

A BUDDING THEORY OF WILLFUL PATENT INFRINGEMENT: ORANGE BOOKS, COLORED PILLS, AND GREENER VERDICTS

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ABSTRACT

The rules of engagement in the brand-name versus generic-drug war are rapidly changing. Brand-name manufacturers face increasing competition from Canadian manufacturers of generic drugs, online drug companies, and Wal-Mart® Super Centers deciding to cash in by turning a piece of the generic prescription drug business into a huge marketing campaign with offerings of generic drugs for four dollar prescriptions. Other discount drug providers are likely to follow suit in hopes of boosting customer traffic and sales of their generic drugs. Now, more than ever before, attorneys representing owners of pharmaceutical patents need to be creative with their damages theories to maximize recovery and help their clients recoup the investments in research and development necessary to bring new and innovative drugs to the marketplace. This article suggests a novel theory of willful infringement to assist a patent owner in recovering treble damages and attorneys' fees.

INTRODUCTION

¶1 Allegations of willful patent infringement frequently take center stage in patent litigation, offering treble damages² and attorneys' fees³ to patent owners eager to turn actual damages into a windfall. From a patent owner's perspective, the possibility of recovering treble damages

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² 35 U.S.C. § 284 (2006) (A "court may increase the damages up to three times the amount found or assessed.").

³ 35 U.S.C. § 285 (2006) ("The court in exceptional cases may award reasonable attorney fees to the prevailing party.").

and attorneys' fees may tip the scales in favor of enforcing its patent in an infringement lawsuit.

¶2 Do allegations of willfulness apply with equal force, or even apply at all, in the context of brand-name versus generic-drug litigation? The answer may depend on whether a party finds itself enforcing patents or defending against them. While patent owners attempted to assert willfulness allegations, generic-drug companies argued with some success that willfulness damages should not apply under the complex and conflicting wording of the Hatch-Waxman Act.⁴

¶3 More than two decades ago, Congress passed the Hatch-Waxman Act, which allowed generic-drug companies to obtain approval by the Food and Drug Administration ("FDA") to market generic drugs that were therapeutically equivalent to previously-approved drugs of brand-name manufacturers shown to be safe and effective. According to the approval process under the Hatch-Waxman Act, the generic company could rely on the safety and efficacy data submitted by the brand-name manufacturer to the FDA, which greatly expedited the approval process for generic companies.⁵ The authoritative reference for FDA-approved drugs, and any patents listed as covering those drugs, is referred to as the "Orange Book."⁶

¶4 Since the passage of the Hatch-Waxman Act, brand-name pharmaceutical companies and their generic competitors have clashed in courts, with each party simultaneously asserting different legal strategies in an attempt to leverage benefits provided them in the intricate and oftentimes contradictory language of the legislation. But, patent owners litigating in the hotly contested fights involving patent-protected pharmaceuticals and generic drugs failed to consider the "Orange Book" as a tool for pleading constructive notice of a patent and thereby acquiring an earlier date from which actual damages accrue—even

⁴ The Hatch-Waxman Act was passed in 1984. The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as 21 U.S.C. § 355 *et seq.* (2006), 35 U.S.C. § 156 (2006), and 35 U.S.C. § 271(e) (2006)).

⁵ Brand-name manufacturers may also seek approval under this abbreviated process set forth in the Hatch-Waxman Act.

⁶ The Orange Book includes certain information provided by the brand-name manufacturer, who is required to list all patent numbers and expiration dates for "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (2006).

though generic-drug manufacturers are obliged to consult the Orange Book. Furthermore, patent owners overlooked the potential for pleading the Orange Book as a basis of showing actual notice of a patent and, as a consequence, possibly proving an intentional violation of the statutory duty to consult the Orange Book, objectively reckless disregard of standards of commercial behavior under the Hatch-Waxman Act requiring a reasonable respect for the intellectual property rights listed in the Orange Book, and ultimately a case of willful infringement.

¶5 Willfulness based on Orange Book notice of a patent is no ordinary theory. Rather, this theory is one of first impression with a proverbial clean slate on which creative theories may be written. In its much-anticipated recent *en banc* decision on willful infringement,⁷ the Federal Circuit endorsed the view that left to district courts the opportunity to develop⁸ the law that governs the evidence necessary to prove willful infringement, and cited as one factor the “standards of commerce.”⁹ In the same decision, Circuit Judge Newman observed: “Industrial innovation would falter without the order that patent property contributes to the complexities of investment in technologic R & D and commercialization in a competitive marketplace. The loser would be not only the public, but also the nation’s economic vigor.”¹⁰

¶6 Without binding law to the contrary, and with support from this recent Federal Circuit decision, the possibility of pleading a new theory is appealing to lawyers serving clients who understandably want to maximize patent damages. After all, today’s patent damages may help to offset current operating expenses, underwrite tomorrow’s research budget, and add to future innovations for pioneering drugs.

¶7 Never in the history of pharmaceutical patent litigation has the need for treble damages and attorneys’ fees mattered as much as now. The 2007 survey published by the American Intellectual Property Law Association affirms what patent owners and attorneys knew all along: patent litigation is expensive.¹¹ Particularly when actual damages might

⁷ In re Seagate Tech., LLC, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*).

⁸ *Id.* at 1371, 1385.

⁹ *Id.* at 1371 n.5.

¹⁰ *Id.* at 1385 (Newman, J., concurring).

¹¹ The Law Practice Management Committee of the American Intellectual Property Law Association (AIPLA) conducts an economic survey every two years relating to, among other things, the costs of patent litigation. The most recent survey from July 2007 found that attorneys’ fees could top \$600,000 when \$1 million is at stake, while those fees could top \$2.5 million and even top \$5.0 million when the damages at issue are in excess of \$1 million and \$25 million, respectively. American Intellectual Prop. Law Ass’n, REPORT OF THE

be low, the possibility of treble damages and attorneys' fees is critical to a plaintiff's competitive edge.¹² Indeed, the cost of patent litigation drives pharmaceutical clients to demand agility from their patent counsel with creative legal pleading and an ability to introduce theories for augmenting recovery.

¶8 Will plaintiffs' attorneys nourish the emerging theories based on using the "Orange Book" to prove both notice of a patent and objective recklessness for purposes of actual damages and willfulness? Or will defense attorneys successfully quash such novel notice theories before the Federal Circuit?

¶9 Section I provides a background discussion on the law of willful infringement. Section II explores the statutory and regulatory schemes under which the Orange Book was created and became law pursuant to the Hatch-Waxman Act. Also, Section II constructs an analysis that might prove useful in asserting, or defending against, allegations that the Orange Book satisfies the notice requirement under the marking statute, notice sufficient to trigger willful infringement, and objective recklessness based on the deliberate failure to comply with a statutory duty or standards of fair commerce. Section III offers suggestions of how the novel Orange Book theory would apply to lawsuits brought under the Hatch-Waxman Act or traditional infringement actions.

I. WILLFUL INFRINGEMENT AND PATENT DAMAGES

¶10 In order to understand the risks of treble damages and attorneys' fees that may be awarded based on a finding of willfulness, one must understand the different ways a defendant may receive "notice" of an asserted patent. Indeed, the Federal Circuit draws a significant

ECONOMIC SURVEY 25–26 (2007). For an analysis of the rising costs of patent litigation, see Christopher A. Harkins, *Fending Off Paper Patents and Patent Trolls: A Novel "Cold Fusion" Defense Because Changing Times Demand It*, 17 ALB. L.J. SCI. & TECH. 407, 434–38 (2007) (discussing an AIPLA survey and arguing how costs of litigation are used by patent trolls asserting paper patents to extort a nuisance settlement, thereby resulting in social harm and crippling innovation; introducing a defense to combat paper patents and patent trolls, *id.* at 453–77); see also *View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000) ("A patent suit can be an expensive proposition.").

¹² For simplicity, the term "plaintiff" refers to patent owners suing for patent infringement or defending against a declaratory judgment action based on their cease-and-desist letter. The term "defendant" refers to a party accused of patent infringement and who is either being sued for patent infringement or is bringing a declaratory judgment action for non-infringement.

distinction between notice for purposes of proving simple infringement¹³ and recovering actual damages on the one hand, compared to notice for purposes of proving willful infringement and recovering enhanced damages on the other.¹⁴ Generally stated, actual damages are decreased when notice fails to meet the requirements of the marking statute under Section 287(a),¹⁵ while enhanced damages are denied when, under the totality-of-circumstances test, the defendant did not have notice sufficient to trigger a duty to investigate and avoid willful infringement.

¶11 In this section, Part A sets forth an overview of the totality of circumstances considered in assessing whether infringement was willful. Part B provides an analytical framework of the types of notice that courts recognized as invoking a defendant's duty to avoid willfully infringing a patent. Part C concludes this section with a discussion of the ways a plaintiff may prove notice in order to recover actual damages.

A. Willful Infringement and the "Totality of Circumstances"

¶12 While innocent parties may be liable for patent infringement,¹⁶ willful infringement does not lie based on "the simple fact of infringement."¹⁷ Instead, it requires culpability on the part of the

¹³ See *infra* note 16 and accompanying text (Strict liability for patent infringement does not depend on negligence or intent to harm, but is actionable simply based on the fact that an accused product or method infringes a patented invention).

¹⁴ See *supra* notes 2–3 (Remedies for willful infringement are founded on § 284 and § 285); see also *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1342 (Fed. Cir. 2004) (en banc).

¹⁵ 35 U.S.C. § 287(a) (2006).

¹⁶ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) ("Because patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted."); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1527 (Fed. Cir. 1995) (en banc) ("[I]ntent is not an element of direct infringement, whether literal or by equivalents . . . Infringement is, and should remain, a strict liability offense.").

¹⁷ *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1332 (Fed. Cir. 2004) ("There is no evidentiary presumption that every infringement is willful.").

infringer.¹⁸ Therefore, a finding of actual infringement is necessary but not sufficient to satisfy willfulness, which is a question of fact.¹⁹

1. A Brief Historical Perspective of Willfulness Prior to the Federal Circuit's *Seagate Technology* Decision

¶13 According to the U.S. Court of Appeals for the Federal Circuit in its 2004 decision in *Knorr-Bremse*, the duty to avoid infringing a known patent is fundamental to determining willful infringement.²⁰ Until recently, there was 24-year precedent, in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*,²¹ for the proposition that, where “a potential infringer has actual notice of another’s patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing.”²²

¶14 While *Underwater Devices* was cited as good law in the Federal Circuit’s *Knorr-Bremse*²³ decision in 2004, and even *EchoStar*²⁴ in 2006, the Federal Circuit’s 2007 decision, *In re Seagate Technology, LLC*, overruled the duty of “due care” as too akin to a negligence-like state of mind as shown in the next subpart.²⁵ However, the Federal Circuit in

¹⁸ *Knorr-Bremse*, 383 F.3d at 1342; *see also Seagate Tech.*, 497 F.3d at 1385 (Newman, J., concurring) (“The fundamental issue remains the reasonableness, or in turn the culpability, of commercial behavior that violates legally protected property rights.”).

¹⁹ *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1368 (Fed. Cir. 2006).

²⁰ *Knorr-Bremse*, 383 F.3d at 1345 (“[T]here continues to be ‘an affirmative duty of due care to avoid infringement of the known patent rights of others.’”) (citation omitted).

