2012) (indicating the burden to prove invalidity rests on the party asserting invalidity); *Handgards I*, 601 F.2d at 996.

45. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

46. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000).

47. *Tyco Healthcare Grp. v. Mut. Pharm. Co.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014).

48. *Id.* at 1345.

49. *Id.*

50. *Id.* at 1345-46.

51. *Id.* at 1346-47.

52. *Id.* at 1347.

In her dissent, Judge Newman accused the majority of inserting “a strong antitrust presence into routine patent litigation” by “adding the potential of antitrust penalties for patent enforcement.”⁵³ She highlighted the Supreme Court’s language in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.* regarding the “chilling effect” of antitrust liability: “The threat of antitrust liability . . . far more significantly chills the exercise of the right to petition than does the mere shifting of attorney’s fees.”⁵⁴ Regarding potential antitrust liability for defending a patent’s validity, the dissent accused the majority of creating a new antitrust dimension—a patent owner must now provide affirmative evidence of validity of its patent, and if such evidence is “objectively baseless,” then the patent owner violates antitrust law.⁵⁵

Although the court applied the generic *PRE* test to the sham litigation claim and then extended the test to apply to a patent owner’s validity defense, the court failed to articulate the appropriate burden of proof to satisfy each prong of the *PRE* test. At least one district court has aptly noted this gap in the Federal Circuit’s jurisprudence.⁵⁶ Throughout its opinion, the court conveniently ignored the well-established *Handgards* line of cases, which does articulate an appropriate burden of proof. The Ninth Circuit’s decisions in *Handgards* espouse a more finessed approach to sham litigation in patent law by emphasizing the statutory presumption of patent validity by requiring that the “bad faith” of the patent owner be established by clear and convincing evidence.⁵⁷ The two approaches—*Handgards* and *PRE*—are not mutually exclusive. Some district courts have successfully blended the two tests by using the clear and convincing evidence standard of *Handgards* when applying the *PRE* test.⁵⁸ The Federal Circuit, meanwhile, has indicated in just one unpublished decision that a clear and convincing evidence standard applies to the objective prong of the *PRE* test.⁵⁹ In that case, because the objective prong was not satisfied, the court did not address the subjective prong—or the evidentiary standard required to satisfy that prong.⁶⁰ If the Federal Circuit in-

53. *Id.* at 1351 (Newman, J., dissenting).

54. *Id.* (internal quotation marks omitted).

55. *Id.* at 1353.

56. *In re Wellbutrin XL Antitrust Litig.*, Civil Action No. 08-2431, 2012 1657734, at *5 (E.D. Pa. May 11, 2012) (noting that “[t]he Federal Circuit has not clarified in a published decision whether the clear and convincing evidence standard required to show objective baselessness in preemption cases also applies in the sham exception context”).

57. *See* 35 U.S.C. § 282 (2012); *Handgards v. Ethicon, Inc.*, 601 F.2d 986, 996 (9th Cir. 1979).

58. *See, e.g.*, *Vaughan Co. v. Global Bio-Fuels Tech., LLC*, No. 1:12-CV-1292, 2013 WL 5755389, at *8 (N.D.N.Y. Oct. 23, 2013) (citing *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009), which applied the *PRE* test); *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 325 (D. Del. 2004) (referencing the *Handgards* decisions and requiring clear and convincing evidence to satisfy each prong of the *PRE* analysis).

59. *Mitek Surgical Prods., Inc. v. Arthrex, Inc.*, Nos. 99-1004, 99-1034, 2000 WL 217637, at *4 (Fed. Cir. Feb. 22, 2000) (stating whether a claim is objectively baseless must be proved by clear and convincing evidence).

60. *Id.*

tends to increase the potential for patent owners to face antitrust liability when attempting to enforce their patent rights, the Court should, at the very least, require an antitrust plaintiff to prove each *PRE* prong according to the high evidentiary burden found in *Handgards*—clear and convincing evidence.

Furthermore, even under the generic *PRE* approach, the Federal Circuit seemed to ignore *PRE*'s “probable cause” language—that the “existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation.”⁶¹ While the court made a point to recognize it is not unreasonable to bring suit if the as-marketed product is likely to infringe (which some evidence here seemed to indicate),⁶² the court apparently expected the patent owner to fully vet its theory of infringement before the court would find sufficient probable cause.⁶³ Given the requirement that a patent owner has just 45 days to file suit after receiving notice of a potentially infringing ANDA (or else the ANDA will become effective immediately),⁶⁴ the factual burden to show “probable cause” should be low—and certainly should be more lenient than what the court implied in this decision.

Now consider Tyco's alleged sham patent validity defense. Although the Federal Circuit found Tyco's evidence in this case sufficient to avoid antitrust liability, the court made it possible for patent owners to face liability if a court finds their evidence supporting the validity of their patents to be insufficient to some degree.⁶⁵ The court, however, claimed this possibility will be a “rare case.”⁶⁶ Nevertheless, this additional avenue for potential antitrust liability severely changes the stakes for patent owners seeking to enforce their patents. The consequences of insufficient validity evidence prior to this decision focused on the loss of patent rights—not the loss of rights *plus* antitrust liability with treble damages.⁶⁷

Ultimately, placing additional risk of antitrust liability on patent owners results in an unnecessary threat of punishment. For the rare case in which a patent owner brings a meritless action in bad faith, other remedies exist. First, an infringement defendant claiming bad faith on the part of the patent owner may find relief through state law malicious prosecution claims.⁶⁸ In fact, the Ninth Circuit specifically left open this possibility when it refused to make patent owners immune from such state claims.⁶⁹ Furthermore, the Supreme Court recently broadened the instances in which attorney fees can be awarded based on “exceptional”

61. See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* 508 U.S. 49, 62-63 (1993).

62. *Tyco Healthcare Grp. v. Mut Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014).

63. See *PRE*, 508 U.S. at 62.

64. 21 U.S.C. § 355(c)(3)(C) (2012).

65. *Tyco Healthcare*, 762 F.3d at 1345-46.

66. *Id.*

67. See *id.* at 1350-51, 1353 (Newman, J., dissenting).

68. *U.S. Aluminum Corp./Texas v. Alumax, Inc.*, 831 F.2d 878, 881 (9th Cir. 1987).

69. *Id.*

conduct by a patent owner.⁷⁰ The Court even noted that “a case presenting *either* subjective bad faith *or* exceptionally meritless claims may . . . warrant a fee award.”⁷¹ Additional antitrust punishment for attempting to enforce patent rights is excessive.

The Federal Circuit’s decision in *Tyco Healthcare* will result in increasingly complex patent litigation suits. An accused patent infringer now has a strong incentive to counterclaim with a Sherman Act violation at every opportunity—especially with treble damages on the line. Such a continual injection of antitrust principles into the historically distinct realm of patent law will continue to undermine confidence in patents, ultimately harming the “Progress of Science and useful Arts.”⁷²

70. *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014).

71. *Id.* at 1757 (emphasis added).

72. U.S. Const. art. I, § 8, cl. 8.