²¹ *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389 (Fed. Cir. 1983).

²² *Id.*

²³ *Knorr-Bremse*, 383 F.3d at 1343.

²⁴ *In re EchoStar Commc’ns Corp.*, 448 F.3d 1294, 1299 (Fed. Cir. 2006); *see also id.* at 1302 n.4 (“noting that an infringer may continue its infringement after notification of the patent by filing suit and that the infringer has a duty of due care to avoid infringement after such notification”) (citing *Crystal Semiconductor Corp. v. TriTech Microelectronics Int’l, Inc.*, 246 F.3d 1336, 1351–53 (Fed. Cir. 2001)).

²⁵ Christopher A. Harkins, *Choosing Between the Advice of Counsel Defense to Willful Patent Infringement or the Effective Assistance of Trial Counsel: A Bridge or the Troubled Waters?*, 5 NORTHWESTERN J. TECH. & INTELL. PROP. 210, 229–33 (2007) (arguing that *Underwater Devices* and *EchoStar* have set off a veritable feeding frenzy against defendants who rely on the opinion of counsel

Seagate Technology reaffirmed²⁶ “willfulness” as the standard for enhanced damages to be evaluated under the “totality of circumstances” discussed below.

¶15 At trial, there must be a finding of actual infringement, and then a separate determination by the fact finder of whether the defendant’s infringement was willful.²⁷ In reaching its decision, the fact finder considers the “totality of circumstances,”²⁸ which include the following factors:

- (1) whether the infringer deliberately copied the ideas or design of another;
- (2) whether the infringer, when he knew of the other’s patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed;
- (3) the infringer’s behavior as a party to the litigation;
- (4) defendant’s size and financial condition;
- (5) closeness of the case;
- (6) duration of defendant’s misconduct;
- (7) remedial action by the defendant;
- (8) defendant’s motivation for harm; and
- (9) whether defendant attempted to conceal its misconduct.²⁹

defense, whereby some courts are putting defendants to a Hobson’s choice of asserting that defense in order to stave off enhanced damages on the one hand, and waiving all privileged communications—even with *trial* counsel itself—on the other), *cited in* H.R. Rep. No. 110-314, at 28 nn.15 & 18 (Sept. 4, 2007) (The “Patent Reform Act of 2007” is pending in the Senate for consideration and is available at http://www.rules.house.gov/110/text/110_hr1908rpt.pdf (last visited October 4, 2007)).

²⁶ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) (“This well-established standard accords with Supreme Court precedent.”); *see also id.* at 1369 (“Over time, our cases evolved to evaluate willfulness . . . under the totality of circumstances.”); *id.* at 1377 (Gajarsa, J., concurring) (“[T]his court has nevertheless read a willfulness standard into the statute.”). Judge Gajarsa wrote separately in a concurring opinion to restore the flexibility of the remedial nature of 35 U.S.C. § 284 such that “a discretionary enhancement of damages would be appropriate for entirely remedial reasons, irrespective of the defendant’s state of mind.” *Seagate Tech.*, 497 F.3d at 1378 (Gajarsa, J., concurring).

²⁷ *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1225 (Fed. Cir. 2006) (“The drawing of inferences, particularly in respect of an intent-implicating question such as willfulness, is peculiarly within the province of the fact finder that observed the witnesses.”) (citation omitted).

²⁸ *Liquid Dynamics.*, 449 F.3d at 1225; *see also* *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1379 (Fed. Cir. 2005); *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1190 (Fed. Cir. 1998).

²⁹ *Liquid Dynamics*, 449 F.3d at 1225 (citation, ellipsis, and internal quotation marks omitted).

¶16 The plaintiff must prove willfulness by clear and convincing evidence.³⁰ Once the plaintiff meets its burden of persuasion and burden of production as to willfulness,³¹ the burden of production shifts to the defendant to introduce evidence to rebut plaintiff's showing that the defendant acted with objective recklessness.³² An express finding of willfulness is necessary before the second step.³³

¶17 Second, the court exercises its discretion in determining whether to increase the damage award based on the fact finder's determination of willfulness.³⁴ An "express finding of willful infringement"³⁵ merely authorizes—it does not mandate—treble damages and attorneys' fees.³⁶ The paramount factor in deciding to grant enhanced damages, and the amount of those damages, is the defendant's culpable conduct or bad faith. In assessing the state of mind of a defendant who the fact finder decides to have infringed a patent willfully, courts consider many factors in addition to the totality of the circumstances listed above.³⁷ These

³⁰ *Seagate Tech.*, 497 F.3d at 1371 ("Accordingly, to establish willful infringement, a patentee must show by clear and convincing evidence" objective recklessness); *nCube Corp. v. Seachange Int'l, Inc.*, 436 F.3d 1317, 1319 (Fed. Cir. 2006) ("A jury verdict of willfulness requires a finding 'by clear and convincing evidence in view of the totality of the circumstances that [the defendant] acted in disregard of the . . . patent and lacked a reasonable basis for believing it had a right to do what it did.'") (quoting *Amsted Indus., Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 181 (Fed. Cir. 1994)).

³¹ *Comark Commc'ns*, 156 F.3d at 1190.

³² *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1332 (Fed. Cir. 2004) ("[A]bsent an initial presentation of evidence . . . this burden of coming forward in defense [does] not arise.").

³³ *Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1308 (Fed. Cir. 2005). An express finding of willful infringement is necessary before the court awards enhanced damages. *Id.*

³⁴ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 n.3 (Fed. Cir. 2007) (en banc) ("Trial courts have had statutory discretion to enhance damages for patent infringement since 1836."); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1371 (Fed. Cir. 2006) ("Any trebling of damages based on a finding of willfulness is reviewed for abuse of discretion.").

³⁵ *Group One*, 407 F.3d at 1308–09 (Fed. Cir. 2005) (When the court exercises its discretion in denying willfulness damages, it must explain why.) (citation omitted).

³⁶ *Seagate Tech.*, 497 F.3d at 1368 ("But, a finding of willfulness does not require an award of enhanced damages; it merely permits it."); *Group One*, 407 F.3d at 1309 (On a jury finding of willful patent infringement, a "court may award attorney fees and not enhanced damages, or vice versa.").

³⁷ *See supra* Part I.A.1 and notes 28–29 (identifying the factors that comprise the "totality of circumstances"); *see also* *Liquid Dynamics Corp. v. Vaughan Co.*,

additional factors include evidence of whether the defendant took (or failed to take) reasonable steps to design around the patent to avoid infringement,³⁸ evidence of whether (and to what extent) the defendant simply copied the patented invention,³⁹ and evidence offered by the defendant that it obtained and relied on the advice of counsel when the defendant decided to continue sales of the accused product.⁴⁰

¶18 In short, when the defendant knows of the patent and fails to carry out its duty to avoid infringing a valid and enforceable patent, a court may find willful infringement provided the defendant was more than merely negligent. As a result, the plaintiff may be entitled to treble damages as well as attorneys' fees,⁴¹ and such an award in patent litigation can be "punitive."⁴²

2. *Seagate Technology* Permits a Finding of Willfulness Based on a Showing of "Objective Recklessness"

¶19 The Federal Circuit, in its *en banc* decision in *In re Seagate Technology, LLC*,⁴³ addressed the issue of whether, given the "impact"

449 F.3d 1209, 1225 (Fed. Cir. 2006) ("A finding of willful infringement is made after considering the totality of the circumstances.").

³⁸ *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1371 (Fed. Cir. 2004) (stating that failure to attempt to design around the patent may justify enhanced damages).

³⁹ *Stryker Corp. v. Intermedics Orthopedics Inc.*, 96 F.3d 1409, 1414 (Fed. Cir. 1997) (holding no need to find "slavish copying" if copying was made "deliberately"); *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996); *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992).

⁴⁰ *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992) (finding that a court may consider evidence that the defendant obtained an opinion of counsel of whether the accused product infringes any valid, enforceable claim of the patent.); *but see In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*) ("Because we abandon the affirmative duty of due care, we also deemphasize that there is no affirmative obligation to obtain opinion of counsel.").

⁴¹ *See* 35 U.S.C. § 285 (2006) ("The court in exceptional cases may award reasonable attorney fees to the prevailing party.").

⁴² *Seagate Tech.*, 497 F.3d at 1370 (characterizing enhanced damages as "punitive damages"); *see also Glenayre Elecs., Inc. v. Jackson*, 443 F.3d 851, 869 (Fed. Cir. 2006) (characterizing as possibly "punitive" the increased damages under the statute's trebling provision in a case of willful infringement); *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1345 (Fed. Cir. 2004) (*en banc*).

⁴³ 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*).

of *Underwater Devices, Inc. v. Morrison-Knudsen Co.*,⁴⁴ the Court should reconsider that decision and the “duty of care standard itself.”⁴⁵ The Federal Circuit overruled the standard of “due care” set forth in *Underwater Devices* and adopted an “objective recklessness” standard.⁴⁶

¶20 One cannot deny that the Federal Circuit’s recent decision in *Seagate Technology* raised the bar on the standard of proof necessary to establish willful infringement. While “due care” appeared simple enough, it could lead to a misapplication of the willfulness standard. If misapplied, a defendant could be found liable for enhanced damages by merely failing to act with “reasonable care,”⁴⁷ which lowered the willfulness standard to one more akin to negligence. According to the court, the reasonable care “standard fails to comport with the general understanding of willfulness in the civil context, and it allows punitive damages in a manner inconsistent with Supreme Court precedent.”⁴⁸

¶21 The Federal Circuit in *Seagate Technology* took a common-sense approach by ridding patent jurisprudence of law allowing enhanced damages under the “due care” standard specifically, but without discarding all other well-developed law on willfulness and the totality of circumstances in general. It follows that, at its core, *Seagate Technology* was not taking patent jurisprudence back to the days “when widespread disregard of patent rights was undermining the national innovation incentive”⁴⁹ and no license was given to a defendant’s “bad faith” infringement.⁵⁰

¶22 So, the Federal Circuit replaced the lower “due care” threshold required for proving willful infringement with a higher threshold that required at least a showing of “objective recklessness.”⁵¹ The new standard has both an objective aspect and a quasi-subjective one:

Accordingly, to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted

⁴⁴ 717 F.2d 1380 (Fed. Cir. 1983).

⁴⁵ *Seagate Tech.*, 497 F.3d at 1397.

⁴⁶ *Id.* at 1371.

⁴⁷ *Id.* at 1385 (Newman, J., concurring).

⁴⁸ *Id.* at 1371 (citation omitted).

⁴⁹ *Id.* at 1369 (citing *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc)).

⁵⁰ *Id.* at 1368; *see also id.* at 1385 (Newman, J., concurring) (“It cannot be the court’s intention to tolerate the intentional disregard or destruction of the value of the property of another, simply because that property is a patent.”).

⁵¹ *Id.* at 1371 (“[W]e abandon the affirmative duty of due care . . .”).

infringement of a valid patent. The state of mind of the accused infringer is not relevant to this objective inquiry. If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer.⁵²

¶23 The Federal Circuit chose not to spell out precisely the meaning of the new standard under the two-prong test quoted above.⁵³ Rather, the Federal Circuit “left it to future cases to further develop.”⁵⁴

¶24 Hence, trial courts remain free to exercise their discretion and to consider unique circumstances showing, by clear and convincing evidence, a high likelihood that a defendant’s acts—or omissions—were objectively unreasonable and, in turn, subjectively or at least objectively culpable. It is on this theory that, when a defendant plays ostrich, it may be held to have acted with objective recklessness: To know, and to want not to know because one suspects infringement, may be, if not the same state of mind, the same degree of fault.

B. “Notice” that Triggers a Defendant’s Duty to Avoid Willful Infringement

¶25 When a company becomes aware of a patent that may be relevant to its products and should realize there is a high likelihood of infringement, it has an affirmative duty to avoid infringement.⁵⁵ In practical application, a test of when this duty arises depends on the particular facts and circumstances surrounding the position of the person

⁵² *Id.* at 1371 (citation omitted). In his concurring opinion, Judge Gajarsa reads the court’s test as requiring “clear and convincing evidence, (1) that [defendant’s] theory of noninfringement/invalidity, was not only incorrect, but was objectively unreasonable, and (2) that [defendant] ran a risk of infringing [plaintiff’s] patents substantially greater than the risk associated with a theory of noninfringement/invalidity that was merely careless.” *Id.* at 1384.

⁵³ *Id.* at 1371 (“We fully recognize that ‘the term [reckless] is not self-defining.’” (quoting *Farmer v. Brennan*, 511 U.S. 825, 836 (1994))).

⁵⁴ *Id.* at 1371; *see also id.* at 1385 (Newman, J., concurring) (“Although new uncertainties are introduced by the court’s evocation of ‘objected standards’ for such inherently subjective criteria as ‘recklessness’ and ‘reasonableness,’ I trust that judicial wisdom will come to show the way, in the common-law tradition.”).

⁵⁵ *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1368 (Fed. Cir. 2006) (citation omitted). Accordingly, the evenhanded recklessness standard modified the “duty” by making clear that objective standards of conduct do not require “that every possibly related patent must be exhaustively studied by expensive legal talent.” *In re Seagate Tech., LLC*, 497 F.3d 1360, 1385 (Fed. Cir. 2007) (en banc) (Newman, J., concurring).

who received notice of the patent, how that person received notice of the patent, a record showing objectively reckless disregard of such notice, and the mindset of the person when he or she received the notice and chose to act or not act.

¶26 This duty arises when the defendant received “actual notice of another’s patent,”⁵⁶ coupled with objective evidence that infringement was highly likely and the defendant knew or should have recognized the infringement risks.⁵⁷ At that moment, there arises an affirmative duty to investigate whether any claim of the patent is being infringed. Notice of the patent may come in the form of a complaint alleging patent infringement,⁵⁸ in the form of a cease-and-desist letter,⁵⁹ or in a letter offering to license the patent.⁶⁰

¶27 However, at least one court held that notice occurred when in-house counsel merely saw a patent that was referenced in the Official

⁵⁶ See *supra* Part I.A.1; see also *nCube Corp. v. Seachange Int’l, Inc.*, 436 F.3d 1317, 1324 (Fed. Cir. 2006).

⁵⁷ This “duty to avoid infringement” as used herein is consistent with the Federal Circuit decision in *Seagate Technology*. The Federal Circuit could not possibly have meant, in adopting the “objective recklessness” test, “to ratify intentional disregard, and to reject objective standards requiring a reasonable respect for property rights.” *Seagate Tech.*, 497 F.3d at 1385 (Newman, J., concurring). To vitiate any duty to avoid infringement—when there is objective evidence of reckless disregard for the risks of infringement—would unwittingly encourage an unscrupulous defendant, in ostrich-like fashion, to seek cover in the sand so as to disavow any specific knowledge of infringement.

⁵⁸ See, e.g., 35 U.S.C. § 287(a) (2006) (“Filing of an action for infringement shall constitute such notice.”); *State Indus. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235–36 (Fed. Cir. 1985) (reversing the finding of willful infringement where the complaint was filed just twenty-two days after the asserted patent had issued and there was no clear evidence that the defendant copied the patented invention).

⁵⁹ *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1339 (Fed. Cir. 2004) (affirming the district court’s finding that infringement was willful based on Wal-Mart’s failure to take appropriate action after receiving the patent owner’s cease-and-desist letter—even if most sales were made prior to receiving the letter, there was evidence that Wal-Mart continued to sell off its remaining inventory after it learned of its possible infringement).

⁶⁰ Evidence supported a determination that infringement was willful when the infringer had actual notice of plaintiff’s patent rights before the infringement began, when the notice was by letter offering a license under the patent before any infringement took place, and defendant chose to proceed without a license. *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1384 (Fed. Cir. 1983), rev’d in part on other grounds, *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (en banc).

Gazette of the United States Patent and Trademark Office.⁶¹ While the defendant argued that it had not recognized the alleged infringement risks posed by its product, the Federal Circuit gave weight to the fact that in-house counsel associated the patent with the accused product in their capacity as counsel for the potential infringer.⁶²

¶28 Another court found a potential infringer to be on notice when the asserted patent was cited by the potential infringer in an information disclosure statement,⁶³ even though the patent application had no direct relationship with the allegedly infringing product.⁶⁴ According to the defendant, in order to trigger the alleged infringer's duty to avoid infringement "in the face of knowledge about the patent, the patent owner must show that the accused infringer both knew about the patent and understood that the patent raised a potential infringement problem."⁶⁵ The court found the defendant's argument "that actual notice requires both knowledge of the patent and knowledge of the potential for infringement to be unpersuasive."⁶⁶

¶29 These cases seem to be converting the notice standard from a question asking what the potential infringer "had known" into a question asking what the defendant "should have known." As district courts struggle over the appropriate question to ask in applying the notice standard for purposes of willful infringement—once the "threshold objective standard is satisfied,"⁶⁷ the Federal Circuit has simply said that there must be something more than mere "constructive notice"⁶⁸ to trigger the duty to avoid infringement and evidence that the objectively-

⁶¹ *Stryker Corp. v. Intermedics Orthopedics Inc.*, 96 F.3d 1409, 1415 (Fed. Cir. 1997).

⁶² *Id.* at 1415–16.

⁶³ 37 C.F.R. §§ 1.97, 1.98 (2006).

⁶⁴ *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 166 F. Supp. 2d 1008, 1037 (D. Del. 2001), *aff'd in part, rev'd in part on other grounds*, 370 F.3d 1131 (Fed. Cir. 2004).

⁶⁵ *Id.* at 1037.

⁶⁶ *Id.* (finding that notice was sufficient to send the issue to the jury, because there was a memorandum in the defendant's files making reference to the patent citing it to the PTO in an application that in-house counsel was prosecuting).

⁶⁷ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc).

⁶⁸ *Imonex Services, Inc., v. Munzprufer Dietmar Trenner GMBH*, 408 F.3d 1374, 1377 (Fed. Cir. 2005) ("Constructive notice, as by marking a product with a patent number, is insufficient to trigger this duty.").

defined risk was “known or so obvious that it should have been known.”⁶⁹

¶30 Indeed, the Federal Circuit held that a potential infringer’s duty may be triggered by notice received by any corporate employee, including engineers.⁷⁰ In other words, a defendant who intentionally blinds itself to the facts and law, and then continues to infringe, may be found to be a willful infringer by imputing⁷¹ the state of mind of employees to the state of mind of the defendant.⁷²

¶31 Therefore, one potential consequence of a defendant who has notice of the patent, but who ignores an objectively high risk of infringement, is being held liable for treble damages.⁷³ The trebling is of all actual damages, which is addressed next.

C. “Notice” that Triggers a Plaintiff’s Actual Damages

¶32 By statute, a plaintiff may only recover actual damages accruing after the date it placed the alleged infringer on notice of infringement.⁷⁴

⁶⁹ *Seagate Tech.*, 497 F.3d at 1371.

⁷⁰ *SRI Int’l v. Advanced Tech. Labs.*, 127 F.3d 1462, 1465 (Fed. Cir. 1997) (finding actual notice when defendant’s “engineers [had] expressed their concerns” about the patent in a memorandum).

⁷¹ “Under the general common law of agency, ‘[e]xcept where the agent is acting adversely to the principal . . . the principal is affected by the knowledge which an agent has a duty to disclose to the principal . . . to the same extent as if the principal had the information.’” *Long Island Sav. Bank v. U.S.*, 476 F.3d 917, 929 (Fed. Cir. 2007) (citing Restatement (Second) of Agency § 275 (1958) and the copyright case *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 751–52 (1989) (relying on the Restatement in determining whether the hired party was an employee or independent contractor for Copyright Act purposes)). For a discussion of *Reid*, see Christopher A. Harkins, *Tattoos and Copyright Infringement: Celebrities, Marketers, and Businesses Beware of the Ink*, 10 LEWIS & CLARK L. REV. 313, 324–26 (2006).

⁷² *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1572 (Fed. Cir. 1996).

⁷³ Another potential consequence is attorneys’ fees, which are based on detailed attorney timesheets, detailed billing statements and invoices showing actual charges billed to the client in connection with the representation, evidence that expenses were both reasonable and necessary in the normal course of attorney services, evidence of the customary attorney rates in the relevant legal community for handling patent litigation, and any premium in attorneys’ rates based on skill and experience. *Junker v. Eddings*, 396 F.3d 1359, 1365–66 (Fed. Cir. 2005).

⁷⁴ 35 U.S.C. § 287(a)–(b) (2006); see also *Am. Med. Sys. v. Med. Eng’g Corp.*, 6 F.3d 1523, 1537 n.18 (Fed. Cir. 1993) (“Section 287(a) requires a party asserting infringement to either provide constructive notice (through marking) or actual notice to avail itself of damages. The notice of infringement must

Here, the notice for purposes of willfulness and the notice for actual damages deviate.

¶33 While willfulness focuses on the time when the potential infringer possessed knowledge of the patent and facts sufficient to establish an objectively high likelihood of infringement, the notice requirement for actual damages under § 287(a) focuses on the conduct of the plaintiff and asks the questions of when the plaintiff gave the defendant notice of the patent and accused the defendant of patent infringement.⁷⁵ Consequently, for actual damages to accrue, mere “notice of the patent’s existence or ownership” is not “notice of infringement” and is not an “affirmative communication [to the potential infringer] of a specific charge of infringement by a specific accused product or device.”⁷⁶

¶34 In contrast to willfulness, the plaintiff may meet its burden of proving notice under § 287(a) by giving the potential defendant “constructive” notice,⁷⁷ such as when the plaintiff and its licensees mark products with patent numbers that cover those products.⁷⁸ Moreover, the

therefore come from the patentee, not the infringer.”); *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir.1994) (“For purposes of section 287(a), notice must be of ‘the infringement,’ not merely notice of the patent’s existence or ownership.”).

⁷⁵ *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1345 (Fed. Cir. 2001) (citing *SRI Int’l v. Advanced Tech. Labs.*, 127 F.3d 1462, 1470 (Fed. Cir. 1997)); *see also Amsted Indus.*, 24 F.3d at 187 (“The correct approach to determining notice under section 287 must focus on the action of the patentee, not the knowledge of the infringer.”).

⁷⁶ *Amsted Indus.*, 24 F.3d at 187.

⁷⁷ *Syngenta Seeds, Inc. v. Delta Cotton Coop. Inc.*, 457 F.3d 1269, 1276 (Fed. Cir. 2006) (recovering damages for patent infringement requires a plaintiff to prove “either actual or constructive notice” to the defendant of plaintiff’s patent); *Sentry Protection Prods., Inc. v. Eagle Mfg. Co.*, 400 F.3d 910, 918 (Fed. Cir. 2005) (“Constructive notice is provided when the patentee consistently marks substantially all of its patented products.”) (internal citation and brackets omitted); *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996) (A plaintiff “is entitled to damages from the time when it either began marking its product in compliance with section 287(a), constructive notice, or when it actually notified the accused infringer of its infringement, whichever was earlier.”) (internal citation and brackets omitted).

⁷⁸ 35 U.S.C. § 287(a) (2006) (“Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word ‘patent’ or the abbreviation ‘pat.’, together with the number of the patent, or when, from the

Federal Circuit held that, to rely on the constructive-notice provisions of § 287(a), full compliance with that section requires the patentee to “consistently mark[] substantially all of its patented products.”⁷⁹

¶35 Absent marking, the plaintiff cannot prove constructive notice or recover actual damages for any period of time prior to the date when the defendant received actual notice of the patent. In that case, actual damages may be recovered, if at all, only from the date on which actual notice was given by the plaintiff⁸⁰ to the defendant. Actual notice may come in the form of the plaintiff filing a lawsuit or sending a letter to the defendant accusing it of infringing the plaintiff’s patent.⁸¹

¶36 Therefore, in some respects, willfulness has a more lenient “notice” requirement than the notice requirement under § 287(a). As a result, the willfulness clock may start to run long before the plaintiff ever informs the defendant, by letter or complaint for patent infringement, that the accused product infringes the asserted patent. The upshot of an early date for willfulness is to put the defendant at risk that all damages will be trebled and that a defendant may owe attorneys’ fees from the onset of the litigation forward.

¶37 To further place the “notice” standard for willfulness in context, it should be noted that the actual notice required under § 287(a) is even lower than the standard necessary to support declaratory judgment jurisdiction.⁸² Moreover, the Federal Circuit recently lowered the requirements necessary to establish an actual controversy under the Declaratory Judgment Act for patent cases in general,⁸³ and for a patent-related declaratory judgment action under the Hatch-Waxman Act and

character of the article, this cannot be done, by fixing to it, or to the package wherein on or more of them is contained, a label containing a like notice.”).

⁷⁹ *Am. Med. Sys., Inc. v. Med. Eng’g Corp.*, 6 F.3d 1523, 1538 (Fed. Cir. 1993).

⁸⁰ *Lans v. Digital Equip. Corp.*, 252 F.3d 1320, 1327 (Fed. Cir. 2001) (“[N]otice from someone closely associated with the patentee does not satisfy § 287(a).”).

⁸¹ *SRI Int’l v. Advanced Tech. Labs.*, 127 F.3d 1462, 1469–70 (Fed. Cir. 1997) (Actual notice may be achieved “when the recipient is informed of the identity of the patent.”).

⁸² *Id.* at 1470 (“Actual notice may be achieved without creating a case of actual controversy in terms of 28 U.S.C. § 2201.”).

⁸³ *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007).

the Orange Book in particular.⁸⁴ However, at least one Federal Circuit judge has hinted that the new declaratory judgment standard is too low.⁸⁵

II. CAN THE “ORANGE BOOK” SATISFY THE “NOTICE REQUIREMENT” FOR WILLFUL INFRINGEMENT?

¶38 In a case of first impression, the Southern District of New York in *Merck & Co. v. Mediplan Health Consulting, Inc.*⁸⁶ decided online pharmacies were entitled to summary judgment on the grounds that the Orange Book did not constitute statutory notice of patent infringement under § 287(a).⁸⁷ Because the patent owner did not mark its product with the patent number and the patent already expired at the time the lawsuit was filed, the patent owner could not recover pre-filing damages⁸⁸ without the Orange Book theory of notice. After the court’s summary judgment order limiting the damages available to plaintiff to the filing date of the complaint, and presumably directly resulting from that order, the case was soon dismissed pending settlement.⁸⁹

¶39 Significantly, it was not argued in *Merck*, and thereby left for another day, another court and other litigants, whether the Orange Book might constitute notice sufficient to trigger willful infringement if coupled with at least a showing of objective recklessness. The question is especially intriguing given a pharmaceutical company’s “obligation”⁹⁰ to consult the Orange Book before selling or offering for sale medication regulated by the FDA. This Section summarizes relevant aspects of the Hatch-Waxman Act and makes some observations about the *Merck* decision and this novel theory of willfulness.

⁸⁴ *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007).

⁸⁵ *SanDisk*, 480 F.3d at 1384 (Bryson, J., concurring) (“[V]irtually any invitation to take a paid license relating to the prospective licensee’s activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent.”).

⁸⁶ 434 F. Supp. 2d 257 (S.D.N.Y. 2006).

⁸⁷ *Id.* at 265.

⁸⁸ *Id.* at 264.

⁸⁹ On February 21, 2007, one month after the trial court’s ruling that the patent owner could not recover pre-filing damages, the court entered an order granting the parties’ stipulated dismissal with prejudice.

⁹⁰ *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004) (“[A] generic company has an obligation to consult the Orange Book.”).

A. An Overview of the Hatch-Waxman Act

¶40 The Drug Price Competition and Patent Term Restoration Act,⁹¹ commonly known as the Hatch-Waxman Act,⁹² allows for FDA approval of generic drugs according to a statutory procedure that is much faster and less expensive than the FDA-approval process the original innovator of the drug followed before introducing its patented medication or method to the consumer market. The Hatch-Waxman Act attempts to balance the interests of generic-drug manufacturers and the innovator companies whose pioneering drugs are subject to patent protection.⁹³ To a large extent, the Hatch-Waxman Act succeeded in striking the difficult balance between inducing “name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to the market.”⁹⁴

¶41 Thus, the Hatch-Waxman Act gave something to both generic companies and brand-name companies. Streamlined guidelines simplified the FDA-approval process for generic drugs, while lower jurisdictional requirements allowed a patent owner to bring a declaratory judgment action for a declaration of infringement and validity of its patents, as shown below. Offsetting the generic company’s relatively speedier process through the FDA, the research-based drug company (a “pioneer” or “innovator”) is compensated for the protracted FDA-

⁹¹ Congress passed the Act as an amendment to the Federal Food, Drug and Cosmetic Act, Pub. L. No. 98-417 (codified at 21 U.S.C. § 355).

⁹² Joel Graham, *The Legality of Hatch Waxman Pharmaceutical Settlements: Is the Terazolin Test the Proper Prescription?*, 84 WASH. U. L. REV. 429, 429 n.2 (2006) (“This Act is typically referred to as the Hatch-Waxman Act because of the congressional sponsors, Senator Orrin Hatch and Representative Henry Waxman.”) (citation omitted).

⁹³ See Abbreviated New Drug Application Regulations; Patent Exclusivity Provisions, 59 Fed. Reg. 50338 (Oct. 3, 1994) (“Congress intended these provisions to provide a careful balance between promoting competition among brand-name and duplicate or ‘generic’ drugs and encouraging research and innovation.”).

⁹⁴ In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 192 (E.D.N.Y. 2003) (citation omitted); see also *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005) (“Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”).

approval process by a patent-term extension of up to five years of patent exclusivity.⁹⁵

¶42 Owing to the Hatch-Waxman Act, generic companies may begin developing their drugs notwithstanding the drug innovator's patent protection.⁹⁶ Before the Hatch-Waxman Act became law, these same activities amounted to patent infringement because they constituted a "use" of the patented composition or method.⁹⁷

¶43 By allowing generic companies to use the patented invention to develop a generic alternative to the patented drug, these generic companies gained advantages to entry into the marketplace in at least two respects. First, generic companies may offer their generic drugs as soon as the patent expires⁹⁸ because they would be allowed to use the patented drug or method during the patent term to develop their own generic counterpart. Second, the generic companies may challenge the validity of the patent, or otherwise compete during the patent term, by seeking FDA approval to market non-infringing alternatives via procedural mechanisms.⁹⁹ Both benefits stem from the companies' qualified use of a patent owner's claimed invention.

¶44 Turning now to relevant procedure under the Hatch-Waxman Act, the generic-drug companies are relieved from submitting the extensive drug safety and efficacy data necessary for FDA approval. Instead of the rigorous process required of a pioneer-drug innovator in its New Drug Application ("NDA"), the generic-drug company only needs to file an Abbreviated New Drug Application ("ANDA") that merely relies on the drug innovator's NDA data, without authorization, permission, or payment to the drug innovator for the use of its data.¹⁰⁰ Under this procedure, generic-drug applicants avoid the tremendous time and capital outlay to obtain the safety and efficacy data necessary for

⁹⁵ Ashlee B. Mehl, *The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive?*, 81 CHI.-KENT L. REV. 649, 653 (2006); *see also* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).

⁹⁶ 35 U.S.C. § 271(e)(1) (2006).

⁹⁷ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984) ("It is well-established, in particular, that the *use* of a patented invention, without either manufacture or sale, is actionable.") (emphasis in original).

⁹⁸ *See* Mehl, *supra* note 95, at 650 ("This allows the generic firm to market its product immediately, driving down drug prices for consumers earlier than otherwise would have been possible.").

⁹⁹ 21 U.S.C. § 355(j)(2)(A)(vii).

¹⁰⁰ 21 U.S.C. § 355(j)(2)(A).

FDA approval. As a result, the ANDA procedure allows the generic-drug applicant to move swiftly through the FDA-approval process either by not challenging the patent issued to the drug innovator or, alternatively, by challenging the patent on grounds the patent is either invalid or would not be infringed, commonly referred to as a Paragraph IV certification.¹⁰¹

¶45 If the generic-drug manufacturer files a Paragraph IV certification asserting that the patent is invalid or not infringed, the ANDA applicant must notify the patent owner.¹⁰² Although the generic drug is not yet on the market at this time (indeed, it still needs FDA approval), the filing of a Paragraph IV certification constitutes an act of infringement upon which the patent owner has forty-five days¹⁰³ to file a federal lawsuit to adjudicate whether the generic-drug manufacturer infringes any valid patent claim.¹⁰⁴ If the patent owner elects to sue, then there is an automatic thirty-month stay of the FDA's examination of the generic-drug company's ANDA while the patent litigation proceeds.¹⁰⁵

¶46 The Orange Book was born out of the ANDA process of the Hatch-Waxman Act. Officially entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," the Orange Book identifies (1) drug products approved by the FDA, (2) therapeutic equivalence evaluations for multi-source prescription-drug products, and (3) patent information concerning the listed drugs. To further the ANDA statutory scheme, the innovator-drug company seeking FDA approval must file information concerning each of its patents claiming a drug or a method of using a drug subject to the patent owner's NDA.¹⁰⁶

¶47 Under the mandate of the Hatch-Waxman Act, the Orange Book is published by the FDA in furtherance of the ANDA process for the generic-drug company to review before seeking approval to manufacture, use, sell, or offer for sale FDA-approved drugs protected by the NDA's

¹⁰¹ 21 U.S.C. § 355(j)(2)(A)(vii).

¹⁰² 21 U.S.C. § 355(j)(2)(B).

¹⁰³ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁰⁴ See 35 U.S.C. § 271(e)(2); *Organon, Inc. v. Teva Pharm., Inc.*, 244 F. Supp. 2d 370, 374 (D.N.J. 2002) ("In order to allow courts to determine in advance whether the sale of a generic will infringe the patent listed in the Orange Book, § 271(e)(2) makes the filing of a paragraph IV certification automatically 'an act of infringement.' This allows courts to peer into the future at the likelihood of infringement once the generic is on the market, without a ripeness deficiency.").

¹⁰⁵ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁰⁶ 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53.

patent protection.¹⁰⁷ Moreover, the information submitted by the NDA (providing notice of the patent and covered products) is included in the Orange Book where ANDA applicants should look—indeed, must look—when seeking FDA approval for generic copies of FDA-approved drugs.

¶48 In this context, the Federal Circuit has recognized that, in at least two respects, the listings in the Orange Book serve the competing interests of generic and brand-name manufacturers as Congress intended when implementing the Hatch-Waxman Act. First, the Orange Book provides “a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products.”¹⁰⁸ Second, the Orange Book facilitates “judicial resolution of the question whether the generic drug would infringe a pertinent patent.”¹⁰⁹

B. A Novel Theory of Notice via the Orange Book

¶49 Can the patent listings in the Orange Book satisfy the notice requirement under § 287(a)?¹¹⁰ Can the Orange Book serve as notice to the accused infringer for purposes of willfulness?¹¹¹

¶50 Until recently, no reported decision addressed the issue of whether a plaintiff can point to the Orange Book to satisfy § 287(a) notice. Moreover, there is still no reported decision on the issue of whether a defendant who reviews the Orange Book before engaging in commercial activity—or deliberately fails to determine the extent of its obligations under the Orange Book—is on notice of infringement sufficient to satisfy the requirements of the “objectively reckless” standard of willfulness. The Federal Circuit has not addressed either scenario.

¹⁰⁷ See Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Equivalence Evaluations, Preface to Twenty Seventh Edition at v, <http://www.fda.gov/cder/orange/obannual.pdf> (last visited October 4, 2007) (“The 1984 Amendments required the Agency to begin publishing an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required.”). The Electronic Orange Book is available at <http://www.fda.gov/cder/ob/default.htm> (last visited October 4, 2007).

¹⁰⁸ *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338–39 (Fed. Cir. 2003).

¹⁰⁹ *Id.*

¹¹⁰ See *supra* Part I.C (discussing the type of notice required to give rise to actual infringement damages).

¹¹¹ See *supra* Part I.B (discussing the type of notice required to give rise to a defendant’s duty to avoid willful infringement).

1. Does the Orange Book Provide Notice Under § 287(a)?

¶51 The first decision to address § 287(a) and the Orange Book is *Merck & Co. v. Mediplan Health Consulting, Inc.* from the Southern District of New York.¹¹² Canadian defendants operated online pharmacies offering generic versions of the plaintiffs' popular cholesterol-lowering medication Zocor®. The plaintiffs did not mark their Zocor® pills with any indication of the patents protecting the composition and methods of making the active ingredient. In compliance with the Hatch-Waxman Act, however, the plaintiffs listed the patent in the FDA's Orange Book. The defendants filed a motion for summary judgment asserting that, because Merck failed to mark its own Zocor® pills and failed to give actual notice of patent infringement, Merck should be prohibited from recovering any damages accrued before filing the patent infringement complaint.

¶52 Initially, the district court addressed the issue of whether marking is required for patents with both method claims and apparatus claims. The court noted the split of authority in a combined method and product patent. According to the plaintiffs in *Merck*, the marking statute only applies where a tangible item exists for marking *and* the patent owner asserts *both* the product and method claims of the same patent. In other words, the plaintiffs in *Merck* argued they could elect to assert only the method of use claim for the patent in suit, in which case Federal Circuit precedent did not require marking because there would be nothing physical to mark in a "process" or "method" claim.

¶53 In distinguishing the ruling in the Federal Circuit decision in *Hanson v. Alpine Valley Ski Area, Inc.* that "the notice requirement . . . does not apply where the patent is directed to a process,"¹¹³ the district court found the *Hanson* rule to be a narrow holding limited to the liability phase and not damages.¹¹⁴ The plaintiffs also relied on the Federal Circuit's decision in *American Medical Systems, Inc. v. Medical Engineering Corp.*¹¹⁵ requiring marking only where "both apparatus and method claims of the . . . patent were asserted."¹¹⁶ The district court disagreed with the conclusion of other courts interpreting *American Medical Systems* to excuse marking where only the method claims were

¹¹² 434 F. Supp. 2d 257 (2006).

¹¹³ 718 F.2d 1075, 1083 (Fed. Cir. 1983).

¹¹⁴ *Merck & Co. v. Mediplan Health Consulting, Inc.*, 434 F. Supp. 257, 262 (S.D.N.Y. 2006).

¹¹⁵ 6 F.3d 1523 (Fed. Cir. 1993).

¹¹⁶ *Id.* at 1538–39.

asserted, and instead found that the marking statute must be followed when a tangible article is “capable” of being marked, even when a plaintiff elects to assert only the method claims of a mixed composition-method patent.¹¹⁷

¶54 Having found the patent-marking statute applied to the patents in suit, the district court acknowledged the issue of whether the Orange Book satisfied the marking statute as “one of first impression.”¹¹⁸ The district court found the Orange Book not to be the type of “affirmative communication of a *specific* charge of infringement by a *specified* accused product”¹¹⁹ as the district court interpreted Federal Circuit precedent.¹²⁰

¶55 But the *Merck* decision is only persuasive precedent, because the Federal Circuit has not decided the issue of whether (and to what extent) a plaintiff may rely on the Orange Book to satisfy the marking statute. Furthermore, there was no evidence that the defendants in *Merck* had notice of the patent from the Orange Book listing, because the defendants did not file an ANDA or a Paragraph IV certification.

2. Does the Orange Book Provide Notice for Proving Willfulness?

¶56 The explosion of ANDA suits signals an intensified struggle over the high-stakes prize of market exclusivity in the brand-name versus generic drug war. When one additional month of exclusivity can significantly impact a company’s revenue stream, as it sometimes can, then the need to optimize the term of exclusivity will transform the rules of engagement under Hatch-Waxman and patent litigation. Indeed, drug innovators face escalating competition from Canadian manufacturers of generic drugs, online drug companies, and retail giants such as Wal-Mart® Super Centers filling prescriptions for four dollars with generic drugs. With so many competitors turning a piece of the generic prescription drug business, drug innovators must turn to their patent counsel in hopes of boosting patent damages to make up for any shortfall in customer traffic and sales of their drugs.

¶57 More precisely, the need for attorneys representing owners of pharmaceutical patents to innovate and quickly respond to client demands is greater than ever. With brand-name clients becoming

¹¹⁷ *Merck*, 434 F. Supp. 2d at 262–63.

¹¹⁸ *Id.* at 264.

¹¹⁹ *Id.* at 263 (emphasis in original) (citing *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir. 1994)).

¹²⁰ In addition to the *Amsted* decision, the *Merck* court relied on *SRI Int’l, Inc. v. Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1470 (Fed. Cir. 1997).

increasingly concerned about diminishing returns, the expensive nature of drug development, and spiraling costs of litigation, their attorneys need to be creative with their damages theories in order to maximize recovery and help their clients recoup the investments in research and development necessary to bring new and innovative drugs to the marketplace, which investments of time and money have been estimated to reach twelve years¹²¹ and \$800 million,¹²² respectively. This article suggests a novel theory of willful infringement in order for a patent owner to recover treble damages and attorneys' fees.

¶58 Toward that end, the decision in *Merck* gives fodder for the argument that the Orange Book provides notice sufficient to trigger willfulness where there is infringing commercial activity. This is especially true when *Merck* is read in conjunction with the Federal Circuit's 2004 decision in *Knorr-Bremse* reaffirming an affirmative duty "to avoid infringement of the known patent rights of others"¹²³ and the Federal Circuit's rebuke of "when widespread disregard of patent rights was undermining the national innovation incentive."¹²⁴

¶59 In conceding that the Orange Book "informs the public of the patent's existence,"¹²⁵ the *Merck* decision arguably allows a finding of willfulness based on a defendant's notice of a patent via the Orange Book. Moreover, the district court in *Merck* noted the contention that the Orange Book gives "notice to an audience that is required by statute to seek out and heed that notice," the "defendants were required to consult the Orange Book under the relevant statutory scheme, and had they done so they would have received notice."¹²⁶ Admittedly, the court found this evidence to "focus on the defendants' actions."¹²⁷

¹²¹ Andrew J. Paprocki, *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.: Can the Patent-Term Extension of the Hatch-Waxman Act Be Used as Leverage in Drug Patent Infringement Settlements?*, 46 JURIMETRICS J. 471, 474 (Summer 2006).

¹²² Daniel F. Coughlin, Ph.D., & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex has Difficulty Telling Who's on First*, 25 BIOTECHNOLOGY L. REP. 525, 526 n.9 (October 2006).

¹²³ *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1345 (Fed. Cir. 2004) (en banc).

¹²⁴ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1369 (Fed. Cir. 2007) (en banc).

¹²⁵ *Merck & Co. v. Mediplan Health Consulting, Inc.*, 434 F. Supp. 257, 264 (S.D.N.Y. 2006).

¹²⁶ *Id.*

¹²⁷ *Id.* at 265.

¶60 While the court granted defendants' motion, the court did not reach the issue of willfulness. Instead, the motion was brought under § 287(a), and the court held that the "defendants' knowledge of the patent's existence is simply irrelevant to the notice determination" under the marking statute.¹²⁸

¶61 Yet, the notice to the defendants in *Merck* is fundamental to a determination of willful infringement¹²⁹ and the "objectively high likelihood that its actions would constitute infringement of a valid patent."¹³⁰

¶62 Notice for purposes of willful infringement focuses on a defendant's knowledge of the patent. Also, notice is evidence that an unjustifiably high risk of infringement, when objectively assessed, was known or so obvious to the defendant that it should have been known. This is true whether the defendant arrives at that knowledge by an engineer's memorandum or by an information disclosure statement the defendant files in its own patent application for an invention unrelated to the accused product.¹³¹ *Merck* may be read to open the door to a plaintiff pleading a willfulness theory that a defendant who reviews the Orange Book is found to possess knowledge of the patent's existence leading to an objectively high risk of willful infringement when coupled with infringing commercial activity.

3. *Seagate Technology* and the "Standards of Commerce"

¶63 *Seagate Technology* sent a message that "standards of behavior by which a possible infringer evaluates adverse patents should be the standards of fair commerce, including reasonableness of the actions taken in the particular circumstances."¹³² If precautions by a defendant are intentionally deficient, then courts ought to adjust accountability, not to deny the opportunity to prove willfulness altogether.

¶64 "Willful" infringement should cover both knowing and reckless disregard of the law. Knowing violations are sensibly understood as

¹²⁸ *Id.*

¹²⁹ *nCube Corp. v. Seachange Int'l, Inc.*, 436 F.3d 1317, 1324 (Fed. Cir. 2006).

¹³⁰ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc).

¹³¹ *SRI Int'l v. Advanced Tech. Labs.*, 127 F.3d 1462, 1465 (Fed. Cir. 1997) (finding actual notice when defendant's "engineers expressed their concerns" about the patent in a memorandum); *see also Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 166 F. Supp. 2d 1008, 1037 (D. Del. 2001) (finding that a reference in defendant's files to the patent satisfied notice requirement for willfulness).

¹³² *Seagate Tech.*, 497 F.3d at 1385 (Newman, J., concurring); *see also id.* at 1371 n.5.

more serious than reckless ones. Actions falling within the “knowing” category include a defendant’s knowing failure to comply with the Hatch-Waxman Act¹³³ and intentionally violating the Act by not consulting (or reviewing and ignoring) the Orange Book and thereby showing an objectively high risk of infringement rather than the defendant being “merely careless.”¹³⁴

¶65 In the recklessness category, the Federal Circuit understood that “recklessness” is a word whose construction often depends on the context in which it appears. A company would not be acting recklessly if it diligently and in good faith attempted to fulfill its statutory obligations under the Hatch-Waxman Act and simply came to an incorrect conclusion.¹³⁵ But a deliberate and objectively reckless failure to comply with the Hatch-Waxman Act in determining the extent of its obligations ought not to evade liability under § 284 any more than “bad faith infringement.”¹³⁶ Any other reading of *Seagate Technology* leaves a loophole for paying mere lip-service to the Hatch-Waxman Act, the costs of which would be too high.

¶66 Instead, courts should entertain theories enhancing accountability rather than denying plaintiffs the tools they need to demonstrate an objectively-defined risk (determined by the record after discovery) and to show the risk “was either known or so obvious that it should have been known to the accused infringer.”¹³⁷ Therefore, recklessness might turn on circumstances showing the defendant acted in reckless disregard of patent rights in violation of the Hatch-Waxman Act.¹³⁸

¶67 This construction of “objective recklessness” comports with common law usage endorsed by the Federal Circuit in *Seagate*

¹³³ *Safeco Ins. Co. of Am. v. Burr*, 127 S. Ct. 2201, 2208 (2007) (“[W]here willfulness is a statutory condition of civil liability, we have generally taken it to cover not only knowing violations of a standard, but reckless ones as well.”)

¹³⁴ *Seagate Tech.*, 497 F.3d at 1384 (Gajarsa, J., concurring); *see also id.* at 1381 (Supreme Court cases “do not hold that a finding of willfulness is *necessary* to support an award of enhanced damages. At most, those cases merely stand for the uncontroversial proposition that a finding of willfulness is *sufficient* to support an award of enhanced damages.”) (emphasis in original).

¹³⁵ *Cf. Seagate Tech.*, 497 F.3d at 1384 (A defendant’s actions must be “not only incorrect, but [] objectively unreasonable.”).

¹³⁶ *Id.* at 1368 (“[B]ad faith infringement” is “a type of willful infringement.”).

¹³⁷ *Id.* at 1371.

¹³⁸ The Federal Circuit did not set forth an absolute definition of the term “reckless” but instead emphasized that the term would be developed by future cases. *Id.* at 1371, 1385.

Technology, which cited both *Prosser and Keeton on Law of Torts*¹³⁹ and the *Restatement (Second) of Torts*.¹⁴⁰ The Restatement, for example, defines recklessness in terms of an actor's conduct as "reckless disregard" when the actor does an act or "intentionally fails" to do an act that it is duty-bound to do, "knowing or having reason to know of facts" that would lead a "reasonable" person to appreciate the risk as substantially greater than simple negligence.¹⁴¹

¶68 Hence, recklessness may consist of either of two different types of conduct. In one, the actor knows or has reason to know of facts that create a high degree of risk, but acts or fails to act "in conscious disregard of, or indifference to, that risk."¹⁴² For the other type of recklessness, the actor either knows, or has "reason to know, the facts, but does not realize or appreciate the high degree of risk involved," although a reasonable person would appreciate the risk.¹⁴³

¶69 After all, when a defendant intentionally violates the Hatch-Waxman Act by failing to comply with its duty to check the Orange Book (or by disregarding the results if it does check the Orange Book) and there is a strong probability that the defendant knew or should have known of an unreasonably high risk of infringement, then the defendant's conscious choice involves a risk substantially greater than mere negligence.¹⁴⁴ Simply put, the defendant cannot stick its head in

¹³⁹ *Id.* at 1371 (citing W. KEETON, D. DOBBS, R. KEETON, & D. OWEN, PROSSER AND KEETON ON LAW OF TORTS § 34, 212-14 (5th ed. 1984)).

¹⁴⁰ *Seagate Tech.*, 497 F.3d at 1371 (citing RESTATEMENT (SECOND) OF TORTS § 500 (1965)).

¹⁴¹ RESTATEMENT (SECOND) OF TORTS, § 500 (1965) [hereinafter RESTATEMENT SECOND]; see also W. KEETON, D. DOBBS, R. KEETON, & D. OWEN, PROSSER AND KEETON ON LAW OF TORTS § 34, 213 (5th ed. 1984) [hereinafter PROSSER] (permitting recklessness to be found when there is evidence of "a known or obvious risk that was so great as to make it highly probable that the harm would follow").

¹⁴² RESTATEMENT (SECOND) OF TORTS, § 500 cmt. A (1965).

¹⁴³ *Id.* An objective standard is applied to this second type of recklessness, and the actor is "held to the realization of the aggravated risk." *Id.*

¹⁴⁴ The American Law Institute has approved the proposed final draft (issued on April 6, 2006) of the RESTATEMENT (THIRD) OF TORTS (2007) [hereinafter RESTATEMENT THIRD]. Unlike § 500 of the RESTATEMENT SECOND cited by the Federal Circuit in *Seagate*, *supra* notes 140-141, which does not require the actor's actual knowledge of the risks (instead, requiring at least actual knowledge of facts leading a reasonable person to realize the risks), Section 2 of the RESTATEMENT THIRD defines "recklessness" to require knowledge of facts making the risk of infringement "obvious" to a person or business subject to the Hatch-Waxman Act:

the sand, and then walk away from all accountability. The result would undermine the public's confidence in the Hatch-Waxman Act and would do little to enhance the public image of the patent system as a whole.

III. SYNTHESIS OF WILLFUL PATENT INFRINGEMENT UNDER THE NOVEL ORANGE BOOK NOTICE THEORY

¶70 It is common advice to check under the hood before buying a used car. Asserting a pharmaceutical patent should be no different, although practitioners overlooked the advantages of using the Orange Book and the ANDA process to establish a theory of willfulness. This section looks under the hood by exploring how the novel Orange Book theory of proving willfulness will work in practice.

A. The Orange Book Theory and Hatch-Waxman Act

¶71 Since 2004, there is a split of authority concerning willful patent infringement in the context of the Hatch-Waxman Act.¹⁴⁵ This chasm will grow until it reaches the Federal Circuit, thereby making the novel Orange Book theory quite timely.

¶72 Plainly stated, the “mere” filing of an ANDA does not—taken *alone*—constitute grounds for finding willful infringement. Indeed, this was the 2004 Federal Circuit holding in *Glaxo Group Ltd. v. Apotex, Inc.*: “[W]e now hold that the mere fact that a company has filed an

A person acts recklessly in engaging in conduct if:

- (a) the person knows of the risk of harm created by the conduct or knows facts that make the risk obvious to another in the person's situation, and
- (b) the precaution that would eliminate or reduce the risk involves burdens that are so slight relative to the magnitude of the risk as to render the person's failure to adopt the precaution a demonstration of the person's indifference to the risk.

RESTATEMENT THIRD, § 2. Therefore, both the Second and Third Restatements support the “Orange Book” theory of willful patent infringement asserted by this article.

¹⁴⁵ *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439 (D.N.J. 2006) (“District courts that have addressed the issue have disagreed as to whether or not there can be a finding of willful infringement based upon the filing of an ANDA and Paragraph IV Certification.”); *Boehringer Ingelheim Int'l GMBH v. Barr Labs., Inc.*, No. 05-700, 2006 WL 1876918, at *2 (D. Del. July 6, 2006) (“The district courts have split on the issue.”); *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, No. 05-1887, 2005 WL 3664014, at *2 (D.N.J. Dec. 30, 2005) (Although “*Glaxo* stands for the proposition that an ANDA filing, without more, does not constitute willful infringement, it is possible that Novartis may be able to show activity in addition to the ANDA filing to support the issue of willfulness.”).

ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorneys' fees pursuant to 35 U.S.C. § 271(e)(4)."¹⁴⁶ Since this ruling, the Federal Circuit has not expounded further on *Glaxo* or the intersection between willfulness and the Hatch-Waxman Act.¹⁴⁷

¶73 A fair reading of *Glaxo*, however, is that the Federal Circuit simply recognized the fact that there was no patent infringement by the "mere"¹⁴⁸ filing of an ANDA or Paragraph IV certification. For this reason, the Supreme Court earlier emphasized that patent litigation initiated in federal courts under §§ 271(e)(2) and (e)(4) constitutes "highly artificial" acts of infringement simply as a vehicle to serve the "very limited and technical purpose" of creating jurisdiction under the fiction of an act of infringement (i.e., "to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend").¹⁴⁹ The *Glaxo* court acknowledged that § 271(e) of the Patent Act was "primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action."¹⁵⁰ In fact, the Federal Circuit recently made it easier to file declaratory judgment actions in ANDA cases,¹⁵¹

¹⁴⁶ 376 F.3d 1339, 1350–51 (Fed. Cir. 2004).

¹⁴⁷ Since handing down *Glaxo*, the Federal Circuit has only cited to that decision on three occasions. In all three cases, *Glaxo* was cited for its discussion of patent invalidity in general, and in particular the high burden of proving invalidity based on prior art references that were before the examiner during prosecution. *Haberman v. Gerber Prods. Co.*, Nos. 2006–1490 & 1516, 2007 WL 1577970, at *4 (Fed. Cir. May 29, 2007) (not selected for publication); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1375 (Fed. Cir. 2006).

¹⁴⁸ *Glaxo*, 376 F.3d at 1350–51.

¹⁴⁹ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 674–78 (1990); *see also* *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1334 (Fed. Cir. 2007) ("Teva's paragraph IV certifications constitute technical infringement under 35 U.S.C. § 271(e)(1).").

¹⁵⁰ *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004).

¹⁵¹ *Teva*, 482 F.3d at 1340–45; *see also* *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1379 (Fed. Cir. 2007). In lowering the standard for patent declaratory judgment actions, both *Teva* and *SanDisk* relied on footnote 11 from the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007). *See Teva*, 482 F.3d at 1339 ("In *MedImmune*, the Supreme Court in a detailed footnote stated that our two-prong 'reasonable apprehension of suit' test 'conflicts' and would 'contradict' several cases in which the Supreme Court found that a declaratory judgment plaintiff had a justiciable controversy."); *SanDisk*, 480 F.3d at 1379; *see also* *SanDisk*, 482 F.3d at 1384 (Bryson, J., concurring) ("The decision in *MedImmune* dealt with a narrow issue. . . . Footnote 11 of the *MedImmune* opinion, however, went further

and by doing so, expressly recognized that the listing of patents “in the Orange Book . . . represents that a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of generic [drugs] covered by the claims of its listed [drug] patents.”¹⁵²

¶74 Notwithstanding its “mere” filing holding, the *Glaxo* court recognized that, even in cases initiated solely based on the defendant’s filing of an ANDA or Paragraph IV certification, a district court may declare the case “exceptional” under 35 U.S.C. § 285.¹⁵³ Section 285 permits an award to the patent owner of its attorneys’ fees resulting from “litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and *willful infringement*.”¹⁵⁴ Thus, even under *Glaxo*, district courts may consider willfulness, provided the allegation does not rest solely on the filing of an ANDA or Paragraph IV certification, such as in determining whether to award attorneys’ fees.¹⁵⁵ In assessing whether a case is exceptional for purposes of awarding attorneys’ fees, a court “must look at the totality of the circumstances.”¹⁵⁶

¶75 The *Glaxo* court also left open the possibility that filing an ANDA in *combination* with other factors should allow a brand-name drug manufacturer to plead both willful infringement as well as

and criticized this court’s ‘reasonable apprehension of suit’ test for declaratory judgment jurisdiction.”).

¹⁵² *Teva*, 482 F.3d at 1341.

¹⁵³ *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350 Fed. Cir. 2004).

¹⁵⁴ *Id.* (emphasis added). The Federal Circuit in *Glaxo* emphasized that a declaratory judgment action alleging anticipatory infringement based on an ANDA was an “artificial” infringement for purposes of establishing jurisdiction:

Because 35 U.S.C. § 271(e)(2) is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts, we hold that the district court committed clear legal error in finding that Apotex’s mere filing of an ANDA could form the basis of a willful infringement finding . . . [S]uch a filing cannot constitute willful infringement for purposes of establishing an exceptional case and the award of attorney’s fees under 35 U.S.C. § 271(e)(4).

Glaxo, 376 F.3d at 1351 (emphasis in original).

¹⁵⁵ *Glaxo*, 376 F.3d at 1350–51.

¹⁵⁶ *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000) (affirming a district court’s finding that the case was “exceptional” based on an ANDA filing that was “without adequate foundation and speculative at best”). The defendant had failed to present a prima facie case of invalidity in filing its Paragraph IV certification, and proceeded with litigation despite “glaring weaknesses” in its case. *Id.* at 1347–48; *see also supra* Part I.A (discussing the factors for determining willful infringement).

attorneys' fees. On the one hand, the Federal Circuit arguably foreclosed a finding of willful infringement when based "merely" on the filing of the ANDA.¹⁵⁷ On the other hand, a patent owner should have the opportunity to establish facts supporting a claim that the "only" act of infringement alleged in the complaint is not simply the defendant's mere filing of an ANDA.

¶76 For example, *Glaxo* arguably recognizes that a claim for willful infringement may be pleaded "when commercial activity has actually occurred in the United States or when the commercial product has been imported."¹⁵⁸ Indeed, it would turn Hatch-Waxman on its head to permit a defendant to file an ANDA and engage in pre-filing or post-filing "commercial activity" or importing a "commercial product" with impunity.

¶77 Just how much commercial activity is necessary or when a commercial product is deemed imported remains an open issue. Will it be enough to "copy" the patentee's drug or combine an ANDA with one or more of the nine factors considered under the "totality of circumstances"?¹⁵⁹ Will it be enough to promote a generic version on the defendant's website?¹⁶⁰ An intriguing Pandora's box opened by the Federal Circuit's highly publicized decision in *NTP, Inc. v. Research in Motion, Ltd.*,¹⁶¹ is the extraterritorial reach of the Patent Act.¹⁶² In *NTP*,

¹⁵⁷ *Glaxo*, 376 F.3d at 1350–51.

¹⁵⁸ *Id.* at 1350.

¹⁵⁹ Deliberate copying is one of the nine factors considered under the "totality of circumstances." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1225 (Fed. Cir. 2006).

¹⁶⁰ Borrowing from the context of § 287(a), a website is arguably a "tangible" item. *Soverain Software L.L.C. v. Amazon.com, Inc.*, 383 F. Supp. 2d 904, 909 (E.D. Tex. 2005) ("[T]he Court . . . defines 'tangible item[s],' as used in *Am[erican] Medical Systems*, as those items that can be marked and intangible items as those that cannot be marked." Applying that definition, the court found screen shots of a website to be a tangible item.) (citing *Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1538–39 (Fed. Cir. 1993)).

¹⁶¹ 418 F.3d 1282 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 1174 (2006).

¹⁶² Commentators debate whether there may ever be extraterritorial enforcement of intellectual property laws under U.S. CONST. art. I, § 8, cl. 8. Compare John W. Osborne, *A Rational Analytical Boundary for Determination of Infringement by Extraterritorially-Distributed Systems*, 46 IDEA 587 (2006) (arguing that, under 35 U.S.C. § 271(c), (f), (g) (2000), a foreign defendant of an extraterritorially-distributed telecommunications system cannot infringe the patent if its activities relating to the patentably distinctive aspect of the claimed invention did not take place in the United States) with Christopher A. Harkins, *Overcoming the Extraterritorial Bar to Bringing Copyright Actions: On*

the Federal Circuit applied § 271(a) to accused products and systems distributed extraterritorially by focusing on the “place at which the system as a whole is put into service,” the “place where control of the system is exercised,” and the place where “beneficial use of the system [is] obtained.”¹⁶³ According to the court, the fact that one element of the system claims took place “in Canada did not, as a matter of law, preclude infringement of the asserted system claims” by Research in Motion.¹⁶⁴

¶78 Patent attorneys have sat by idly when merely asserting a defendant’s ANDA or Paragraph IV certification as a basis for jurisdiction and the limited relief under § 271(e). In a case where there is commercial activity or a commercial product, however, the patent owner’s willful infringement claim no longer rests entirely on the “mere filing”¹⁶⁵ of an ANDA. The defendant’s knowledge of the asserted patent, whether from the Orange Book or otherwise, and a showing that its actions constitute “objective recklessness,”¹⁶⁶ are relevant to the totality of circumstances and to the time-honored duty to avoid willful infringement.

B. The Orange Book Theory and Traditional Infringement

¶79 The *Glaxo* decision seems to have set many in the patent community buzzing about a perceived deathblow to willful infringement pharmaceutical litigation. But there is a different way of looking at the *Glaxo* decision: The Federal Circuit was simply recognizing the “highly artificial” act of infringement as a necessary requirement for satisfying justiciability when the generic companies “have *not yet infringed* the patents in issue.”¹⁶⁷

¶80 Once defendants have committed at least one primary act of patent infringement, however, then the *Glaxo* decision ought not apply. In other words, a claim for willful infringement should be actionable

Pleading Copyright Infringement to Protect Copyrighted Works from the Defendant that Ships Overseas for Distribution Abroad, 17 INTELL. PROP. & TECH. L.J. 1, 7 (May 2005) (noting the extraterritorial bar to bringing copyright infringement suits but arguing for an exception to that rule, because “[w]hen defendants have committed at least one primary act of copyright infringement in the United States, the presumption against extraterritoriality ought not to defeat a court’s subject matter jurisdiction”).

¹⁶³ *NTP*, 418 F.3d at 1317.

¹⁶⁴ *Id.*

¹⁶⁵ *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1342, 1349 (Fed. Cir. 2004).

¹⁶⁶ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc).

¹⁶⁷ *Glaxo*, 376 F.3d at 1351 (emphasis added).

under the Patent Act and Federal Circuit precedent, if the willfulness claim is not based solely on defendants' filing of an ANDA.¹⁶⁸ The bottom line is: Look under the hood of that used car for evidence of infringement. Also, a patent owner should learn to plead offensively to rebut a future motion to dismiss a claim of willful infringement, which facts may otherwise escape the complaint in favor of clutching to the more habitual practice of notice pleading.¹⁶⁹

¶81 Consequently, a patent owner may affirmatively plead theories of direct infringement when the defendant is offering to sell, selling, or importing into the United States any product that embodies the patented invention.¹⁷⁰ Or the patent owner may seek to hold the defendant liable under a theory of indirect infringement,¹⁷¹ such as by inducement of infringement¹⁷² or by contributory infringement.¹⁷³

¹⁶⁸ The plaintiff should be allowed to develop evidence necessary to show a primary act of infringement. *See* Fed. R. Civ. P. 56(f) (1987). Rule 56(f) provides a non-movant with protection from being "railroaded" by a defendant's premature motion for summary judgment. *Opryland USA, Inc. v. Great Am. Music Show, Inc.*, 970 F.2d 847, 852 (Fed. Cir. 1992).

¹⁶⁹ Fed. R. Civ. P. 8(a), (e) (1987); *see also* HARKINS, *supra* note 162, at 4 ("Rather than abiding by that longstanding rule, fact pleading (as opposed to federal notice pleading) should be considered. Indeed, using an appropriate level of fact pleading in a well-pleaded complaint may dissuade motion practice . . . as well as help to broaden the scope of allowable discovery.").

¹⁷⁰ 35 U.S.C. § 271(a) (2006) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.").

¹⁷¹ The Federal Circuit uses the term "indirect infringement" to describe active inducement of infringement or contributory infringement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006) (citing *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993)). Furthermore, "the patentee always has the burden to show direct infringement for each instance of indirect infringement." *DSU*, 471 F.3d at 1303; *see also* *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746, 1751 & n.2 (2007) (Without direct infringement, there can be no inducing or contributing to an infringement.).

¹⁷² 35 U.S.C. § 271(b) (1952) ("Whoever actively induces infringement of a patent shall be liable as an infringer."). There can be no inducement to infringe a patent unless the defendant "knew of the patent." *DSU*, 471 F.3d at 1304. Once the defendant "knew" of the patent, the defendant must "actively and knowingly" aid and abet another's direct infringement—knowledge of another's acts (alleged to be infringing the patent) is not enough to show "specific intent and action to induce infringement." *Id.* at 1305 (emphasis in original). The defendant's state of mind must show the defendant "knowingly induced

¶82 For example, the first decision expressly dealing with marking in the context of the Orange Book was *Merck & Co. v. Mediplan Health Consulting, Inc.*¹⁷⁴ In *Merck*, defendants operated Canadian-based Internet pharmacies, promoted their products in the United States via their websites, and sold, offered for sale, or promoted generic versions of plaintiff's patented drug to defendants' customers in the United States through the Internet.¹⁷⁵ Furthermore, all of the defendants knowingly sold and advertised the accused generic drugs in the United States without FDA approval.¹⁷⁶

¶83 Under those circumstances, the defendants arguably can be said to commit at least one primary act of patent infringement.¹⁷⁷ Consequently, they should not be allowed to rely on the Hatch-Waxman Act, which limits a plaintiff's remedy to declaratory relief, to avoid damages stemming from patent infringement liability. Plainly stated,

infringement, not merely knowingly induced the acts that constitute direct infringement." *Id.* at 1306 (emphasis in original) (citation omitted). In other words, "the inducer must have an affirmative intent to cause direct infringement." *Id.*; see also *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005).

¹⁷³ The statutory source for contributory infringement is § 271(c):

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c) (2006); see also *DSU*, 471 F.3d at 1303 (Contributory infringement requires a plaintiff to prove that the defendant made or sold the accused product, that no substantial non-infringing uses existed, that the defendant's acts of contributory infringement occurred within the United States, and that an act of direct infringement was made within the United States.); *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) (stating that one who sells articles for use in a patented combination will be "presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent").

¹⁷⁴ 434 F. Supp. 2d 257 (S.D.N.Y. 2006).

¹⁷⁵ *Id.* at 260.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 266 ("Accordingly, defendants' motion for partial summary judgment is granted only with respect to any claims for injunctive relief and damages resulting from purported infringement following patent expiration."); see also *id.* at 263 n.5 (acknowledging the plaintiffs' allegations of patent infringement based on product and method claims).

defendants who have not complied with the Hatch-Waxman Act should not benefit from it. Conversely, if defendants complied with US law and filed an ANDA *before* selling or promoting drugs in the US during the term of the asserted patent, then Merck might be limited to declaratory relief under Hatch-Waxman. The defendants in that scenario, however, were not selling infringing products and the issue of damages and a claim of willful infringement would never arise.

¶84 Moreover, there is an “obligation”¹⁷⁸ to consult the Orange Book before promoting, selling, or offering for sale generic medication regulated by the FDA. Use of a patented invention constitutes infringement, and knowledge of the patent triggers a duty to avoid directly and indirectly infringing the claims of the patent.¹⁷⁹ And as a practical matter, sellers of generic versions of brand-name drugs can hardly dispute they were unaware of the plaintiff’s product—after all, their business models encourage Americans to save money on prescriptions by switching from the more costly brand-name drugs to their more affordable generic drugs. In most cases, defendants acknowledge on their websites that their products are equivalent, safe, and as effective as the brand-name drug.¹⁸⁰

¶85 Consequently, once a defendant has committed a primary act of infringement in the prescription-drug arena, the patent owner should be

¹⁷⁸ *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004) (“[A] generic company has an obligation to consult the Orange Book”).

¹⁷⁹ *See supra* Part I.A and II.B.3 (Discussing case law holding that patent infringement is a strict liability offense and that the accused infringer has a duty to investigate and avoid willful infringement); *see also supra* notes 171–74 (discussing case law relating to indirect infringement theories such as inducement of infringement and contributory infringement).

¹⁸⁰ If an ANDA were filed, then the generic-drug company’s offers represent therapeutic equivalence under the Hatch-Waxman Act and relies on the new drug applicant’s full reports demonstrating safety and effectiveness. 21 U.S.C. § 505 (2006). Even when a generic-drug company sells without filing an ANDA, as in *Merck*, the company is likely to boast equivalence to, without the price of, brand-name pharmaceuticals. Indeed, in *Merck & Co. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402 (S.D.N.Y. 2006), a companion opinion to the *Merck* decision discussed above but relating to the allegations of unfair competition, the district court described how the defendants’ websites offered generic versions of plaintiff’s popular cholesterol medication, Zocor, and did so “to identify their products as more affordable generic versions of Zocor,” *id.* at 406, advertised as “safe affordable” alternatives, *id.* at 407, and used Merck’s Zocor work mark in connection with their advertisements, *id.* at 408–09.

allowed to assert a claim for willful infringement¹⁸¹ and to pursue that theory in discovery.¹⁸² Otherwise, there is a highly irregular disconnect whereby defendants may eschew both the FDA and patent laws on the one hand, and attempt to shield from discovery evidence of blatant copying and intentional disregard for the patent on the other. Such a result would undercut the policy of the Patent Act that patents constitute rights of exclusivity,¹⁸³ that there be a “remedy by civil action for infringement” of a patent,¹⁸⁴ and that the patent owner be awarded damages adequate to compensate the owner for the infringement, but in no event less than a reasonable royalty, treble damages,¹⁸⁵ and attorneys’ fees if the case is exceptional.¹⁸⁶

¶86 Therefore, when a potential plaintiff performs the necessary pre-filing investigation¹⁸⁷ of the would-be defendant’s commercial activities and commercial product before bringing a claim for patent infringement,

¹⁸¹ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1374 (Fed. Cir. 2007) (en banc) (“However, when a complaint is filed, a patentee must have a good faith basis for alleging willful infringement. Fed. R. Civ. Pro. 8, 11(b). So a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer’s pre-filing conduct.”).

¹⁸² As antecedent to the issue of willfulness before it, a court may consider allowing a plaintiff discovery relating to willful infringement. *Seagate Tech.*, 497 F.3d 1371–72 (“The ultimate dispute in this case is the proper scope of discovery. While it is true that the issue of willful infringement, or even infringement for that matter, has not been decided by the trial court, it is indisputable that the proper legal standard for willful infringement informs the relevance of evidence relating to that issue and, more importantly here, the proper scope of discovery.”).

¹⁸³ 35 U.S.C. 154 (2006) (Every patent shall grant to the patentee the “right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”); 35 U.S.C. § 261 (2006) (“patents shall have attributes of personal property”); U.S. CONST. art. I, § 8, cl. 8 (“[S]ecuring for limited Times to Authors and Inventors the exclusive Right to their Respective Writings and Discoveries.”).

¹⁸⁴ 35 U.S.C. § 281 (2006).

¹⁸⁵ 35 U.S.C. § 284 (2006) (“[T]he court may increase the damages up to three times the amount found or assessed.”).

¹⁸⁶ 35 U.S.C. § 285 (2006) (“The court in exceptional cases may award reasonable attorney fees to the prevailing party.”).

¹⁸⁷ *View Eng’g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000) (“In bringing a claim for infringement, the patent holder, if challenged, must be prepared to demonstrate to both the court and the alleged infringer exactly why it believed before filing the claim that it had a reasonable chance of proving infringement.”).

consider drafting the complaint with an eye toward the nine non-exclusive factors that make up the “totality of the circumstances”¹⁸⁸ for proving willful infringement. After all, the Federal Circuit considers willfulness to be one of degree: “Willfulness in infringement, as in life, is not an all-or-nothing trait, but one of degree. It recognizes that infringement may range from unknowing, or accidental, to deliberate, or reckless, disregard of a patentee’s legal rights.”¹⁸⁹

¶87 Patent infringement is a strict-liability action requiring no intent or wrongdoing on the part of the defendant,¹⁹⁰ but an act of infringement rarely exists in a vacuum. When coupled with just one of the nine factors, perhaps a plaintiff might not be alerted to willfulness. When a potential plaintiff can show two factors in addition to the infringement, a warning flag should be raised in the plaintiff’s mind. And when there are three or more factors, the flag should start waving back and forth.

¶88 However, one never reaches the totality of circumstances, objective recklessness, and ultimately willfulness without showing the defendant had notice of the patent.¹⁹¹ Why settle on the date when the patent infringement complaint was filed? At the very least, give thought to bringing the date back to when the defendant first possessed actual knowledge of the asserted patent—the date when, according to its legal obligation or business practice, the defendant checked the Orange Book. When the dust settles, the Orange Book might very well entitle the patent owner to damages from the inception of the defendant’s infringing activities.

CONCLUSION

¶89 The debate about willful infringement under the Hatch-Waxman Act is represented by strong advocacy on opposing sides.¹⁹² One side

¹⁸⁸ See *supra* text accompanying notes 28–29 (Listing nine factors that comprise the totality of circumstances; see also *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1342–43 (Fed. Cir. 2004) (en banc) (“Determination of willfulness is made on consideration of the totality of the circumstances, and may include contributions of several factors These contributions are evaluated and weighed by the trier of fact.”) (citations omitted)).

¹⁸⁹ *Knorr-Bremse*, 383 F.3d at 1343.

¹⁹⁰ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc); *Hilton Davis Chem Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1527 (Fed. Cir. 1995) (en banc).

¹⁹¹ See *supra* Part I.B and notes 56–71 (discussing cases addressing the types of notice necessary and sufficient to create a duty to avoid willful infringement).

¹⁹² See *supra* Part II.A and note 94.

sets the bar very high, such that willfulness damages are never available. These advocates claim the Hatch-Waxman policy in favor of cheaper, generic copies of drugs should carry the day. Brand-name manufacturers, on the other side, warn that an absolute bar against willfulness damages will stymie research. They would call for willfulness damages in order to promote the Hatch-Waxman policy encouraging new drug development. This article seeks a carefully crafted balance by focusing on the public interest that lies somewhere between those two equally important sides.

¶90 Accordingly, in the high stakes of brand-name versus generic-drug litigation, plaintiffs bringing patent infringement actions can be expected to start testing the theory of whether (and to what extent) the Orange Book provides “notice” of the asserted patents. First, plaintiffs may argue the Orange Book fully serves the purpose of notifying potential infringers that the would-be defendants’ generic drugs will infringe the listed patents for purpose of the notice requirements under § 287(a).

¶91 Second, the *Merck*¹⁹³ case—and its nascent theory of asserting “notice” based on the Orange Book—has a potentially far-reaching impact on willful infringement. Future plaintiffs might develop a theory of willful infringement by arguing the Orange Book provides direct and specific notice to a unique audience required by statute to seek out and heed the notice that generic drugs will infringe the patents listed within. Consequently, defendants who consult the Orange Book would be under a duty to avoid infringing a patent relevant to their products. If the defendants are found to have willfully failed to comply with (or to be in reckless disregard of) this duty and “standards of commerce,”¹⁹⁴ there may be a determination of willful infringement and a finding that they owe treble damages and attorneys’ fees.

¶92 As one contemplates these novel theories, one should not lose sight of the price paid for innovation, which the Hatch-Waxman Act seeks to encourage. Indeed, achievements have not always resulted in immediate commercial success, but resulting in expensive undertakings and long-term investments. More precisely, innovative pharmaceutical companies may spend as much as a dozen years and \$800 million to

¹⁹³ *Merck & Co. v. Mediplan Health Consulting, Inc.*, 434 F. Supp. 2d 257 (S.D.N.Y. 2006).

¹⁹⁴ *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 n.5 (Fed. Cir. 2007) (en banc) (In recognizing that the “objective recklessness” standard of willfulness is not self-defining, the Federal Circuit stated: “We would expect, as suggested by Judge Newman, that the standards of commerce would be among the factors a court might consider.”) (internal citation omitted).

bring a pioneering drug to the market,¹⁹⁵ and FDA-required testing at times effectively reduces the life of patent protection to seven years or less.¹⁹⁶ Moreover, the compromise leading to the Hatch-Waxman Act was intended to facilitate and expedite generic-drug market entry without harming, and indeed while concurrently safeguarding, pharmaceutical companies bringing new and innovative drugs to the marketplace.

¶⁹³ Only a year ago, who thought Wal-Mart would offer four dollar prescriptions for generic drugs? Tomorrow, Wal-Mart might become the Spacely Space Sprockets of generic-drug prescriptions. When generic drugs fly off the shelves faster than the speed of light, brand-name pharmaceutical companies are slowed by plunking down hefty sums in R&D necessary to develop innovative drugs that foster the high standard of living in America as well as to help developing countries in need of better medicine.

¶⁹⁴ To stay competitive, stimulate invention of new products, and innovate ways to save and improve lives, pioneering drug manufacturers must look to the courts more than ever for patent protection, injunctive relief, and money damages that help to underwrite costly research. Therefore, to offset the generic's edge, a budding theory of Orange Book notice and willfulness might well be the innovator's diamond in the rough.

¹⁹⁵ See Paprocki, *supra* note 121, at 474; Coughlin & Dede, *supra* note 122, at 526 n.9.

¹⁹⁶ Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 864 (Fed. Cir. 1984).